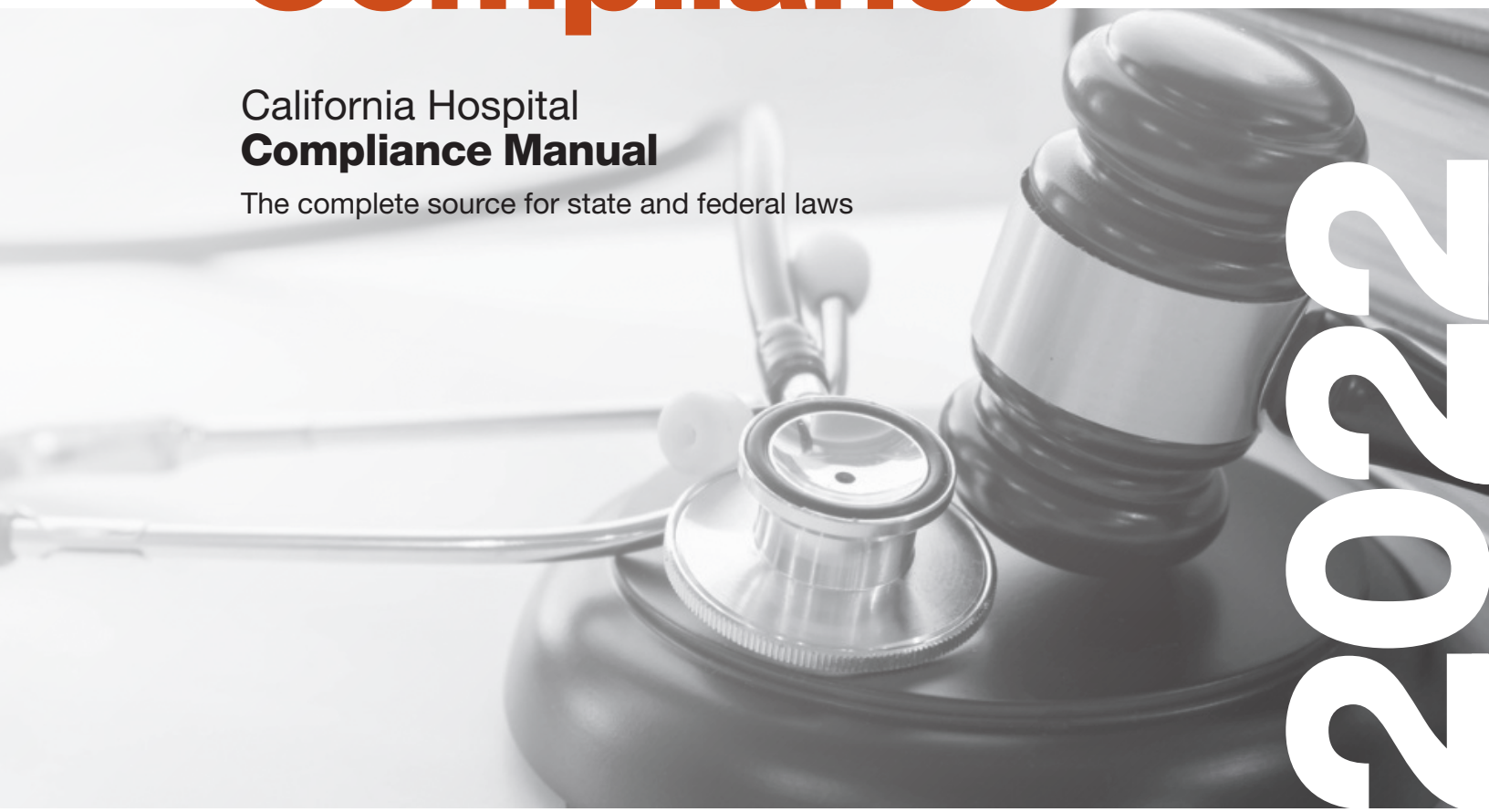
Compliance



California Hospital
Compliance Manual

The complete source for state and federal laws

2022

Hooper, Lundy & Bookman, PC

California Hospital Association

California Hospital Compliance Manual

March 2022
13th Edition

Written by
Hooper, Lundy & Bookman, PC
California Hospital Association

California Hospital Association

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Quick Reference

PREFACE

AUTHOR ACKNOWLEDGMENTS

WHERE TO FIND LAWS REFERENCED IN THE MANUAL

CHAPTERS

Chapter 1	Hospital Compliance Plans
Chapter 2	Governing Boards
Chapter 3	Federal and State False Claims Acts
Chapter 4	Submission of Accurate Claims Information
Chapter 5	Proper Cost Reporting Practices
Chapter 6	Physician Self-Referral Laws
Chapter 7	Federal and State Anti-Kickback Laws
Chapter 8	Financial Assistance Policies
Chapter 9	Issues for Tax-Exempt Hospitals
Chapter 10	Fundamentals of Hospital Licensing and Certification
Chapter 11	Screening for Excluded Providers and Suppliers
Chapter 12	Hospital Signage Requirements
Chapter 13	Patient Safety Organizations
Chapter 14	Other Laws
Chapter 15	Repayment and Self-Disclosure
Chapter 16	Responding to Government Audits and Investigations
Chapter 17	Surprise Billing and Price Transparency

INDEX

Preface

The *California Hospital Compliance Manual* provides guidance to hospitals and health systems on how to comply with myriad California and federal statutes, regulations, agency guidelines and judicial decisions.

Written specifically for California's hospital compliance officers, chief financial officers, in-house legal counsel, risk managers, and other members of the hospital's compliance committee, the manual focuses on complex and high-risk compliance issues. It is the only hospital compliance manual that is specific to California. State law is addressed throughout the manual where applicable. In particular, the sections regarding hospital financial assistance policies, pricing transparency, community benefit law, and licensing and certification describe the extensive state laws that have been enacted concerning these subjects, as well as the applicable federal law.

CHA gratefully acknowledges the work of Hooper, Lundy & Bookman, PC, and in particular lead author Lloyd Bookman, Esq. At best this is an arduous task and one that requires both a firm grasp of many complex legal matters, as well as meticulous attention to detail. Many members of the firm contributed their expertise writing this manual.

CHA is pleased to publish this manual as a service to our members. If you have any comments or suggestions on how to improve the *California Hospital Compliance Manual*, please feel free to contact me.

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Where to Find Laws Referenced in the Manual

All of the laws discussed in the *California Hospital Compliance Manual* can be found on the Internet.

FEDERAL LAW

A federal statute is written by a United States Senator or Representative. It is voted on by the United States Senate and the House of Representatives, and then signed by the President. A federal statute is referenced like this: 42 U.S.C. Section 1395. "U.S.C." stands for "United States Code." Federal statutes may be found at www.govinfo.gov/app/collection/uscode or at www.law.cornell.edu.

A federal regulation is written by a federal agency such as the U.S. Department of Health and Human Services or the U.S. Food and Drug Administration. The proposed regulation is published in the Federal Register, along with an explanation (called the "preamble") of the regulation, so that the general public and lobbyists may comment on it. The federal agency must summarize and respond to each comment it receives on the proposed regulation. The agency may or may not make changes to the proposed regulation based on the comments. The final regulation is also published in the Federal Register. A federal regulation is referenced like this: 42 C.F.R. Section 482.1 or 42 C.F.R. Part 2. "C.F.R." stands for "Code of Federal Regulations." Federal regulations may be found at www.ecfr.gov. The preamble, however, is only published in the Federal Register and not in the Code of Federal Regulations. The Federal Register may be found at www.federalregister.gov.

The Centers for Medicare & Medicaid Services publishes its *Interpretive Guidelines* for surveyors on the internet. The *Interpretive Guidelines* include information for surveyors on how CMS interprets the Conditions of Participation, and instructions for surveyors on how to assess hospitals' compliance with the Conditions of Participation. They may be found at www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs.html (click on Publication 100-07, "State Operations Manual," then "Appendicestoc" (short for "Appendices Table of Contents")). There are several appendices that hospitals will find useful, for example, A (hospitals), V (EMTALA), and W (critical access hospitals).

A federal law must be obeyed throughout the United States, including in California, unless the federal law expressly states otherwise. As a general rule, if a federal law conflicts with a state law, the federal law prevails, unless the federal law expressly states otherwise.

If there is no conflict, such as when one law is stricter but they don't actually conflict with each other, both laws generally must be followed. For example, under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the federal law states that providers must conform to whichever provision of federal or state law provides patients with greater privacy protection or gives them greater access to their medical information.

STATE LAW

A state statute is written by a California Senator or Assembly Member. It is voted on by the California Senate and Assembly, and then signed by the Governor. A state statute is referenced like this: Civil Code Section 56 or Health and Safety Code Section 819. State statutes may be found at www.leginfo.legislature.ca.gov/. Proposed laws (Assembly Bills and Senate Bills) may also be found at this website.

A state regulation is written by a state agency such as the California Department of Public Health or the California Department of Managed Health Care. A short description of the proposed regulation is published in the *California Regulatory Notice Register*, more commonly called the *Z Register*, so that the general public and lobbyists may request a copy of the exact text of the proposed regulation and comment on it. The state agency must summarize and respond to each comment it receives on the proposed regulation. The agency may or may not make changes to the proposed regulation based on the comments. A notice that the final regulation has been officially adopted is also published in the *Z Register*. The *Z Register* may be found at oal.ca.gov/california_regulatory_notice_online.

A state regulation is referenced like this: Title 22, C.C.R., Section 70707. "C.C.R." stands for "California Code of Regulations." State regulations may be found at https://govt.westlaw.com/calregs/search/index. The California Department of Public Health sometimes issues letters explaining its regulations or processes; these All Facilities Letters are found at https://www.cdph.ca.gov/programs/chcq/lcp/pages/lncafl.aspx.

A state law must be obeyed in California only. As a general rule, if a California law conflicts with a federal law, the federal law prevails, unless the federal law expressly states otherwise. (If there is no conflict, such as when one law is stricter but they don't actually conflict with each other, both laws generally must be followed.)

1 Hospital Compliance Plans

I. Introduction 1.1

A. The Benefits of a Compliance Program 1.2

B. Federal Sentencing Guidelines for Organizations 1.3

C. OIG Compliance Program Guidance 1.8

D. OIG Annual Work Plan 1.13

E. Department of Justice Criminal Division Guidance on Evaluating Corporate Compliance Programs 1.13

Is the Corporation's Compliance Program Well Designed? 1.14

Is the Corporation's Compliance Program Adequately Resourced and Empowered to Function Effectively? 1.14

Does the Corporation's Compliance Program Work in Practice? 1.15

F. Mandatory Hospital Policies and Procedures Under DRA 1.16

Who is Required to Comply with Section 6032 Requirements? 1.17

How is the $5 Million Annual Medicaid Reimbursement Calculated? 1.17

What is Required to Comply With Section 6032? 1.18

Related California Law 1.19

G. Conflict of Interest 1.19

H. Compliance Program for Skilled Nursing Facilities and Nursing Facilities 1.19

I. Model Hospital Compliance Plan 1.22

J. Useful Compliance Websites 1.22

Model Hospital Compliance Plan

Section I — Compliance Program Summary MP.1

Definitions of Commonly Used Terms MP.1

Purpose of This Compliance Program MP.1

Who is Affected MP.2

How to Use This Compliance Program MP.2

Section II — Code of Conduct MP.3

Our Compliance Mission MP.3

Compliance With Laws MP.4

Open Communication MP.4

Your Personal Conduct MP.4

The Work Environment MP.4

Employee Privacy MP.5

Use of Hospital Property MP.5

Use of Hospital Computers MP.5
Use of Proprietary Information MP.6
Proprietary Information MP.6
Inadvertent Disclosure MP.6
Direct Requests for Information MP.7
Disclosure and Use of Hospital Proprietary Information MP.7
Proprietary and Competitive Information About Others MP.7
Recording and Reporting Information MP.7
Exception MP.7
Gifts and Entertainment MP.7
General Policy MP.8
Spending Limits — Gifts, Dining and Entertainment MP.8
Marketing and Promotions in Health Care MP.8
Marketing MP.8
Conflicts of Interest MP.9
Outside Employment and Business Interests MP.9
Contracting with the Hospital MP.9
Required Standards MP.9
Disclosure of Potential Conflict Situations MP.11
Anti-Competitive Activities MP.12
Reporting Violations MP.12

Section III — Compliance Program Systems and Processes MP.12
Compliance Officers and Committee MP.13
Chief Compliance Officer MP.13
Compliance Committee MP.14
Compliance as an Element of Performance MP.15
Training and Education MP.16
Lines of Communicating and Reporting MP.17
Open Door Policy MP.17
Submitting Questions or Complaints MP.17
Non-Retaliation Policy MP.18
Enforcing Standards and Policies MP.18
Policies MP.18
Discipline Procedures MP.19
Auditing and Monitoring MP.19
Corrective Action MP.20
Violations and Investigations MP.20
Reporting MP.21

Section IV — Compliance Policies MP.21

FORMS & APPENDICES

HC 1-A Acknowledgment of Receipt of Hospital Compliance Plan
HC 1-B Conflict of Interest Certification Form

1 Hospital Compliance Plans

I. INTRODUCTION

There is currently no law that expressly requires a hospital to have a compliance program. However, the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act) authorizes the Secretary of the federal Department of Health and Human Services (DHHS) to require providers and suppliers to establish a compliance program as a condition of enrollment in Medicare, Medicaid and Children's Health Insurance Program (CHIP). The Secretary of DHHS will establish which categories of providers and suppliers must establish compliance programs, what the core elements of the compliance program will be, and the implementation dates. As of this printing, the Secretary has not issued any regulations, guidance or other clarification of this requirement for providers. [Section 6401 of the Patient Protection and Affordable Care Act of 2010, codified at 42 U.S.C. Section 1395cc(j)(9)]

The Centers for Medicare & Medicaid Services (CMS) issued the Final Compliance Program Guidelines for Medicare Advantage (MA) organizations (MAOs) and Prescription Drug Plan (PDP) sponsors on July 27, 2012 (www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/CP-Guidelines-Issuance-Memo.pdf). These guidelines set forth and elaborate on the seven essential elements of an effective compliance program *(see B. "Federal Sentencing Guidelines for Organizations," page 1.3)*. Although these guidelines apply only to sponsors, they will likely influence and inform the final compliance program regulations CMS will issue for health care providers.

While current law does not expressly require a hospital to have a compliance program, hospitals operating skilled nursing or nursing facilities should be aware that the law does expressly mandate that these types of facilities have a compliance program [42 U.S.C. Section 1320a-7j(a)&(b)]. *(See H. "Compliance Program for Skilled Nursing Facilities and Nursing Facilities," page 1.19.)*

The Office of the Inspector General (OIG) of DHHS strongly urges every hospital to develop and implement a voluntary compliance program to demonstrate its good faith commitment to ensuring and promoting integrity and to combating fraud, abuse and waste. Some hospitals may have entered into a Corporate Integrity Agreement or other agreement with the OIG that requires the hospital to maintain a compliance program.

In addition, the Federal Sentencing Guidelines for Organizations (FSGO), which guides judges in the sentencing of organizations for federal criminal violations (including violations of federal health care fraud and abuse laws), requires an organization to have an effective compliance plan in order to receive the benefit of discretion from a federal prosecutor to recommend a reduction in the fines and penalties that would otherwise be applicable or sentencing mitigation (a sentencing credit) from a federal judge.

Finally, the Deficit Reduction Act (DRA) of 2005 requires specified health care providers to establish and disseminate detailed written policies and procedures to inform their employees and others about federal and state false claims laws and whistleblower laws. Although DRA falls short of requiring a full compliance program, clearly hospitals are required to have

at least the beginnings of an effective compliance program in place. *(See F. "Mandatory Hospital Policies and Procedures Under DRA," page 1.16.)* It is recommended that tax-exempt hospitals also establish and disseminate a detailed written conflict of interest policy that can be incorporated into the hospital's compliance program. *(See chapter 9 concerning issues for tax-exempt hospitals.)*

This chapter contains a model compliance plan that a hospital may use as a starting point in drafting its own plan.

A. The Benefits of a Compliance Program

The benefits of a compliance program are many. Perhaps most importantly, an effective compliance program raises awareness of compliance issues and creates a "culture of compliance" throughout the organization. As the OIG has stated:

> Fundamentally, compliance efforts are designed to establish a culture within a hospital that promotes prevention, detection and resolution of instances of conduct that do not conform to Federal and State law, and Federal, State and private payor health care program requirements, as well as the hospital's ethical and business policies. In practice, the compliance program should effectively articulate and demonstrate the organization's commitment to the compliance process. [63 Fed. Reg. 8987, 8988 (Feb. 23, 1998)]

Compliance programs help hospitals develop effective internal controls that promote adherence to applicable state and federal laws and the program requirements of state, federal and private health plans. A hospital may gain important additional benefits by voluntarily implementing a compliance program, including:

1. Demonstrating the hospital's commitment to honest and responsible corporate conduct;
2. Increasing the likelihood of preventing, identifying, and correcting unlawful and unethical behavior at an early stage;
3. Encouraging employees to report potential problems to allow for appropriate internal inquiry and corrective action; and
4. Through early detection and reporting, minimizing any financial loss to government and taxpayers, as well as any corresponding financial loss to the hospital.

[70 Fed. Reg. 4858, 4859 (Jan. 31, 2005)]

Compliance programs are taken into consideration directly by the OIG in implementing its permissive exclusion authority. On April 18, 2016, the OIG issued a revised policy statement containing criteria that the OIG uses in implementing its permissive authority to exclude individuals and entities from participation in federal health programs. This OIG guidance may be found on the OIG website at https://oig.hhs.gov/exclusions/files/1128b7exclusion-criteria.pdf. *(See chapter 11 for more information about excluded providers.)*

The revised policy includes guidance regarding compliance programs. This guidance states the existence of a compliance program alone does not affect risk assessment of whether or not the individual or entity continues to pose a threat to federal health programs. However, the absence of a compliance program indicates higher risk, and if an entity has devoted significantly more resources to the compliance function of a compliant program, this indicates a lower risk.

A compliance program will also have beneficial implications with respect to the 60-day rule. Section 6402 of the Affordable Care Act established a statutory provision that requires providers, Medicare Advantage organizations, prescription drug plan sponsors, and Medicaid managed care organizations to report and return Medicare and Medicaid overpayments within the later of (a) 60 days after the overpayment is "identified," or (b) the date any corresponding cost report is due, if applicable. [42 U.S.C. Section 1320a-7k(d)(2)]

CMS regulations implementing Section 6402 were issued on Feb. 12, 2016. The regulatory provisions define "identified an overpayment" as when a provider or supplier "has, or should have through the exercise of reasonable diligence, determined that [it] has received an overpayment and quantified the amount of the overpayment." **"Should have determined"** occurs when the provider or supplier failed to exercise reasonable diligence and in fact received an overpayment.

Under the regulations, reasonable diligence "includes both proactive compliance activities conducted in good faith by qualified individuals to monitor for the receipt of overpayments and investigations conducted in good faith and in a timely manner by qualified individuals in response to obtaining credible information of a potential overpayment." "[U]ndertaking no or minimal compliance activities" could result in the government finding the provider did not comply with the 60-day rule "based on failure to exercise reasonable diligence" if the provider has received an overpayment.

Thus, under the regulations, an effective compliance program can establish that a hospital has exercised reasonable diligence in attempting to identify any overpayments for purposes of the 60-day rule. *(See chapter 15 for further discussion of the 60-day rule.)*

[81 Fed. Reg. 7954, 7661, 7663 (Feb. 12, 2016); 42 C.F.R. Sections 401.301-305]

The Justice Manual (JM) of the United States Department of Justice (DOJ) includes a section entitled "Principles of Federal Prosecution of Business Organizations," that describes various factors that DOJ prosecutors consider when investigating a corporation, determining whether or not to bring charges, and negotiating pleas or other agreements. One of these factors is "the adequacy and effectiveness of the corporation's compliance program at the time of the offense, as well as at the time of a charging decision." [JM 9-28.000, 9-28.800, available at https://www.justice.gov/jm/jm-9-28000-principles-federal-prosecution-business-organizations]

The DOJ's Criminal Division has also released a guidance document (updating and adopting prior guidance that was issued by the Division's Fraud Section in February 2017) for white-collar prosecutors regarding the evaluation of corporate compliance programs. This guidance is discussed in more detail in E. "Department of Justice Criminal Division Guidance on Evaluating Corporate Compliance Programs," page 1.13.

B. Federal Sentencing Guidelines for Organizations

As mentioned above, the FSGO guides federal judges in the sentencing of organizations for federal criminal violations, including violations of federal health care fraud and abuse laws. The FSGO is available at https://www.ussc.gov/guidelines/2018-guidelines-manual/annotated-2018-chapter-8. The guidelines are advisory in nature; judges are required to consult the FSGO, but are not required to follow them. The FSGO rewards hospitals that have effective compliance programs by recommending a reduction in the fines and penalties that would otherwise be applicable. For example, the FSGO provides that a hospital's guilt

will be lessened if the hospital "had in place at the time of the offense an effective compliance and ethics program." [FSGO Section 8C2.5(f)(1)] Therefore, having an effective compliance program in place may protect a hospital from receiving harsher fines and sanctions when a violation does occur.

The FSGO sets forth the purpose of a compliance and ethics plan and lists seven essential elements that must be part of every compliance program. According to the guidelines, the purpose of an effective compliance and ethics program is to "exercise due diligence to prevent and detect criminal conduct" and "otherwise promote an organizational culture that encourages ethical conduct and a commitment to compliance with the law." To be effective, the compliance and ethics program must be "designed, implemented, and enforced so that the program is generally effective in preventing and detecting criminal conduct." However, even if criminal conduct still occurs when an organization has a compliance plan in place, the FSGO states that the "failure to prevent or detect the instant offense does not necessarily mean that the program is not generally effective in preventing and detecting criminal conduct." [FSGO Section 8B2.1(a)]

The FSGO sets forth seven minimum requirements that an organization must meet in order for a compliance and ethics program to be considered effective in preventing and detecting criminal conduct. They are as follows:

1. **Establish standards and procedures to prevent and detect violations of law.** These standards and procedures are often set forth in a generalized code of conduct and additional policies that are tailored to the specific laws that are applicable to a hospital. There are often separate policies for particular units because of specialized laws that apply to the units. The code of conduct and related policies should set forth the specific standards and conduct that an organization expects its employees to follow, including conduct that is not to occur. CHA's Model Hospital Compliance Plan includes a code of conduct.

2. **Provide appropriate oversight.** "The organization's governing authority shall be knowledgeable about the content and operation of the compliance and ethics program and shall exercise reasonable oversight with respect to the implementation and effectiveness of the compliance and ethics program." A specific senior employee should be assigned the overall responsibility for the compliance program (usually known as the "compliance officer" or the "chief compliance officer"). This person should actively investigate the organization and promote a culture within the organization that encourages ethical conduct and a commitment to comply with the law. There also should be a compliance committee and other managers who are responsible for the day-to-day implementation of the compliance program. The compliance officer, along with the whole compliance team, must be given the resources, authority, and access to the governing board that are necessary to carry out the compliance program.

3. **Exhibit due diligence in hiring and assigning personnel to positions with substantial authority.** "The organization shall use reasonable efforts not to include within the 'substantial authority personnel' of the organization any individual whom the organization knew, or should have known through the exercise of due diligence, has engaged in illegal activities or other conduct inconsistent with an

effective compliance and ethics program." **"Substantial authority personnel"** are defined in the FSGO to mean "individuals who within the scope of their authority exercise a substantial measure of discretion in acting on behalf of an organization." [Commentary to FSGO Section 8A1.2 at 3.(C)] In most instances, high-level, senior employees, and management personnel should be considered to be employees who have substantial authority. (Many professionals, such as physicians, may also fall within this category.) Organizations should conduct background checks on new employees who have substantial authority and review personnel records before employees are promoted to positions where they exercise substantial authority. (Hospitals should consult their labor/employment counsel regarding which employees may be subject to background checks as well as the permissible scope of background checks under California law.) In addition, organizations should promptly remove employees from positions of substantial authority if they have engaged in illegal activities or have shown disregard for the compliance program or applicable program standards.

4. **Communicate compliance standards and procedures to all employees and train employees at all levels.** "The organization shall take reasonable steps to communicate periodically and in a practical manner its standards and procedures, and other aspects of the compliance and ethics program, to [members of the governing authority, high-level personnel, substantial authority personnel, the organization's employees, and, as appropriate, the organization's agents] by conducting effective training programs and otherwise disseminating information appropriate to such individuals' respective roles and responsibilities." Periodic training should be provided to the organization's board, all levels of employees, and, as appropriate, the organization's agents and independent contractors, including physicians. In an easy to understand manner, the training program should include:

    a. An overview of the compliance program,

    b. An explanation of the laws applicable to all individuals,

    c. An explanation of the laws applicable to the individual's specific job, and

    d. Specific information about how the individual must comply with the compliance program.

5. **Monitor, audit and evaluate.** The organization shall take reasonable steps to:

    a. Ensure that the organization's compliance and ethics program is followed, including monitoring and auditing to detect criminal conduct;

    b. Evaluate periodically the effectiveness of the organization's compliance and ethics program; and

    c. Have and publicize a system, which may include mechanisms that allow for anonymity or confidentiality, whereby the organization's employees and agents may report or seek guidance regarding potential or actual criminal conduct without fear of retaliation.

It is important organizations tell employees it is their duty to report suspected violations of law and provide a workable avenue for employees to do so without

fear of retaliation. The organization's reporting system should include a way to make reports anonymously or confidentially. Once an organization receives a report, it should promptly investigate the potential wrongdoing.

6. **Promote and enforce compliance and ethical conduct.** "The organization's compliance and ethics program shall be promoted and enforced consistently throughout the organization through:

   a. Appropriate incentives to perform in accordance with the compliance and ethics program; and

   b. Appropriate disciplinary measures for engaging in criminal conduct and for failing to take reasonable steps to prevent or detect criminal conduct."

   Hospitals must have written policies that provide a mechanism to discipline employees who violate the compliance standards or applicable laws and regulations. The disciplinary system must include measures that are severe enough to deter wrongdoing. Organizations must be able to demonstrate that they have, in fact, disciplined not only employees who violated the compliance plan and applicable laws, but also employees who failed to report suspected violations. It is important to include incentives and rewards for those who actively observe and encourage a culture of compliance.

7. **Investigate and remediate upon detecting a violation.** "After criminal conduct has been detected, the organization shall take reasonable steps to respond appropriately to the criminal conduct and to prevent further similar criminal conduct, including making any necessary modifications to the organization's compliance and ethics program." Once an organization has evidence that a violation has occurred, it must take reasonable steps to correct the violation. These steps may include the organization voluntarily disclosing the violation to the government. Once a violation is identified, the hospital must determine the underlying causes of the violation and take action to prevent future violations. This may require that the organization modify or improve its compliance program in an effort to prevent similar violations from occurring in the future.

The FSGO also provides that the organization is to periodically assess the risk of criminal conduct and take appropriate action to modify the seven requirements as necessary to reduce the risk of the criminal conduct identified. The seven requirements of an effective compliance program are discussed further in the *Federal Sentencing Guidelines Manual* in chapter eight at Section 8B2.1 and the related commentary. The latest manual can be found on the U.S. Sentencing Commission's website at www.ussc.gov/Guidelines/index.cfm.

The U.S. Sentencing Commission announced changes to the FSGO effective Nov. 1, 2010. In essence, the changes provide a decrease in the offense level if:

1. The individual with operational responsibility for the compliance and ethics program has direct reporting obligations to the organization's governing authority (for example, the Board of Directors) or appropriate subgroup thereof (for example, the Audit Committee of the Board);

2. The compliance and ethics program detects the offense before discovery outside the organization or before such discovery was reasonably likely;

3. The organization promptly reported the offense to the appropriate governmental authorities; and

4. No individual with operational responsibility for the compliance and ethics program participated in, condoned, or was willfully ignorant of the offense.

The Commission notes that an individual has "direct reporting obligations" if the individual has express authority to communicate personally to the governing authority "promptly on any matter involving criminal conduct or potential criminal conduct" and "no less than annually on the implementation and effectiveness of the compliance and ethics program."

[75 Fed. Reg. 27387, 27394 (May 14, 2010)]

Section 10606 of the Patient Protection and Affordable Care Act of 2010 directed the U.S. Sentencing Commission to review the FSGO that apply to persons convicted of federal health care offenses, to increase the penalties for defendants convicted of federal health care offenses involving government health care programs, and to provide that the amount of fraudulent bills submitted is evidence of the amount of the intended loss by the defendant. The Sentencing Commission was directed to ensure that the FSGO and policy statements "reflect the serious harms associated with health care fraud and the need for aggressive and appropriate law enforcement action to prevent such fraud."

The Sentencing Commission amended the provision relating to larceny, embezzlement, and other forms of theft to provide a tiered enhancement that applies in cases where a defendant was convicted of a federal health care offense involving a government health care program. If the loss to the government health care program was more than $1 million, the penalty is increased by two levels. If the loss was more than $7 million, the penalty is increased by three levels. If the loss was more than $20 million, the penalty is increased by four levels. [FSGO Section 2B1.1.(b)(7)] The commentary defines a **"government health care program"** as "any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by federal or state government. Examples of such programs are the Medicare program, the Medicaid program, and the CHIP program." The commentary also provides that the aggregate dollar amount of fraudulent bills submitted to the government health care program shall be deemed to be the amount of the intended loss, if not rebutted. The amendment went into effect Nov. 1, 2011.

The FSGO applies to all organizations and businesses. The OIG has developed compliance program guidance (currently non-mandatory) for hospitals and other types of health care organizations based upon the seven essential elements of the FSGO. It is essential that hospital compliance officers review the OIG compliance program guidance for hospitals, discussed below. Unlike hospitals, for which a compliance plan is not yet mandatory, accountable care organizations (ACOs) are required to have a compliance plan in place that includes a designated compliance officer, mechanisms for identifying and addressing compliance problems, a method for anonymous reporting of suspected problems, compliance training and required reporting of probable violations to law enforcement authorities. [42 C.F.R. Section 425.300] An ACO is a group of providers and suppliers of health services that:

1. Work together to coordinate care for Medicare fee-for-service beneficiaries,

2. Agree to be accountable for the quality and cost of care for a defined group of assigned Medicare fee-for-service beneficiaries, and

3. Share in savings (and potentially losses) associated with the care for those assigned beneficiaries.

C. OIG Compliance Program Guidance

The OIG has developed compliance program guidance for hospitals and other types of health care organizations. The initial guidance for hospitals was published on Feb. 23, 1998, and a supplement was published on Jan. 31, 2005. The suggestions made in these documents are not mandatory. However, it is essential that compliance officers review these documents (as well as any other applicable guidance) and consider adopting the OIG suggestions as appropriate.

The OIG recognizes that a compliance program is not a one-size-fits-all program. Instead, the OIG encourages hospitals to identify and focus their compliance efforts on those areas of potential concern or risk that are most relevant to their individual organizations. Compliance measures adopted by a hospital to address identified risk areas should be tailored to fit the unique environment of the organization, including its structure, operations, resources, and prior enforcement experience.

OIG guidance may be found on the OIG website at https://oig.hhs.gov/compliance/compliance-guidance/index.asp. At this time, the OIG has published a final guidance for hospitals; clinical laboratories; home health agencies; third-party medical billing companies; the durable medical equipment, prosthetics, orthotics, and supply industry; hospices; Medicare+Choice organizations; nursing facilities; individual and small group physician practices; ambulance suppliers; and pharmaceutical manufacturers. A draft guidance is available for recipients of Public Health Services research awards.

The OIG believes that every effective compliance program must begin with a formal commitment by the hospital's governing body to include all of the applicable elements listed below, which are based on the seven elements of the FSGO. The OIG emphasizes that a good faith and meaningful commitment on the part of the hospital administration, especially the governing body and the CEO, will substantially contribute to a program's successful implementation. The OIG has published several resources for hospitals' governing bodies regarding corporate responsibility and corporate compliance, including "Practical Guidance for Health Care Governing Boards on Compliance Oversight," "An Integrated Approach to Corporate Compliance: A Resource for Health Care Boards of Directors" and "Corporate Responsibility and Corporate Compliance: A Resource for Health Care Boards of Directors," which are available on the OIG's website at https://oig.hhs.gov/compliance/compliance-guidance/compliance-resource-material.asp.

The OIG's hospital compliance program guidance contains the following elements:

1. **Standards and Procedures** — The hospital should develop and distribute written standards of conduct *(see "Section II — Code of Conduct," page of the Model Hospital Compliance Plan)* as well as written policies and procedures that promote the hospital's commitment to compliance (for example, including adherence to compliance as an element in evaluating managers and employees). The hospital should also implement written policies and procedures that address specific areas of potential fraud or exposure, such as claims development and submission processes, code gaming, financial relationships with physicians and other health care professionals, providing medically unnecessary services, outpatient services

rendered in connection with inpatient stays, interfering with patients' freedom of choice, and patient "dumping." Written policies should be provided to all individuals who are affected by the particular policy at issue, including the hospital's agents and independent contractors.

The hospital's written standards should state the organization's mission, goals and ethical requirements of compliance. They should reflect a clear expression of expectations for all governing body members, officers, managers, employees, physicians and, where appropriate, contractors and other agents. They should be distributed to all employees, and comprehensible to all (translated into other languages and written at appropriate reading levels, where appropriate). They should be updated regularly not only to address new laws, regulations or guidance, but also to describe how the compliance program will specifically address any compliance issue that may have been identified by the organization, as well as the requirements of any corporate integrity agreements, deferred prosecution agreements or other settlements that impact compliance.

The OIG believes that a hospital's written policies and procedures should take into consideration the regulatory exposure for each function or department of the hospital. Written policies should be coordinated with appropriate training with an emphasis on areas of special concern that have been identified by the OIG. Some of these areas are identified in the OIG Compliance Program Guidance. In addition, the OIG identifies areas of concern in its annual work plan. Compliance officers should obtain the annual OIG work plan each year, review it carefully, and identify any auditing or operational changes that should be completed. *(See D. "OIG Annual Work Plan," page 1.13.)*

2. **Oversight** — The hospital should designate a chief compliance officer who reports directly to the CEO and the governing body; establish a compliance committee charged with the responsibility of advising the compliance officer and operating and monitoring the compliance program; and appropriate sufficient funding and staff to fulfill necessary compliance functions *(see "Section III — Compliance Program Systems and Processes," page MP.12 of the Model Hospital Compliance Plan, for further discussion of this and the following compliance program elements)*.

3. **Education and Training** — The hospital should develop and implement regular, effective education and training programs for all affected employees at all levels. A minimum number of educational and training hours should be required for all employees based upon the employee's position at the hospital (the OIG recommends a minimum of one to three hours annually for basic compliance training, and more for specialty fields such as billing and coding). The programs should be repeated periodically to ensure that new employees receive timely training. The compliance officer should document all formal training provided as part of the compliance program and retain records of the employees trained and materials provided.

   The OIG has provider compliance training materials available on its website that include a compliance training webcast with 16 individual modules, as well as videos, audio podcasts, and presentation materials that address such topics as fraud and

abuse laws, the physician self-referral law, health care compliance program tips, information on operating an effective compliance program, and recommended compliance resources. These materials are available at https://oig.hhs.gov/compliance/provider-compliance-training/index.asp. The OIG also has educational materials available to assist in teaching physicians about the five main federal fraud and abuse laws and how to comply with these laws. The materials include a booklet for physicians' self-study, a PowerPoint presentation that can be used to teach the material contained in the booklet, and speaker notes to assist in giving the PowerPoint presentation. These materials are available at https://oig.hhs.gov/compliance/physician-education/index.asp.

4. **Reporting** — The hospital should maintain a process, such as a hotline, to receive complaints, and adopt procedures to protect the anonymity of complainants and to protect whistleblowers from retaliation. There should be an open line of communication between the compliance officer and hospital personnel, as well as written confidentiality and non-retaliation policies. The compliance committee should also develop several independent reporting paths for an employee to report fraud, waste or abuse so that such reports cannot be diverted by supervisors or other personnel.

5. **Enforcement and Discipline** — The hospital should develop a system to respond to allegations of improper/illegal activities, and enforce appropriate disciplinary action against employees who have violated internal compliance policies, applicable statutes, regulations, or federal health care program requirements. The OIG believes that the compliance program should include a written policy statement setting forth the degrees of disciplinary actions that may be imposed upon corporate officers, managers, employees, physicians, and other professionals (for example, oral warnings to suspension, privilege revocation, termination, financial penalties, etc.). The consequences of noncompliance should be consistently applied and enforced, in order for the disciplinary policy to have the required deterrent effect.

   The OIG also states that, for all new employees with discretionary authority to make decisions that may involve compliance with the law or compliance oversight, hospitals should conduct a reasonable and prudent background investigation, including a reference check. (Hospitals should consult their labor/employment counsel regarding which employees may be subject to background checks as well as the permissible scope of background checks under California law.) The application for employment should specifically require the applicant to disclose any criminal conviction under health care fraud and abuse laws as well as exclusion from federally-funded health care programs.

6. **Monitoring and Auditing** — The hospital should monitor and audit to assess compliance and to assist in the reduction of identified problem areas. At a minimum, the OIG states a compliance program should focus on the hospital's compliance with laws governing kickback arrangements, physician self-referral prohibitions, coding, claim development and submission, reimbursement, cost reporting, and marketing. The program also should address any specific rules or areas that are currently the focus of particular attention by governmental agencies or law enforcement, as well as areas of concern identified by any governmental entity

that are specific to the hospital. The OIG suggests that hospitals also may want to undertake a review of any reserves the hospital has established for payments that it may owe to federal health care programs. The OIG recommends that when a compliance program is established, the hospital take a "snapshot" of its operations from a compliance perspective to be used as part of benchmarking analyses.

Compliance monitoring consists of the routine quality assurance activities a hospital conducts that often involve spot checks to evaluate compliance with policies. There are many monitoring techniques available to assess compliance including:

a. On-site visits (scheduled and unscheduled);

b. Mock surveys;

c. Personnel interviews (especially with personnel involved in management, operations, coding, claim development and submission, patient care, and other related activities);

d. Focus group discussions;

e. Questionnaires to the hospital's employees and staff about their understanding of the compliance program and the laws and regulations applicable to their jobs;

f. Reviews of medical and financial records to support claims for reimbursement and cost reports;

g. Reviews of written materials and documentation prepared by different departments (including compliance logs);

h. Trend analysis, or longitudinal studies, that seek positive or negative deviations in specific areas over a given period; and

i. Sampling protocols to identify and review variations from an established baseline. If there are significant variations from the baseline, a reasonable inquiry should follow to determine the cause of the deviation.

One example of a monitoring technique would be for the compliance officer to sit in on a marketing presentation to evaluate whether the hospital's marketing policy is being followed. Other examples would be to review all of the hospital's contracts with physicians for compliance with fraud and abuse and physician self-referral laws, or to review personnel files of new employees to determine whether the hospital's screening policy for exclusion from participation in federal and state health care programs was followed *(see chapter 11 regarding screening for excluded providers).*

Auditing is a formal process that is conducted on a defined schedule in accordance with professional standards. Usually a baseline audit is performed as a reference point for future audits and also to establish priorities for policies, training and corrective action. Regular, periodic audits are then performed to validate compliance with a particular regulation or to quantify error rates. The first step in the audit process is to clearly identify what is being evaluated. Once the particular issue is identified, then the specific auditing steps and type of audit can be selected. Routine audits may sample all claims or evaluate specific services or claims. Audits

can be limited reviews (sometimes referred to as "probe" audits) or much larger reviews that are statistically valid. Sometimes the audits will be conducted on data analysis alone, and at other times medical records and claims documentation will be used as well. Hospitals must evaluate any error rates identified in the audits. If error rates are not decreasing, the hospital must conduct further investigation to determine why that is the case.

In addition to routine audits and audits that target specific risk areas, the hospital may wish to conduct investigatory audits in response to specific identified problem areas. The main purposes of an investigatory audit are to determine whether a problem exists, to address and correct the problem, and to identify any reporting, repayment or other remediation obligations.

The auditing and monitoring process will be successful only if it is conducted by internal or external auditors who have expertise pertaining to the applicable health care laws, regulations, and program requirements. Audits that pertain to billing and coding of claims must be conducted by audit personnel who are qualified and have the applicable certifications. The auditors must also be sufficiently independent of management and physicians to maintain credibility in the audit process. For investigatory audits it is often advisable to use an outside firm with expertise in the specific area being audited, particularly if the hospital believes that there is a reasonable likelihood that a problem exists. In such a case, the hospital will need to consider whether the audit should be conducted under attorney-client privilege. The decision of whether to conduct an investigatory audit requires the balancing of many factors, and should be made with the advice of the hospital's legal counsel.

The monitoring and auditing plan should be re-evaluated annually to address areas of concern and to incorporate findings from previous years. The overall compliance program also should be reviewed at least annually to determine whether the compliance program's elements have been satisfied by all departments. The reports generated by the monitoring and auditing process should be maintained by the compliance officer and shared with senior hospital or corporate officers and the compliance committee.

7. **Investigation and Remediation** — The hospital should investigate to identify violations of a hospital's compliance program, failures to comply with applicable law, and the presence of systemic problems, and implement procedures to remedy any problems discovered. An effective compliance program should have procedures that provide for the prompt and thorough investigation by the compliance office of all reasonable indications of noncompliance and potential violations. Complete documentation of all investigations should be maintained that includes the outcome of each investigation and any remedial action taken. Hospitals should also have in place procedures to check all employees, contractors, and medical and clinical staff members at least annually against government sanctions lists to ensure that sanctioned individuals are not employed or retained. *(See chapter 11 for information on screening for excluded providers.)*

8. **Corrective Action** — The OIG takes a dim view of detected but uncorrected

misconduct; taking appropriate corrective action is important. Therefore, hospitals must have procedures in place to respond quickly to detected deficiencies and must develop effective corrective action plans. In addition, the OIG recommends that hospitals voluntarily self-report violations of federal and state laws promptly. For example, if the compliance officer has reason to believe that misconduct may violate criminal, civil or administrative law, the OIG suggests that the hospital report the misconduct to the appropriate governmental authority within 60 days after determining that there is credible evidence of a violation. With respect to Medicare or Medicaid (Medi-Cal) overpayments, the Patient Protection and Affordable Care Act of 2010 provides that hospitals must report and return overpayments by the later of 60 days after the date the overpayment was identified or the date a corresponding cost report is due. *(See chapter 15 regarding repayment and self-disclosure.)*

This brief description of the eight elements contains only the highlights of the information found in the OIG Program Guidance for Hospitals. As noted above, hospital compliance officers should carefully read these documents in full.

On Jan. 17, 2017, a group of compliance professionals and staff from the OIG and the Department of Health and Human Services met to discuss ways to measure the effectiveness of compliance programs. This Health Care Compliance Association (HCCA)-OIG Compliance Effectiveness Roundtable resulted in a resource guide for measuring the effectiveness of a compliance program. The list is intended to provide measurement options to a wide range of organizations with diverse size, operational complexity, industry sectors, resources, and compliance programs. The resource guide is available at https://assets.hcca-info.org/portals/0/PDFs/Resources/library/2017-01-HCCA-OIG-Report.pdf.

D. OIG Annual Work Plan

The OIG publishes a work plan describing its priorities for fraud and abuse enforcement efforts for the Medicare, Medicaid (Medi-Cal), and other federally-funded health care programs. The plan is updated monthly. Hospitals are strongly encouraged to review the work plan and review their compliance in the areas identified by the OIG as high enforcement priorities. The work plan is available at https://oig.hhs.gov/reports-and-publications/workplan/index.asp.

E. Department of Justice Criminal Division Guidance on Evaluating Corporate Compliance Programs

The DOJ's Criminal Division has published guidance on the "Evaluation of Corporate Compliance Programs." This guidance is available at https://www.justice.gov/criminal-fraud/page/file/937501/download. This guidance is intended to assist prosecutors in making informed decisions as to whether, and to what extent, the corporation's compliance program was effective at the time of the offense, and is effective at the time of a charging decision or resolution, for purposes of determining the appropriate:

1. Form of any resolution or prosecution;
2. Monetary penalty, if any; and
3. Compliance obligations contained in any corporate criminal resolution (e.g., monitorship or reporting obligations).

This guidance, originally published in 2017, was modified in April 2019 with the intention to "better harmonize the [prior] guidance with other Department guidance and standards while providing additional context to the multifactor analysis of a company's compliance program."

[U.S. Dept. of Justice, "Criminal Division Announces Publication of Guidance on Evaluating Corporate Compliance Programs" (Apr. 30, 2019), https://www.justice.gov/opa/pr/criminal-division-announces-publication-guidance-evaluating-corporate-compliance-programs.]

This guidance was again modified in June 2020. These 2020 modifications left the core and structure of the guidance but made notable changes signaling the importance of a corporation's compliance program when determining how and whether to penalize the corporation as a result of a criminal investigation.

The following summarizes the major components of the guidance.

Is the Corporation's Compliance Program Well Designed?

Risk Assessment

One of the first factors in evaluating whether a program is well-designed is how the company has "identified, assessed, and defined its risk profile, and the degree to which the program devotes appropriate scrutiny and resources to the spectrum of risk."

Policies and Procedures

A well-designed compliance program "entails policies and procedures that give both content and effect to ethical norms and that address and aim to reduce risks identified by the company as part of its risk assessment process."

Training and Communication

A "well-designed compliance program is appropriately tailored to training and communications."

Confidential Reporting Structure and Investigation Process

A "hallmark of a well-designed compliance program is the existence of an efficient and trusted mechanism by which employees can anonymously or confidentially report allegations of a breach of the company's code of conduct, company policies, or suspected or actual misconduct."

Third-Party Management

A "well-designed compliance program should apply risk-based due diligence to its third-party relationships."

Mergers and Acquisitions

"A well-designed compliance program should include comprehensive due diligence of any acquisition targets, as well as a process for timely and orderly integration of the acquired entity into existing compliance program structures and internal controls."

Is the Corporation's Compliance Program Adequately Resourced and Empowered to Function Effectively?

Commitment by Senior and Middle Management

According to the guidance, "it is important for a company to create and foster a culture of ethics and compliance with the law at all levels of the company," and as such, an effective

"compliance program requires company leadership to implement a culture of compliance from the middle and the top."

Autonomy and Resources

"Effective implementation also requires those charged with a compliance program's day-to-day oversight to act with adequate authority and stature."

Incentives and Disciplinary Measures

"Another hallmark of effective implementation of a compliance program is the establishment of incentives for compliance and disincentives for non-compliance."

Does the Corporation's Compliance Program Work in Practice?

The guidance notes that this last question is the most difficult question to answer in evaluating a compliance program after misconduct has occurred. The guidance stresses that the existence of misconduct does not necessarily mean a compliance program was ineffective at the time the misconduct occurred. In order to assess the efficacy of a company's compliance program at the time of misconduct, prosecutors should consider whether the misconduct was detected and if so, how was it detected, what investigation resources were in place to investigate, and the nature and thoroughness of remedial efforts.

Continuous Improvement, Periodic Testing, and Review

To evaluate whether a compliance program works in practice, prosecutors should evaluate whether the compliance program has evolved over time to address existing and changing compliance risks and how a program has changed in response to lessons learned.

Investigation of Misconduct

"Another hallmark of a compliance program that is working effectively is the existence of a well-functioning and appropriately funded mechanism for the timely and thorough investigations of any allegations or suspicions of misconduct by the company, its employees, or agents."

Analysis and Remediation of Any Underlying Misconduct

Lastly, "a hallmark of a compliance program that is working effectively in practice is the extent to which a company is able to conduct a thoughtful root cause analysis of misconduct and timely and appropriately remediate to address the root causes."

The recent changes to the guidance underscore certain areas of focus for prosecutors to consider. These questions fall within the above-listed components of the guidance.

Consideration of unique circumstances. The guidance emphasizes the importance of prosecutors understanding each company's unique circumstances and how they have influenced the development of the company's compliance program. The guidance notes that prosecutors "should endeavor to understand why the company has chosen to set up the compliance program the way that it has, and why and how the company's compliance program has evolved over time."

Importance of data. The guidance advises prosecutors to assess whether compliance personnel have "sufficient direct or indirect access to relevant sources of data" to conduct effective monitoring of compliance. When evaluating a company's updates and revisions to its compliance program, prosecutors are to inquire whether the company's periodic review is

limited to a "snapshot in time" or whether it is based on "continuous access to operational data and information across functions?"

Periodic review and enhancement. The guidance also requires an examination of the company's processes for updating existing policies and procedures, in addition to implementing new policies and procedures. Updates to existing policies and procedures should be made in accordance with the company's periodic risk assessments, and should be based on "lessons learned" from the company's experience and that of others in the same industry and geographical region.

Monitoring of third-party agents. The updates underscore the importance of careful oversight of the company's third-party agents, asking whether "the company engage[s] in risk management of third parties throughout the lifespan of the relationship, or primarily during the onboarding process."

Confidential reporting and investigation process. The updated guidance further contemplates an anonymous or confidential reporting mechanism for alleged compliance violations and asks not only how "the reporting mechanism [is] publicized to the company's employees" but also to "other third parties."

Integration of acquisitions. With respect to mergers and acquisitions, the updated guidance instructs prosecutors to consider whether the company has "a process for timely and orderly integration of the acquired entity into existing compliance program structures and internal controls." This language is consistent with the statement that the extent of scrutiny that a company applies to its acquisition targets "is indicative of whether its compliance program is, as implemented, able to effectively enforce its internal controls and remediate misconduct at all levels of the organization."

Assessment of the compliance program before and after. The guidance explicitly instructs prosecutors to consider a company's compliance program both at the time of the offense and at the time of the charging decision and resolution."

F. Mandatory Hospital Policies and Procedures Under DRA

On January 1, 2007, Section 6032 of the Deficit Reduction Act (DRA) of 2005 ("Employee Education About False Claims Recovery") took effect as part of an aggressive plan to cut Medicare and Medicaid (Medi-Cal) spending. This law obligates certain health care providers receiving $5 million per year or more of Medicaid reimbursement to establish and disseminate detailed written policies and procedures to inform their employees, contractors and agents about federal and state false claims laws and whistleblower laws. A discussion of these policies and procedures, the rights of employees to be protected as whistleblowers, and policies and procedures for detecting and preventing fraud, waste and abuse must be included in any employee handbook if such a handbook exists. [42 U.S.C. Section 1396a(a)(68)]

Despite its title, "Employee Education," Section 6032 does not require providers to perform any live education or other actual training. Nevertheless, it is suggested that providers determine whether such training is necessary or desirable, as training may be useful to document an employee's receipt of the required information, and can thus be offered as evidence of a provider's good faith attempt to comply with the DRA.

Although there are no specific penalties for providers' failure to meet Section 6032's requirements, compliance with this law is a condition of Medicaid payment. Failure to comply may result in the forfeiture of all Medicaid payments during the period of noncompliance. Further, such noncompliance may ultimately expose the entity to a False Claims Act lawsuit. *(See chapter 3 regarding state and federal false claims acts.)*

The following information provides a more detailed description of how Section 6032 works. This discussion is based on Section 6032 itself, as well as guidance and Frequently Asked Questions (FAQs) published by CMS. The guidance is available at www.cms.hhs.gov/smdl/downloads/SMD121306.pdf. The FAQs are available at www.cms.hhs.gov/smdl/downloads/SMD032207Att1.pdf.

Who is Required to Comply with Section 6032 Requirements?

Section 6032 applies to any "entity" receiving $5 million or more of Medicaid reimbursement annually. An **"entity"** subject to Section 6032 includes a governmental agency, organization, unit, corporation, partnership, or other business arrangement (including any Medicaid managed care organization, irrespective of the form of business structure or arrangement by which it exists), whether for-profit or not-for-profit, which receives or makes payments, under a state plan approved under Title XIX [42 U.S.C. Section 1396 *et seq.*, "Grants to States for Medical Assistance Programs"] or under any waiver of such plan, totaling at least $5 million annually.

For the purposes of Section 6032, the "entity" is the largest separate organizational unit that furnishes Medicaid health care items or services, and includes all sub-units of that organizational unit that furnish Medicaid health care items or services, even if the components are separately incorporated or located in different states. Unless the organizational unit is part of a health system *(see below)*, each organizational unit is viewed separately for purposes of determining whether the $5 million threshold has been met, and the other requirements of Section 6032 are applicable. [FAQ 5]

With respect to a health system, the parent corporation, partnership, government agency or other owner, and its sub-units, are all integrally involved in furnishing Medicaid items or services. Therefore, regardless of whether some or all of the system's sub-units do not individually receive $5 million in Medicaid payments annually, the entire organization is the entity for purposes of determining the requirements of section 6032. [FAQ 6]

Note that while an organization may have multiple subsidiaries with different federal employer identification numbers or provider numbers, this is irrelevant for the purposes determining whether these subsidiaries would be aggregated or viewed as separate organizational units. [FAQ 7]

How is the $5 Million Annual Medicaid Reimbursement Calculated?

The $5 million annual threshold can be reached based on the aggregate payments received (rather than accrued) by an organization. For example, payments are aggregated where an entity furnishes items or services at more than a single location or under more than one contractual or other payment arrangement. This aggregation rule applies regardless of whether the entity submits claims for payments using one or more provider identification or tax identification numbers.

For the purposes of Section 6032, "patient pay amounts" are not included in the calculation of the $5 million threshold. While Medicare payments are not considered for purposes of determining whether an individual or organization must comply with Section 6032, Medicare deductibles and coinsurance that the State Agency pays for dual-eligible individuals and Qualified Medicare Beneficiaries should be included when determining whether compliance with Section 6032 is required. [FAQ 19]

For purposes of determining when an entity must comply with Section 6032, if an entity receives or makes payments totaling $5 million during a federal fiscal year, then that entity must comply as of January 1 of the following calendar year. For instance, the $5 million threshold is met by an entity as of Jan. 1, 2022 (and Section 6032 applies) if that entity received or made such payments in federal fiscal year 2019 (Oct. 1, 2020 to Sept. 30, 2021). Subsequent determinations are to be made by January 1 of each following year, according to the amount of payments the entity received or made under the State Plan during the preceding federal fiscal year. [FAQ 13]

When determining whether an individual or organization must comply with Section 6032, only the amounts received from a state Medicaid agency should be counted when calculating the $5 million in payments. The amounts an individual or organization may receive from a Medicaid managed care organization should not be included in that calculation. [FAQ 15]

What is Required to Comply With Section 6032?

Section 6032 requires covered entities to establish, for all employees and contractors or agents, written policies that provide "detailed information" about the following:

1. The federal False Claims Act;
2. Administrative remedies for false claims and statements;
3. State laws pertaining to civil or criminal penalties for false claims or statements; and
4. Legal protections for whistleblowers under federal and state law.

[42 U.S.C. Section 1396a(a)(68)(A)]

(See chapter 2 for information about state and federal false claims acts and whistleblower protections.)

The law provides no guidance as to what "detailed information" means.

It is the responsibility of each entity to establish and disseminate written policies. These policies must be adopted by the entity's contractors and agents. Specifically, a contractor or agent must abide by an entity's Section 6032 policies insofar as they are relevant and applicable to the contractor or agent's interaction with the entity. For example, to the extent that an entity's policies provide for reviews or audits of claims or services, the contractor or agent is required to participate in those reviews or audits. [FAQ 39] While written policies may be on paper or in electronic form, they must be readily available to all employees, contractors and agents. An entity is not required to create an employee handbook if it doesn't already have one.

Currently, Section 6032 does not require any particular recitals in an entity's contract with its contractors. However, each state is expected to establish specific requirements regarding language that must be included in such contracts. [FAQ 27] California has not established such requirements.

The entity must establish (or update) its own policies and procedures for detecting and preventing fraud, waste and abuse, and must include in its employee handbook (if one exists) a specific discussion of the rights of employees to be protected as whistleblowers and the entity's policies for detecting fraud, waste and abuse.

Related California Law

California law requires as a condition of payment from the Medi-Cal program that providers that receive or make annual payments of at least $5 million comply with the federal False Claims Act employee training and policy requirements set forth in Section 6032, described above [Welfare and Institutions Code Section 14115.75]. Also, all new Medi-Cal provider applicants and all providers subject to re-enrollment processing are required to sign the Medi-Cal Certification of Compliance form certifying that they have read and understand the federal and state law regarding employee education on false claims recovery and that they are in compliance with the training and policy requirements. The form may be found at 2019-2020 Certification of Compliance Federal Deficity Reduction Act of 2005 (MC 0805).

G. Conflict of Interest

A conflict of interest is any situation in which financial or other personal considerations may compromise or appear to compromise any personnel's business judgment, delivery of patient care, or ability to do his or her job or perform his or her responsibilities.

The CMS guidelines for Medicare managed care and prescription drug program sponsors specify that a general compliance training program should communicate a review of potential conflicts of interest and the system for disclosure of conflicts [Medicare Managed Care Manual, Pub 100-16, chapter 21, Section 50.3.1]. These compliance program guidelines also require that sponsors develop a work plan to examine the performance of the compliance program, including a review of conflict of interest disclosures and attestations [Medicare Managed Care Manual, Pub 100-16, chapter 21, Section 50.6.4].

A hospital compliance program should include policies for review of potential conflicts of interest and communicate to employees what may qualify as potential conflicts of interest. Further, the policy should also include a procedure for disclosure and continued review of conflicts of interest. *(See "Section IV — Compliance Policies," page MP.21 of the Model Hospital Compliance Plan.)*

H. Compliance Program for Skilled Nursing Facilities and Nursing Facilities

Section 6102 of the Affordable Care Act requires skilled nursing facilities (SNFs) and nursing facilities (NFs) to "have in operation a compliance and ethics program that is effective in preventing and detecting criminal, civil, and administrative violations under this Act." Section 6102 also required the Secretary of DHHS and OIG to "promulgate regulations for an effective compliance and ethics program for operating organizations, which may include a model compliance program." [42 U.S.C. Section 1320a-7j(b)(2)(A)]

Section 6102 sets forth eight minimum required components for a compliance and ethics program:

1. Establishment of compliance standards and procedures to be followed by its employees that are reasonably capable of reducing the prospect of violations;
2. Assignment of specific high-level individuals with the overall responsibility of overseeing compliance with such standards and procedures, and with sufficient resources and authority to assure compliance of standards;

3. Use of due care not to delegate substantial discretionary authority to individuals whom the organization knew or should have known had a propensity to engage in violations;
4. Effective communication of standards and procedures to all employees;
5. Establishment of monitoring and auditing systems reasonably designed to detect violations by employees, and establishment of a reporting system whereby employees may report violations by others without fear of retribution;
6. Consistent enforcement of standards through appropriate disciplinary mechanisms, including discipline of individuals responsible for the failure to detect a violation;
7. Establishment of a procedure for responding appropriately to any violations and to prevent further similar violations; and
8. Periodic assessments of the compliance program to identify changes necessary to reflect changes within the organization.

[42 U.S.C. Section 1320a-7j(b)(4)]

These eight core components are very similar to the OIG compliance guidelines issued for individual sectors of the health care industry, such as the guidelines for hospitals. *(See C. "OIG Compliance Program Guidance," page 1.8)* The OIG Compliance Program Guidance for Nursing Facilities is available at https://oig.hhs.gov/authorities/docs/cpgnf.pdf. The OIG Supplemental Compliance Program Guidance for Nursing Facilities is available at https://oig.hhs.gov/compliance/compliance-guidance/docs/complianceguidance/nhg_fr.pdf.

On Oct. 4, 2016, CMS issued the Final Rule for Reform of Requirements for Long-Term Care Facilities implementing the requirements of Section 6102. Under the Final Rule, beginning on Nov. 28, 2019, the **"operating organization"** (defined as the "individual(s) or entity that operates a facility") of any SNFs and NFs must have developed and have in operation a compliance and ethics program that:

1. Has been reasonably designed, implemented, and enforced so that it is likely to be effective in preventing and detecting criminal, civil, and administrative violations of federal law and in promoting quality of care; and
2. Includes, at minimum, the following required components:
    a. Established written compliance and ethics standards, policies, and procedures to follow that are reasonably capable of reducing the prospect of criminal, civil, and administrative violations and promote quality of care. SNFs and NFs must designate of an appropriate compliance and ethics program contact to whom individuals may report suspected violations, as well as an alternate method of reporting suspected violations anonymously without fear of retribution. SNFs and NFs must also adopt disciplinary standards that set out the consequences for committing violations for the operating organization's entire staff, individuals providing services under a contractual arrangement, and volunteers, consistent with the volunteers' expected roles;
    b. Assignment of specific individuals within high-level personnel at the operating organization with the overall responsibility to oversee compliance with the compliance and ethics program's standards, policies, and procedures, such

as, but not limited to, the chief executive officer, members of the board of directors, or directors of major divisions in the operating organization;

c. Sufficient resources and authority to the assigned individuals to reasonably assure compliance with standards, polices, and procedures;

d. Due care not to delegate substantial discretionary authority to individuals who the operating organization knew, or should have known through the exercise of due diligence, had a propensity to engage in criminal, civil, and administrative violations;

e. Steps to effectively communicate the standards, policies, and procedures in the operating organization's compliance and ethics program to the operating organization's entire staff; individuals providing services under a contractual arrangement; and volunteers, consistent with the volunteers' expected roles;

f. Reasonable steps to achieve compliance with the program's standards, policies, and procedures. Such steps include, but are not limited to, utilizing monitoring and auditing systems reasonably designed to detect criminal, civil, and administrative violations under the Act by any of the operating organization's staff, individuals providing services under a contractual arrangement, or volunteers; having in place and publicizing a reporting system whereby any of these individuals could report violations by others anonymously within the operating organization without fear of retribution; and having a process for ensuring the integrity of any reported data;

g. Consistent enforcement of the operating organization's standards, policies, and procedures through appropriate disciplinary mechanisms, including, as appropriate, discipline of individuals responsible for the failure to detect and report a violation to the facility's compliance and ethics program; and

h. After a violation is detected, the operating organization must ensure that all reasonable steps identified in its program are taken to respond appropriately to the violation and to prevent further similar violations, including any necessary modification to the operating organization's program to prevent and detect criminal, civil, and administrative violations under the Act.

In addition to the above-listed components, any organizations with five or more facilities must also include the following components:

1. A mandatory annual training program on the operating organization's compliance and ethics program;

2. A designated compliance officer for whom the operating organization's compliance and ethics program is a major responsibility and who reports directly to the organization's governing body; and

3. Designated compliance liaisons located at each of the facilities.

Lastly, the compliance and ethics program must be reviewed annually and revised to reflect changes in all applicable laws or regulations, to improve performance in deterring, reducing, and detecting violations and to promote quality of care.

[42 C.F.R. Section 483.85; 81 Fed. Reg. 68688, 68869-70 (Oct. 4, 2016)]

I. Model Hospital Compliance Plan

A model hospital compliance plan follows. A hospital may use this model as a starting point in drafting its own plan. It should be noted that this model does not replace the employee handbook or any hospital policies and procedures. A hospital must ensure that this model is revised as appropriate to maintain consistency with the employee handbook (if any), the hospital's personnel policies, and other hospital policies and procedures. Legal counsel should be involved in this process.

- Section I of the model is a Compliance Program Summary.
- Section II is a Code of Conduct.
- Section III discusses Compliance Program Systems and Processes.
- Section IV lists Compliance Policies that a hospital should develop and implement; most hospitals already have such policies in place.
- CHA Appendix HC 1-A, "Acknowledgement of Receipt of Hospital Compliance Plan," is a form that hospitals may use for employees, volunteers and contractors to sign acknowledging receipt of the hospital compliance program information.
- CHA Appendix HC 1-B, "Conflict of Interest Certification Form," is a form for employees, volunteers and contractors to use to disclose actual or potential conflicts of interest they may have with the hospital or to confirm that they do not have any such conflicts of interest.

J. Useful Compliance Websites

Below is a non-exhaustive list of OIG websites that provide useful guidance in the development, implementation, updating and evaluation of a compliance plan:

- www.ussc.gov/guidelines
- https://oig.hhs.gov/compliance/compliance-resource-portal/
- http://oig.hhs.gov/compliance/compliance-guidance/index.asp
- http://oig.hhs.gov/compliance/alerts/index.asp
- http://oig.hhs.gov/compliance/101/index.asp
- http://oig.hhs.gov/compliance/provider-compliance-training/index.asp
- http://oig.hhs.gov/compliance/compliance-guidance/compliance-resource-material.asp
- http://oig.hhs.gov/compliance/physician-education/index.asp

Model Hospital Compliance Plan

Dear Colleague:

[This letter is only a sample. It should be modified to incorporate the hospital's philosophy and compliance objectives.]

The Hospital is fully committed to compliance with the law and ethical standards. In this age of strict government regulation and public scrutiny of business practices, a high level of commitment to compliance is essential.

The Hospital has developed this Compliance Program to further our mission to provide high-quality patient care in a manner that ensures compliance with the law and the highest business ethics. This Compliance Program includes a comprehensive discussion of certain laws, the hospital's policies, and expectations about your conduct. However, no written program or policy can cover all circumstances. We therefore ask that you read this Compliance Program carefully to understand not only its written words, but its purpose and meaning as well.

If you have any questions about this Compliance Program or think an event has occurred that violates this Compliance Program, you should contact our Chief Compliance Officer. Alternatively, you can anonymously contact our Compliance Hotline by calling _____ _____ or sending a fax to _____. You are encouraged to ask questions and to report violations of this Compliance Program.

You can count on the Hospital to provide the support and environment necessary to make this Compliance Program a success. Similarly, the Hospital is counting on you to take this Compliance Program seriously and conduct yourself accordingly.

Sincerely,

President and Chief Executive Officer
[Hospital Name]

Model Hospital Compliance Plan

SECTION I — COMPLIANCE PROGRAM SUMMARY

Definitions of Commonly Used Terms

A list of words that are commonly used in this Compliance Program and their meanings follows:

- **"Hospital"** means the Hospital, and all of its subsidiaries and affiliates that are covered by this Compliance Program. [Each hospital should list its subsidiaries and affiliates covered by its compliance program.]
- **"Personnel"** means all employees and volunteers of the Hospital, and all contractors or others who are required to comply with this Compliance Program. Each of these persons must sign an Acknowledgment of Receipt of Hospital Compliance Plan and a Conflict of Interest Certification Form.

Purpose of This Compliance Program

The Hospital is committed to ensuring compliance with all applicable statutes, regulations and policies governing our daily business activities. To that end, the Hospital created this Compliance Program to serve as a practical guidebook that can be used by all Personnel to assist them in performing their job functions in a manner that complies with applicable laws and policies. This Compliance Program is intended to further our day-to-day commitment that our operations comply with federal and state laws, to provide guidance for all employees, and to serve as a mechanism for preventing and reporting any violation of those laws.

While this Compliance Program contains policies regarding the business of the Hospital, it does not contain every policy that Personnel are expected to follow. For example, this Compliance Program does not cover payroll, vacation and benefits policies. The Hospital maintains other policies with which employees are required to comply. You should discuss with your supervisor any questions regarding which policies apply to you.

It is the policy of the Hospital that:

- All employees are educated about applicable laws and trained in matters of compliance;
- There is periodic auditing, monitoring and oversight of compliance with those laws;
- An atmosphere exists that encourages and enables the reporting of noncompliance without fear of retribution; and
- Mechanisms exist to investigate, discipline and correct noncompliance.

Who is Affected

Everyone employed by the Hospital is required to comply with the Compliance Program. Because not all sections of the Compliance Program will apply to your job function, you will receive training and other materials to explain which portions of this Compliance Program apply to you.

While this Compliance Program is not intended to serve as the compliance program for all of our contractors, it is important that all contractors perform services in a manner that complies with the law. To that end, agreements with contractors may incorporate certain provisions of this Compliance Program.

This Compliance Program is effective only if everyone takes it seriously and commits to comply with its contents. It is important that you not only understand and comply with the written words of this Compliance Program, but that you also understand and appreciate the spirit and purpose of this Compliance Program. When in doubt, ask your supervisor, review the appropriate section of this Compliance Program, or take other steps to ensure that you are following the Compliance Program.

Compliance requirements are subject to change as a result of new laws. We must all keep this Compliance Program current and useful. You are encouraged to let your supervisor know when you become aware of changes in law or hospital policy that might affect this Compliance Program.

HOW TO USE THIS COMPLIANCE PROGRAM

The Hospital has organized this Compliance Program to be understandable and easy to navigate. A brief description of how this Compliance Program manual is organized follows.

Section I – Compliance Program Summary

Section II – Code of Conduct

This section contains specific policies related to your personal conduct while performing your job function. The primary objective of these policies is to create a work environment that promotes cooperation, professionalism and compliance with the law. Compliance with the Code of Conduct is a significant factor in employee performance evaluations. All Personnel will receive training on this section.

Section III – Compliance Program Systems and Processes

This section explains the roles of the Chief Compliance Officer and the Compliance Committee. It also contains information about Compliance Program education and training, auditing and corrective action. Most importantly, this section explains how to report violations anonymously, either in writing or by calling the Hospital's Compliance Hotline at _____ _____ or sending a fax to _____.
All Personnel will receive training on this section.

Section IV – Compliance Policies

This section includes specific policies that apply to various aspects of the Hospital's business and operations. Some of these policies may not apply to your specific job function, but it is still important that you are aware of their existence and importance. All Personnel will receive training regarding the policies that apply to their job function.

Here are some tips on how to effectively use this Compliance Program:

- **Refer to Table of Contents.** The Table of Contents contains a thorough list of topics covered in this Compliance Program. Use the Table of Contents to quickly locate the topic you are looking for.
- **Important Reference Tool.** This Compliance Program should be viewed as an important reference manual that can be referred to on a regular basis to answer questions about how to perform your job. Although it may not contain all of the answers, it will contain many and can save you time.
- **Read it in Context.** The Hospital has created this Compliance Program to incorporate numerous compliance policies, many of which may not apply to you. When reviewing this Compliance Program and the policies contained in it, keep in mind that the policies are to be applied in the context of your job. If you are uncertain about if or how a policy applies to you, ask your supervisor.
- **Keep it Handy.** Keep this Compliance Program manual easily accessible and refer to it on a regular basis.
- **Talk to Your Co-Workers.** Regular dialogue among co-workers and supervisors is a great way to ensure that policies are being uniformly applied. While this discussion is encouraged, always remember that the provisions of this Compliance Program should guide you on compliance matters.

SECTION II — CODE OF CONDUCT

Our Compliance Mission

[Include the Hospital's mission statement. The following is an example.]

In concert with our medical staff, the Hospital strives to provide comprehensive quality health care to our community. Our team of dedicated health care professionals shall provide a compassionate and caring environment for patients, and their families and friends, while continuously striving to improve the quality of care that is accessible and affordable.

The Hospital shall collaborate with its medical staff and affiliated organizations to improve health outcomes, enhance quality of life, and promote human dignity through health education, prevention and services across the health care continuum.

The Hospital's Board of [insert as appropriate: "Directors" or "Trustees"] (referred to herein as the "Governing Board") adopted the Compliance Program, including this Code of Conduct, to provide standards by which Personnel must conduct themselves in order to protect and promote the Hospital's integrity and to enhance the Hospital's ability to achieve its objectives. The Hospital believes this Code of Conduct will significantly contribute to a positive work environment for all.

No written policies can capture every scenario or circumstance that can arise in the workplace. The Hospital expects Personnel to consider not only the words written in this Code of Conduct, but the meaning and purpose of those words as well. You are expected to read this Code of Conduct and exercise good judgment. You are encouraged to talk to your supervisor or the Hospital's Chief Compliance Officer if you have any questions about this Code of Conduct or what is expected of you.

All Personnel are expected to be familiar with the contents of this Code of Conduct. Training and education will be provided periodically to further explain this Code of Conduct and its application.

Compliance With Laws

It is the policy of the Hospital, its affiliates, contractors and employees to comply with all applicable laws. When the application of the law is uncertain, the Hospital will seek guidance from legal counsel.

Open Communication

The Hospital encourages open lines of communication between Personnel. If you are aware of an unlawful or unethical situation, there are several ways you can bring this to the Hospital's attention. Your supervisor is the best place to start, but you can also contact the Hospital's Chief Compliance Officer or call the Compliance Hotline to express your concerns. All reports of unlawful or unethical conduct will be investigated promptly. The Hospital does not tolerate threats or acts of retaliation or retribution against employees for using these communication channels.

Your Personal Conduct

The Hospital's reputation for the highest standards of conduct rests not on periodic audits by lawyers and accountants, but on the high measure of mutual trust and responsibility that exists between Personnel and the Hospital. It is based on you, as an individual, exercising good judgment and acting in accordance with this Code of Conduct and the law.

Ethical behavior on the job essentially comes down to honesty and fairness in dealing with other Personnel and with patients, vendors, competitors, the government and the public. It is no exaggeration to say that the Hospital's integrity and reputation are in your hands.

The Hospital's basic belief in the importance of respect for the individual has led to a strict regard for the privacy and dignity of Personnel. When management determines that your personal conduct adversely affects your performance, that of other Personnel, or the legitimate interests of the Hospital, the Hospital may be required to take action.

The Work Environment

The Hospital strives to provide Personnel with a safe and productive work environment. All Personnel must dispose of medical waste, environmentally sensitive materials, and any other hazardous materials correctly. You should immediately report to your to supervisor any situations that are likely to result in falls, shocks, burns, or other harm to patients, visitors, or Personnel.

The work environment also must be free from discrimination and harassment based on race, color, religion, sex, sexual orientation, age, national origin, disability, veteran status or other factors that are unrelated to the Hospital's legitimate business interests. The Hospital will not tolerate sexual advances, actions, comments or any other conduct in the workplace that creates an intimidating or otherwise offensive environment. Similarly, the use of racial or religious slurs — or any other remarks, jokes or conduct that encourages or permits an offensive work environment — will not be tolerated.

If you believe that you are subject to such conduct, you should bring such activity to the attention of the Hospital, either by informing your supervisor, the Hospital's Chief Compliance Officer, or by calling the Compliance Hotline. The Hospital considers all complaints of such conduct to be serious matters, and all complaints will be investigated promptly.

Some other activities that are prohibited because they clearly are not appropriate are:

- Threats;
- Violent behavior;
- The possession of weapons of any type;
- The distribution of offensive jokes or other offensive materials via e-mail or any other manner; and
- The use, distribution, sale or possession of illegal drugs or any other controlled substance, except to the extent permitted by law for approved medical purposes.

In addition, Personnel may not be on the Hospital premises or in the Hospital work environment if they are under the influence of or affected by illegal drugs, alcohol or controlled substances used other than as prescribed.

Employee Privacy

The Hospital collects and maintains personal information that relates to your employment, including medical and benefit information. Access to personal information is restricted solely to people with a need to know this information. Personal information is released outside the Hospital or to its agents only with employee approval, except in response to appropriate investigatory or legal requirements, or in accordance with other applicable law. Employees who are responsible for maintaining personal information and those who are provided access to such information must ensure that the information is not disclosed in violation of the Hospital's Personnel policies or practices.

Use of Hospital Property

Hospital equipment, systems, facilities, corporate charge cards and supplies must be used only for conducting Hospital business or for purposes authorized by management.

Personal items, messages or information that you consider private should not be placed or kept in telephone systems, computer systems, offices, work spaces, desks, credenzas or file cabinets. Employees should have no expectation of privacy with regard to items or information stored or maintained on Hospital equipment or premises. Management is permitted to access these areas. Employees should not search for or retrieve articles from another employee's workspace without prior approval from that employee or management.

Since supplies of certain everyday items are readily available at Hospital work locations, the question of making personal use of them frequently arises. The answer is clear: employees may not use Hospital supplies for personal use.

Use of Hospital Computers

The increasing reliance placed on computer systems, internal information and communications facilities in carrying out Hospital business makes it absolutely essential to ensure their integrity. Like other Hospital assets, these facilities and the information they

make available through a wide variety of databases should be used only for conducting Hospital business or for purposes authorized by management. Their unauthorized use, whether or not for personal gain, is a misappropriation of Hospital assets.

While the Hospital conducts audits to help ensure that Hospital systems, networks and databases are being used properly, it is your responsibility to make sure that each use you make of any Hospital system is authorized and proper.

Personnel are not allowed to load or download software or data onto Hospital computer systems unless it is for business purposes and is approved in advance by the appropriate supervisor. Personnel shall not use Hospital e-mail systems to deliver or forward inappropriate jokes, unauthorized political materials, or any other potentially offensive materials. Personnel are strictly forbidden from using computers to access the Internet for purposes of gambling, viewing pornography or engaging in any illegal activities.

Employees should have no expectation of privacy with regard to items or information stored or maintained on Hospital premises or computer, information, or communication systems.

Use of Proprietary Information

Proprietary Information

Proprietary information is generally confidential information that is developed by the Hospital as part of its business and operations. Such information includes, but is not limited to, the business, financial, marketing and contract arrangements associated with Hospital services and products. It also includes computer access passwords, procedures used in producing computer or data processing records, personnel and medical records, and payroll data. Other proprietary information includes management know-how and processes; Hospital business and product plans with outside vendors; a variety of internal databases; and copyrighted material, such as software.

The value of this proprietary information is well known to many people in the Hospital industry. Besides competitors, they include industry and security analysts, members of the press, and consultants. The Hospital alone is entitled to determine who may possess its proprietary information and what use may be made of it, except for specific legal requirements such as the publication of certain reports.

Personnel often have access to information that the Hospital considers proprietary. Therefore, it is very important not to use or disclose proprietary information except as authorized by the Hospital.

Inadvertent Disclosure

The unintentional disclosure of proprietary information can be just as harmful as intentional disclosure. To avoid unintentional disclosure, never discuss with any unauthorized person proprietary information that has not been made public by the Hospital. This information includes unannounced products or services, prices, earnings, procurement plans, business volumes, capital requirements, confidential financial information, marketing and service strategies, business plans, and other confidential information. Furthermore, you should not discuss confidential information even with authorized Hospital employees if you are in the presence of others who are not authorized — for example, at a conference reception or in a public area such as an airplane. This also applies to discussions with family members or with friends, who might innocently or inadvertently pass the information on to someone else.

Direct Requests for Information

If someone outside the Hospital asks you questions about the Hospital or its business activities, either directly or through another person, do not attempt to answer them unless you are certain you are authorized to do so. If you are not authorized, refer the person to the appropriate source within the Hospital. Under no circumstances should you continue contact without guidance and authorization. If you receive a request for information or to conduct an interview from an attorney, investigator, or any law enforcement officer, and it concerns the Hospital's business, you should refer the request to the office of the Hospital's Chief Executive Officer. Similarly, unless you have been authorized to talk to reporters, or to anyone else writing about or otherwise covering the Hospital or the industry, direct the person to your supervisor.

Disclosure and Use of Hospital Proprietary Information

Besides your obligation not to disclose any Hospital proprietary information to anyone outside the Hospital, you are also required to use such information only in connection with the Hospital's business. These obligations apply whether or not you developed the information yourself.

Proprietary and Competitive Information About Others

In the normal course of business, it is not unusual to acquire information about many other organizations, including competitors (competitors are other hospitals and health facilities). Doing so is a normal business activity and is not unethical in itself. However, there are limits to the ways that information should be acquired and used. Improper solicitation of confidential data about a competitor from a competitor's employees or from Hospital patients is prohibited. The Hospital will not tolerate any form of questionable intelligence gathering.

Recording and Reporting Information

You should record and report all information accurately and honestly. Every employee records information of some kind and submits it to the Hospital (for example, a time card, an expense account record, or a report). To submit a document that contains false information — an expense report for meals not eaten, miles not driven, or for any other expense not incurred — is dishonest reporting and is prohibited.

Dishonest reporting of information to organizations and people outside the Hospital is also strictly prohibited and could lead to civil or even criminal liability for you and the Hospital. This includes not only reporting information inaccurately, but also organizing it in a way that is intended to mislead or misinform those who receive it. Personnel must ensure that they do not make false or misleading statements in oral or written communications provided to organizations outside of the Hospital.

Exception

Nothing contained herein is to be construed as prohibiting conduct legally protected by the National Labor Relations Act or other applicable state or federal law.

Gifts and Entertainment

The Hospital understands that vendors and others doing business with the Hospital may wish to provide gifts, promotional items and entertainment to Hospital Personnel as part of such vendors' own marketing activities. The Hospital also understands that there may be occasions where the Hospital may wish to provide reasonable business gifts to promote the

Hospital's services. However, the giving and receipt of such items can easily be abused and have unintended consequences; giving and receiving gifts, particularly in the health care industry, can create substantial legal risks.

General Policy

It is the general policy of the Hospital that neither you nor any member of your family may solicit, receive, offer or pay any money or gift that is, or could be reasonably construed to be, an inducement in exchange for influence or assistance in conducting Hospital business. It is the intent of the Hospital that this policy be construed broadly such that all business transactions with vendors, contractors and other third parties are transacted to avoid even the appearance of improper activity.

Spending Limits — Gifts, Dining and Entertainment

The Hospital has developed policies that clearly define the spending limits permitted for items such as gifts, dining and entertainment. All Personnel are strictly prohibited from making any expenditures of Hospital or personal funds for gifts, dining or entertainment in any way related to Hospital business, unless such expenditures are made in strict accordance with Hospital policies.

Marketing and Promotions in Health Care

As a provider of health care services, the marketing and promotional activities of the Hospital may be subject to anti-kickback and other laws that specifically apply to the health care industry. The Hospital has adopted policies elsewhere in this Compliance Program to specifically address the requirements of such laws.

It is the policy of the Hospital that Personnel are not allowed to solicit, offer or receive any payment, compensation or benefit of any kind (regardless of the value) in exchange for referring, or recommending the referral of, patients or customers to the Hospital.

Marketing

The Hospital has expended significant efforts and resources in developing its services and reputation for providing high-quality patient care. Part of those efforts involve advertising, marketing and other promotional activities. While such activities are important to the success of the Hospital, they are also potential sources of legal liability as a result of health care laws (such as the anti-kickback laws) that regulate the marketing of health care services. Therefore, it is important that the Hospital closely monitor and regulate advertising, marketing and other promotional activities to ensure that all such activities are performed in accordance with Hospital objectives and applicable law.

This Compliance Program contains various policies applicable to specific business activities of the Hospital. In addition to those policies, it is the general policy of the Hospital that no Personnel engage in any advertising, marketing or other promotional activities on behalf of the Hospital unless such activities are approved in advance by the appropriate Hospital representative. You should ask your supervisor to determine the appropriate Hospital representative to contact. In addition, no advertising, marketing or other promotional activities targeted at health care providers or potential patients may be conducted unless approved in advance by the Hospital's legal counsel.

All content posted on Internet websites maintained by the Hospital must be approved in advance by the Hospital's Chief Compliance Officer or legal counsel.

Conflicts of Interest

[The Hospital must ensure that this section on conflicts of interest is in agreement with any separate conflict of interest policy (including any separate policies for the governing body or medical staff) and separate policies that address such topics as gifts, gratuities or business arrangements, and that the procedure to disclose and manage potential conflicts of interest is in agreement with applicable policies.]

A conflict of interest is any situation in which financial or other personal considerations may compromise or appear to compromise any Personnel's business judgment, delivery of patient care, or ability of any Personnel to do his or her job or perform his or her responsibilities. A conflict of interest may arise if you engage in any activities or advance any personal interests at the expense of the Hospital's interests. An actual or potential conflict of interest occurs when any Personnel is in a position to influence a decision that may result in personal gain for that Personnel, a relative or a friend as a result of the Hospital's business dealings. A relative is any person who is related by blood or marriage, or whose relationship with the Personnel is similar to that of persons who are related by blood or marriage, including a domestic partner, and any person residing in the Personnel's household. You must avoid situations in which your loyalty may become divided.

An obvious conflict of interest is providing assistance to an organization that provides services and products in competition with the Hospital's current or potential services or products. You may not, without prior consent, work for such an organization as an employee (including working through a registry or "moonlighting" and picking up shifts at other health care facilities), independent contractor, a consultant, or a member of its Governing Board. Such activities may be prohibited because they divide your loyalty between the Hospital and that organization. Failure to obtain prior consent in advance from the Hospital's Chief Compliance Officer or legal counsel may be grounds for termination.

Outside Employment and Business Interests

You are not permitted to work on any personal business venture on the Hospital premises or while working on Hospital time. In addition, you are not permitted to use Hospital equipment, telephones, computers, materials, resources or proprietary information for any outside work. You must abstain from any decision or discussion affecting the Hospital when serving as a member of an outside organization or board or in public office, except when specific permission to participate has been granted by the Hospital's Chief Compliance Officer or legal counsel.

Contracting with the Hospital

You may not contract with the Hospital to be a supplier, to represent a supplier to the Hospital, or to work for a supplier to the Hospital while you are an employee of the Hospital. In addition, you may not accept money or benefits, of any kind, for any advice or services you may provide to a supplier in connection with its business with the Hospital.

Required Standards

All decisions and transactions undertaken by Personnel in the conduct of the Hospital's business must be made in a manner that promotes the best interests of the Hospital, free from the possible influence of any conflict of interest of such Personnel or the Personnel's family or friends. Personnel have an obligation to address both actual conflicts of interest and

the appearance of a conflict of interest. You must always disclose and seek resolution of any actual or potential conflict of interest — whether or not you consider it an actual conflict — before taking a potentially improper action.

No set of principles or standards can cover every type of conflict of interest. The following standards address conduct required of all Personnel and provide some examples of potential conflict of interest situations in addition to those discussed above.

1. Personnel may not make or influence business decisions, including executing purchasing agreements (including but not limited to agreements to purchase or rent equipment, materials, supplies or space) or other types of contracts (including contracts for personal services), from which they, a family member, or a friend may benefit.
2. Personnel must disclose their "significant" (defined below) financial interests in any entity that they know to have current or prospective business, directly or indirectly, with the Hospital. There are two types of significant financial interests:
    a. Receipt of anything of monetary value from a single source in excess of $_____ annually. Examples include salary, royalties, gifts and payments for services including consulting fees and honoraria; and
    b. Ownership of an equity interest exceeding 5 percent in any single entity, excluding stocks, bonds and other securities sold on a national exchange; certificates of deposit; mutual funds; and brokerage accounts managed by third parties.
3. Personnel must disclose any activity, relationship or interest that may be perceived to be a conflict of interest so that these activities, relationships and interests can be evaluated and managed properly.
4. Personnel must disclose any outside activities that interfere, or may be perceived to interfere, with the individual's capacity to satisfy his or her job or responsibilities at the Hospital. Such outside activities include leadership participation (such as serving as an officer or member of the board of directors) in professional, community or charitable activities; self-employment; participation in business partnerships; and employment or consulting arrangements with entities other than the Hospital.
5. Personnel may not solicit personal gifts or favors from vendors, contractors, or other third parties that have current or prospective business with the Hospital. Personnel may not accept cash gifts and may not accept non-monetary gifts including meals, transportation or entertainment valued in excess of $_____ from vendors, contractors or other third parties that have current or prospective business with the Hospital. Questions regarding the gift limitations should be directed to the Hospital's Chief Compliance Officer.
6. Any involvement by Personnel in a personal business venture shall be conducted outside the Hospital work environment and shall be kept separate and distinct from the Hospital's business in every respect.
7. Personnel should not accept employment or engage in a business that involves, even nominally, any activity during hours of employment with the Hospital, the use

of any of the Hospital's equipment, supplies or property, or any direct relationship with the Hospital's business or operation.

8. Personnel must guard patient and Hospital information against improper access or use by unauthorized individuals.
9. The Hospital's materials, products, designs, plans, ideas and data are the property of the Hospital and should never be given to an outside firm or individual, except through normal channels with appropriate prior authorization.
10. Personnel must avoid any appearance of impropriety when dealing with clinicians and referral sources.
11. All vendors and contractors who have or desire business relationships with the Hospital must abide by this Code of Conduct. Personnel having knowledge of vendors or contractors who violate these standards in their relationship with the Hospital must report these to their supervisor or manager.
12. Personnel shall not sell any merchandise on Hospital premises and shall not sell any merchandise of a medical nature that is of a type or similar to what is sold or furnished by the Hospital, whether on or off Hospital premises, unless prior approval is obtained from the Hospital's Chief Compliance Officer.
13. Personnel shall not request donations for any purpose from other Personnel, patients, vendors, contractors or other third parties, unless prior approval is obtained from the Hospital's Chief Compliance Officer.
14. Personnel may not endorse any product or service without explicit prior approval to do so by the Hospital's Chief Compliance Officer.

Disclosure of Potential Conflict Situations

You must disclose any activity, relationship, or interest that is or may be perceived to be a conflict of interest and complete the attached Conflict of Interest Certification Form within 90 days of being subject to this Code of Conduct (that is, being hired by the Hospital, beginning to volunteer at the Hospital, or assuming any responsibilities at the Hospital). At least annually thereafter, you must review this Code of Conduct and your most recent Conflict of Interest Certification. You are not required to file a Conflict of Interest Certification Form annually unless there is a change in your circumstances that you have not previously reported. At any time during the year, when an actual, potential, or perceived conflict of interest arises, you must revise your certification form and contact the Hospital's Chief Compliance Officer. It is your responsibility to promptly report any actual or potential conflicts.

All certification forms must be sent to the Hospital's Chief Compliance Officer. The Chief Compliance Officer will review all disclosures and determine which disclosures require further action. The Chief Compliance Officer will consult with the Hospital's Chief Executive Officer or legal counsel if it is unclear whether an actual conflict of interest exists or if the Chief Compliance Officer determines that an actual conflict of interest exists. The outcome of these consultations will result in a written determination, signed by all decision-makers involved, stating whether or not an actual conflict of interest exists. If a conflict of interest is determined to exist, the written determination shall set forth a plan to manage the conflict of interest which may include that:

1. The conflict of interest is permitted;
2. The conflict of interest is permitted with modification or oversight, including such steps as reassignment of responsibilities or establishment of protective arrangements;
3. The conflict of interest will require the Personnel to abstain from participating in certain governance, management or purchasing activities related to the conflict of interest; or
4. The conflict of interest must be eliminated or, if it involves a proposed role in another organization or entity, must not be undertaken.

The Chief Compliance Officer will review any written determination with you, discuss any necessary action you are to take, and ask you to sign the written determination. The signed written determination will be kept with your certification form.

Anti-Competitive Activities

If you work in sales or marketing, the Hospital asks you to perform your job not just vigorously and effectively, but fairly, as well. False or misleading statements about a competitor are inappropriate, invite disrespect and complaints, and may violate the law. Be sure that any comparisons you make about competitors' products and services are fair and accurate. (Competitors are other hospitals and health facilities.)

Reporting Violations

The Hospital supports and encourages each employee and contractor to maintain individual responsibility for monitoring and reporting any activity that violates or appears to violate any applicable statutes, regulations, policies or this Code of Conduct.

The Hospital has established a reporting mechanism that permits anonymous reporting, if the person making the report desires anonymity. Employees who become aware of a violation of the Hospital Compliance Program, including this Code of Conduct, must report the improper conduct to their departmental compliance officer or the Chief Compliance Officer. That officer, or a designee, will then investigate all reports and ensure that appropriate follow-up actions are taken.

Hospital policy prohibits retaliation against an employee who makes such a report in good faith. In addition, it is the policy of the Hospital that no employee will be punished on the basis that he/she reported what he/she reasonably believed to be improper activity or a violation of this Program.

However, employees are subject to disciplinary action if after an investigation the Hospital reasonably concludes that the reporting employee knowingly fabricated, or knowingly distorted, exaggerated or minimized the facts to either cause harm to someone else or to protect or benefit themselves.

SECTION III — COMPLIANCE PROGRAM SYSTEMS AND PROCESSES

This Compliance Program contains a comprehensive set of policies. In order to effectively implement and maintain these policies, the Hospital has developed various systems and processes. The purpose of this section of the Compliance Program is to explain the various

systems and processes that the Hospital has established for the purpose of providing structure and support to the Compliance Program.

Compliance Officers and Committee

Chief Compliance Officer

The Hospital has a Chief Compliance Officer who serves as the primary supervisor of this Compliance Program. The Hospital's Chief Compliance Officer occupies a high-level position within the organization and has authority to carry out all compliance responsibilities described in this Compliance Program. The Chief Compliance Officer is responsible for assuring that the Compliance Program is implemented to ensure that the Hospital at all times maintains business integrity and that all applicable statutes, regulations and policies are followed.

The Chief Compliance Officer provides frequent reports to the Governing Board about the Compliance Program and compliance issues. The Governing Board is ultimately responsible for supervising the work of the Chief Compliance Officer, and maintaining the standards of conduct set forth in the Compliance Program. The Governing Board oversees all of the Hospital's compliance efforts and takes any appropriate and necessary actions to ensure that the Hospital conducts its activities in compliance with the law and sound business ethics.

The Chief Compliance Officer and Governing Board shall consult with legal counsel as necessary on compliance issues raised by the ongoing compliance review.

Responsibilities of the Chief Compliance Officer

The Chief Compliance Officer's responsibilities include the following:

- Overseeing and monitoring the implementation and maintenance of the Compliance Program.
- Reporting on a regular basis to the Governing Board (no less than annually) on the progress of implementation and operation of the Compliance Program and assisting the Governing Board in establishing methods to reduce the Hospital's risk of fraud, abuse and waste.
- Periodically revising the Compliance Program in light of changes in the needs of the Hospital and changes in applicable statutes, regulations and government policies.
- Reviewing at least annually the implementation and execution of the elements of this Compliance Program. The review includes an assessment of each of the basic elements individually and the overall success of the program, and a comprehensive review of the compliance department.
- Developing, coordinating and participating in educational and training programs that focus on elements of the Compliance Program with the goal of ensuring that all appropriate Personnel are knowledgeable about, and act in accordance with, this Compliance Program and all pertinent federal and state requirements.
- Ensuring that independent contractors and agents of the Hospital are aware of the requirements of this Compliance Program as they affect the services provided by such contractors and agents.
- Ensuring that employees, independent contractors, and agents of the Hospital have not been excluded from participating in Medicare, Medicaid (Medi-Cal) or any other federal or state heath care program.

- Ensuring that the Hospital does not employ or contract with any individual who has been convicted of a criminal offense related to health care within the previous five years, or who is listed by a federal or state agency as debarred, excluded, or otherwise ineligible for participation in Medicare, Medicaid (Medi-Cal), or any other federal or state health care program.
- Coordinating internal compliance review and monitoring activities.
- Independently investigating and acting on matters related to compliance, including design and coordination of internal investigations and implementation of any corrective action.
- Maintaining a good working relationship with other key operational areas, such as internal audit, coding, billing and clinical departments.
- Designating work groups or task forces needed to carry out specific missions, such as conducting an investigation or evaluating a proposed enhancement to the Compliance Program.

The Chief Compliance Officer has the authority to review all documents and other information relevant to compliance activities, including, but not limited to, patient records, billing records, records concerning marketing efforts and all arrangements with third parties, including without limitation employees, independent contractors, suppliers, agents and physicians.

The Chief Compliance Officer has direct access to the Governing Board, Chief Executive Officer and other senior management, and to legal counsel. The Chief Compliance Officer has the authority to retain, as he or she deems necessary, outside legal counsel.

Compliance Committee

The Hospital has established a Compliance Committee to advise the Chief Compliance Officer and assist in monitoring this Compliance Program. The Compliance Committee provides the perspectives of individuals with diverse knowledge and responsibilities within the Hospital.

Members of the Compliance Committee

The Compliance Committee consists of _____ representatives. The members of the Compliance Committee include those individuals designated below and other members, including representatives of senior management, chosen by the Hospital's Chief Executive Officer in consultation with the Chief Compliance Officer:

- Chief Compliance Officer
- Chief Financial Officer
- Chief Information Officer
- Privacy Officer
- Chief Nursing Officer
- Medical Staff Representative
- Human Resources Executive
- Risk Manager/Officer

- Quality Management Director
- Health Information Director
- As appropriate, Directors of Emergency Department, Laboratory, Pharmacy, Imaging, Purchasing and Clinical Research
- [Hospital should list others as appropriate]

The Chief Compliance Officer serves as the chairperson of the Compliance Committee. The Compliance Committee serves in an advisory role and has no authority to adopt or implement policies. The Chief Compliance Officer will consult with members of the Compliance Committee on a regular basis and may call meetings of all or some members of the Compliance Committee.

Functions of the Compliance Committee

The Compliance Committee's functions include the following:

- Assessing existing and proposed compliance policies for modification or possible incorporation into the Compliance Program.
- Working with the Chief Compliance Officer to develop further standards of conduct and policies to promote compliance.
- Recommending and monitoring, in conjunction with the Chief Compliance Officer, the development of internal systems and controls to carry out the standards and policies of this Compliance Program.
- Reviewing and proposing strategies to promote compliance and detection of potential violations.
- Assisting the Chief Compliance Officer in the development and ongoing monitoring of systems to solicit, evaluate and respond to complaints and problems related to compliance.
- Assisting the Chief Compliance Officer in coordinating compliance training, education and other compliance-related activities in the departments and business units in which the members of the Compliance Committee work.
- Consulting with vendors of the Hospital on a periodic basis to promote adherence to this Compliance Program as it applies to those vendors and to promote their development of formal Compliance Programs.

The tasks listed above are not intended to be exhaustive. The Compliance Committee may also address other compliance-related matters as determined by the Chief Compliance Officer.

Compliance as an Element of Performance

The promotion of, and adherence to, the elements of this Compliance Program is a factor in evaluating the performance of all Hospital employees. Personnel will be trained periodically regarding the Compliance Program, and new compliance policies that are adopted. In particular, all managers and supervisors involved in any processes related to the evaluation, preparation, or submission of medical claims must do the following:

- Discuss, as applicable, the compliance policies and legal requirements described in this Compliance Program with all supervised Personnel.
- Inform all supervised Personnel that strict compliance with this Compliance Program is a condition of continued employment.
- Inform all supervised Personnel that disciplinary action will be taken, up to and including termination of employment or contractor status, for violation of this Compliance Program.

Managers and supervisors will be subject to discipline for failure to adequately instruct their subordinates on matters covered by the Compliance Program. Managers and supervisors will also be subject to discipline for failing to detect violations of the Compliance Program where reasonable diligence on the part of the manager or supervisor would have led to the discovery of a problem or violation and thus would have provided the Hospital with the opportunity to take corrective action.

Training and Education

The Hospital acknowledges that this Compliance Program will be effective only if it is communicated and explained to Personnel on a routine basis and in a manner that clearly explains its requirements. For this reason, the Hospital requires all Personnel to attend specific training programs on a periodic basis. Training requirements and scheduling are established by the Hospital for its departments and affiliates based on the needs and requirements of each department and affiliate. Training programs include appropriate training in federal and state statutes, regulations, guidelines, the policies described in this Compliance Program, and corporate ethics. Training will be conducted by qualified internal or external personnel. New employees are trained early in their employment. Training programs may include sessions highlighting this Compliance Program, summarizing fraud and abuse laws, physician self-referral laws, claims development and submission processes, and related business practices that reflect current legal standards.

All formal training undertaken as part of the Compliance Program is documented. Documentation includes at a minimum the identification of the Personnel participating in the training, the subject matter of the training, the length of the training, the time and date of the training, the training materials used, and any other relevant information.

The Chief Compliance Officer evaluates the content of the training program at least annually to ensure that the subject content is appropriate and sufficient to cover the range of issues confronting the Hospital's employees. The training program is modified as necessary to keep up-to-date with any changes in federal and state health care program requirements, and to address results of the Hospital's audits and investigations; results from previous training and education programs; trends in Hotline reports; and guidance from applicable federal and state agencies. The appropriateness of the training format is evaluated by reviewing the length of the training sessions; whether training is delivered via live instructors or via computer-based training programs; the frequency of training sessions; and the need for general and specific training sessions.

The Chief Compliance Officer seeks feedback to identify shortcomings in the training program, and administers post-training tests as appropriate to ensure attendees understand and retain the subject matter delivered.

Specific training for appropriate corporate officers, managers, and other employees may include areas such as:

- Restrictions on marketing activities.
- General prohibitions on paying or receiving remuneration to induce referrals.
- Proper claims processing techniques.
- Monitoring of compliance with this Compliance Program.
- Methods for educating and training employees.
- Duty to report misconduct.

The members of the Hospital's Governing Board will be provided with periodic training, not less than annually, on fraud and abuse laws and other compliance matters.

Attendance and participation in compliance training programs is a condition of continued employment. Failure to comply with training requirements will result in disciplinary action, including possible termination.

Adherence with the provisions of this Compliance Program, including training requirements, is a factor in the annual evaluation of each Hospital employee. Where feasible, outside contractors will be afforded the opportunity to participate in, or be encouraged to develop their own, compliance training and educational programs, to complement the Hospital's standards of conduct and compliance policies. The Chief Compliance Officer will ensure that records of compliance training, including attendance logs and copies of materials distributed at training sessions, are maintained.

The compliance training described in this program is in addition to any periodic professional education courses that may be required by statute or regulation for certain Personnel. The Hospital expects its employees to comply with applicable education requirements; failure to do so may result in disciplinary action.

Lines of Communicating and Reporting

Open Door Policy

The Hospital recognizes that clear and open lines of communication between the Chief Compliance Officer and Hospital Personnel are important to the success of this Compliance Program. The Hospital maintains an open door policy with regard to all Compliance Program related matters. Hospital Personnel are encouraged to seek clarification from the Chief Compliance Officer in the event of any confusion or question about a statute, regulation, or policy discussed in this Compliance Program.

Submitting Questions or Complaints

The Hospital has established a telephone hotline for use by Hospital Personnel to report concerns or possible wrongdoing regarding compliance issues. We refer to this telephone line as our "Compliance Hotline."

The Compliance Hotline contact numbers are:

Phone: _____

Fax: _____

Personnel may also submit compliance-related questions or complaints in writing. Letters may be sent anonymously. All such letters should be sent to the Chief Compliance Officer at the following address:

Chief Compliance Officer
[insert name of Hospital]

_____

_____

The Compliance Hotline numbers and the Chief Compliance Officer's address are posted in conspicuous locations throughout the Hospital's facilities.

Calls to the Compliance Hotline are answered by an independent contractor, not by Hospital employees [Hospital should revise this sentence if this task is handled by employees]. All calls are treated confidentially and are not traced. The caller need not provide his or her name. The Hospital's Chief Compliance Officer or designee investigates all calls and letters and initiates follow-up actions as appropriate.

Communications via the Compliance Hotline and letters mailed to the Chief Compliance Officer are treated as privileged to the extent permitted by applicable law; however, it is possible that the identity of a person making a report may become known, or that governmental authorities or a court may compel disclosure of the name of the reporting person.

Matters reported through the Compliance Hotline, or in writing, that suggest violations of compliance policies, statutes or regulations, are documented and investigated promptly. A log is maintained by the Chief Compliance Officer of calls or communications, including the nature of any investigation and subsequent results. A summary of this information is included in reports by the Chief Compliance Officer to the Hospital's Governing Board and Chief Executive Officer.

Non-Retaliation Policy

It is the Hospital's policy to prohibit retaliatory action against any person for making a report, anonymous or otherwise, regarding compliance. However, Hospital Personnel cannot use complaints to the Chief Compliance Officer to insulate themselves from the consequences of their own wrongdoing or misconduct. False or deceptive reports may be grounds for termination. It will be considered a mitigating factor if a person makes a forthright disclosure of an error or violation of this Compliance Program, or the governing statutes and regulations.

Enforcing Standards and Policies

Policies

It is the policy of the Hospital to appropriately discipline Hospital Personnel who fail to comply with the Code of Conduct or the policies set forth in, or adopted pursuant to, this Compliance Program or any federal or state statutes or regulations.

The guiding principles underlying this policy include the following:

- Intentional or reckless noncompliance will subject Personnel to significant sanctions, which may include oral warnings, suspension or termination of employment, depending upon the nature and extent of the noncompliance.

- Negligent failure to comply with the policies set forth in this Compliance Program, or with applicable laws, will also result in sanctions.
- Disciplinary action will be taken where a responsible employee fails to detect a violation, if this failure is attributable to his or her negligence or reckless conduct.
- Internal audit or review may lead to discovering violations and result in disciplinary action.

Because the Hospital takes compliance seriously, the Hospital will respond to Personnel misconduct.

Discipline Procedures

Employees found to have violated any provision of this Compliance Program are subject to discipline consistent with the policies set forth herein, including termination of employment if deemed appropriate by the Hospital. Any such discipline is within the sole discretion of the Hospital. Each instance involving disciplinary action shall be thoroughly documented by the employee's supervisor and the Chief Compliance Officer.

Upon determining that an employee of the Hospital or any of its affiliates has committed a violation of this Compliance Program, such employee shall meet with his or her supervisor to review the conduct that resulted in violation of the Compliance Program. The employee and supervisor will contact the Chief Compliance Officer to discuss any actions that may be taken to remedy such violation. All employees are expected to cooperate fully with the Chief Compliance Officer during the investigation of the violation. Legal counsel will be consulted prior to final actions or disciplinary measures, as appropriate.

Auditing and Monitoring

The Hospital conducts periodic monitoring of this Compliance Program. Compliance reports created by this monitoring, including reports of suspected noncompliance, will be reviewed and maintained by the Chief Compliance Officer.

The Chief Compliance Officer will develop and implement an audit plan. The plan will be reviewed at least annually to determine whether it addresses the proper areas of concern, considering, for example, findings from previous years' audits, risk areas identified as part of the annual risk assessment, and high-volume services.

Periodic compliance audits are used to promote and ensure compliance. These audits are performed by internal or external auditors who have the appropriate qualifications and expertise in federal and state health care statutes and regulations and federal health care program requirements. The audits will focus on specific programs or departments of the Hospital, including external relationships with third-party contractors. These audits are designed to address, at a minimum, compliance with laws governing kickback arrangements, physician self-referrals, claims development and submission (including an assessment of the Hospital's billing system), reimbursement and marketing. All Personnel are expected to cooperate fully with auditors during this process by providing information, answering questions, etc. If any employee has concerns regarding the scope or manner of an audit, the employee should discuss this with his or her immediate supervisor.

The Hospital shall conduct periodic reviews, including unscheduled reviews, to determine whether the elements of this Compliance Program have been satisfied. Appropriate

modifications to the Compliance Program will be implemented when monitoring discloses that compliance issues have not been detected in a timely manner due to Compliance Program deficiencies.

The periodic review process may include the following techniques:

- Interviews with Personnel involved in management, operations, claim development and submission, and other related activities.
- Questionnaires developed to solicit impressions of the Hospital Personnel.
- Reviews of all billing documentation, including medical and financial records and other source documents that support claims for reimbursement and claims submissions.
- Presentations of a written report on compliance activities to the Chief Compliance Officer. The report shall specifically identify areas, if any, where corrective actions are needed. In certain cases, subsequent reviews or studies may be conducted to ensure that recommended corrective actions have been successfully implemented.

Error rates shall be evaluated and compared to error rates for prior periods as well as available norms. If the error rates are not decreasing, the Hospital shall conduct a further investigation into other aspects of the Compliance Program in an effort to determine hidden weaknesses and deficiencies.

Corrective Action

Violations and Investigations

Violations of this Compliance Program, failure to comply with applicable federal or state laws, and other types of misconduct threaten the Hospital's status as a reliable and honest provider of health care services. Detected but uncorrected misconduct can seriously endanger the Hospital's business and reputation, and can lead to serious sanctions against the Hospital. Consequently, upon reports or reasonable indications of suspected noncompliance, prompt steps to investigate the conduct in question will be initiated under the direction and control of the Chief Compliance Officer to determine whether a material violation of applicable law or the requirements of the Compliance Program has occurred. The Chief Compliance Officer may create a response team to review suspected noncompliance including representatives from the compliance, audit and other relevant departments.

If such a violation has occurred, prompt steps will be taken to correct the problem, taking into account the root cause of the problem. As appropriate, such steps may include an immediate referral to criminal and/or civil law enforcement authorities, a corrective action plan, a report to the Office of Inspector General (OIG) or any other appropriate government organization, and/or submission of any overpayments. The specific steps that are appropriate in any given case will be determined after consultation with legal counsel.

Depending upon the nature of the alleged violations, the Chief Compliance Officer's internal investigation could include interviews with relevant Personnel and a review of relevant documents. Legal counsel, auditors or health care experts may be engaged by the Chief Compliance Officer to assist in an investigation where the Chief Compliance Officer deems such assistance appropriate. Complete records of all investigations will be maintained which contain documentation of the alleged violations, a description of the investigative process,

copies of interview notes and key documents, a log of the witnesses interviewed and the documents reviewed, results of the investigation (e.g., any disciplinary action taken), and corrective actions implemented.

If an investigation of an alleged violation is undertaken and the Chief Compliance Officer believes the integrity of the investigation may be at stake because of the presence of employees under investigation, those employees will be removed from their current work activity until the investigation is completed. Where necessary, the Chief Compliance Officer will take appropriate steps to secure or prevent the destruction of documents or other evidence relevant to the investigation.

Reporting

If the Chief Compliance Officer or a management official discovers credible evidence of misconduct from any source and, after reasonable inquiry, has reason to believe that the misconduct may violate criminal, civil or administrative law, then the misconduct will promptly be reported as appropriate to the OIG or any other appropriate governmental authority or federal and/or state law enforcement agency having jurisdiction over such matter. Such reports will be made by the Chief Compliance Officer on a timely basis.

All overpayments identified by the Hospital shall be promptly disclosed and/or refunded to the appropriate public or private payer or other entity.

SECTION IV — COMPLIANCE POLICIES

The Hospital may wish to attach relevant policies and procedures. Some of the policies and procedures that may be relevant, depending upon the employee's position, are listed below.

1. Confidential Reporting
    - Confidential Disclosure System
    - Non-Retaliation for Reporting (Whistleblower Laws)
    - Documenting Reports of Noncompliance Received by Compliance Officer
2. Compliance Enforcement
    - Screening of Ineligible Persons
    - Investigating Reports of Noncompliance
    - Enforcement of Compliance Program Obligations
    - Auditing the Compliance Program
3. Federal and State Fraud and Abuse
    - Federal and State False Claims Laws
    - Anti-Kickback Laws
    - Self-Referral Laws
    - Physician Recruitment
    - State Corporate Practice of Medicine
    - Inducement to Lower Utilization

- Provision of Inducements to Patients
- Waivers of Coinsurance
- Vendor Contracts

4. Patient Care and Rights
    - Patient Rights and Responsibilities
    - Informed Consent
    - Patient Freedom of Choice/Disclosures of Financial Interests
    - Patient Privacy — HIPAA
    - Advance Beneficiary Notice
    - EMTALA
    - HMO/Managed Care Patient Treatment
    - Independent Contractor Credentialing
    - Quality Care
5. Government Billing
    - Claim Development and Submission — Generally
    - Medical Necessity — Patient Services
    - Medical Necessity — Laboratory Services
    - Outpatient Billing Prior to Inpatient Stay (Three-Day Window)
    - Claims for Teaching Physicians
    - Patient Transfer Versus Discharge
    - Provider-Based Rules
    - Bad Debts
    - Credit Balance
    - Billing and Coding under Medicare Outpatient Prospective Payment System
    - National Correct Coding Initiative
    - Charge Description Master
    - Same-Day Discharges and Readmissions
    - Claims for Outlier Payments
    - Claims for Services in Clinical Trials

6. Health Information Management Services
    - Coding Documents for Inpatient Services
    - Coding Documents for Outpatient Services
    - Availability of Coding Reference Materials
    - Patient Record Documentation
    - Record Retention
    - Claims Submission Policy Manual
7. Reimbursement
    - Cost Report Documentation
    - Cost Report Disclosure Statements
    - Reporting Cost Report Errors
    - Independent Review of Cost Reports
    - Medicare Contractor Audits of Cost Reports
    - Treatment of Non-Allowable Costs
    - Treatment of Protested Items
    - Graduate Medical Education
    - Organ Acquisition Costs
    - Reimbursement Policy Manual
8. Office of Statewide Health Planning and Development (OSHPD) Reporting
9. Charity and Discounted Care
10. External Investigations
    - Responding to Subpoenas and Search Warrants
    - Responding to Audits, such as Audits by Medicare Administrative Contractors, Fiscal Intermediaries, Carriers, Quality Improvement Organizations (QIO) and Recovery Audit Contractors
    - Responding to Government Investigations
11. Employment-Related Policies
    - Nondiscrimination
    - Sexual Harassment
    - Drug-Free Workplace
    - Smoking

APPENDIX HC 1-A

Acknowledgment of Receipt of Hospital Compliance Plan

I, _____, am a/an:
☐ Employee ☐ Volunteer ☐ Contractor of the Hospital.

By my signature below, I acknowledge that I have received a copy of the following sections of the Hospital Compliance Program.

- ☑ Compliance Program Summary *(see Section I of the Model Hospital Compliance Program)*
- ☑ Code of Conduct *(see Section II of the Model Hospital Compliance Program)*
- ☑ Compliance Program Systems and Processes *(see Section III of the Model Hospital Compliance Program)* which includes information on how to report a suspected violation of law or hospital policy

Compliance Policies as follows:

- ☑ Required DRA Policies and Procedures (federal and state false claims laws and whistleblower laws)
- ☐ Other: _____
- ☐ Other: _____

I further acknowledge that I have been informed about where to locate a complete copy of the Hospital Compliance Program if I so desire.

Date: _____

Print Name: _____

Signature: _____

☑ Indicates that every employee/volunteer/contractor must be given this information.

HC 1-B

Conflict of Interest Certification Form

Please initial the Attestations below indicating agreement as appropriate, and then complete the Disclosure of Interest section to disclose any actual or potential conflicts of interests you may have with the Hospital or that you are required to report by the Hospital's Code of Conduct [and Conflict of Interest policy]:

Attestations

_____ I hereby attest that neither I nor any relative[1] now has, nor since my date of employment or association with the Hospital has had, any significant financial interest[2] in any organization or enterprise with which the Hospital has done or now does business, or any interest in any business transaction involving the Hospital.

_____ I hereby attest that I am not in an employed or consulting position outside the Hospital that would potentially constitute a conflict of interest.

_____ I hereby attest that I do not serve as an officer or member of the board of directors or trustees in any professional, community, or charitable activities that would potentially constitute a conflict of interest.

Disclosure of Interest

Please explain in detail the activity, relationship, interest, or financial interest being reported:

_____

_____

_____

_____

_____

_____

1 For purposes of this Conflict of Interest Certification Form, a relative is any person who is related to you by blood or marriage, or whose relationship with you is similar to that of persons who are related by blood or marriage, including a domestic partner, and any person residing in your household.

2 For purposes of this Conflict of Interest Certification Form, there are two types of significant financial interests: (1) Receipt of anything of monetary value from a single source in excess of $____ annually (examples include salary, royalties, gifts, and payments for services including consulting fees and honoraria); (2) Ownership of an equity interest exceeding 5% in any single entity, excluding stocks, bonds, and other securities sold on a national exchange, certificates of deposit, mutual funds, and brokerage accounts managed by third parties.

Certification

I hereby certify that this accurately and completely describes, to the best of my knowledge and belief, all activities, relationships, interests, and financial interests, which present actual or potential conflicts of interest with the Hospital or that are required to be reported under the provisions of the Hospital's Code of Conduct [and Conflict of Interest Policy]. I hereby further certify that I agree to comply with the conflict of interest provisions in the Hospital's Code of Conduct [and Conflict of Interest Policy] and to report any actual or potential conflicts of interest to the Hospital's Chief Compliance Officer when they arise.

Your Signature: _____

Your Typed/Printed Name: _____

Your Relationship to the Hospital (Employee, Volunteer, or Contractor): _____

Date: _____

Chief Compliance Officer Review

I have reviewed this certification form and determined that (check one):

- ☐ No activities, relationships, interests, or financial interests were disclosed so there are no actual or potential conflicts of interest.
- ☐ The activities, relationships, interests, or financial interests that were disclosed do not pose actual or potential conflicts of interest.
- ☐ Based on the activities, relationships, interests, or financial interests that were disclosed, it is unclear whether actual or potential conflicts of interest exist. Therefore, the Hospital's Chief Executive Officer and/or legal counsel will be consulted and a written determination will be made with respect to whether actual or potential conflicts of interest exist, and, if actual or potential conflicts of interest are found to exist, the written determination will include a plan to manage the actual or potential conflicts of interest.
- ☐ The activities, relationships, interests, or financial interests that were disclosed do pose actual or potential conflicts of interest. Therefore, the Hospital's Chief Executive Officer and/or legal counsel will be consulted and a written plan will be developed to manage the actual or potential conflicts of interest.

Reviewed by: _____

Title: _____

Date: _____

Review of Written Determination and Management Plan by Employee, Volunteer, or Contractor

I have reviewed and understand the attached written determination and/or plan to manage the actual or potential conflicts of interest identified. I further agree to comply with the plan to manage the actual or potential conflicts of interest identified, if any.

Your Signature: _____

Your Typed/Printed Name: _____

Date: _____

2 Governing Boards

I. Introduction 2.1

II. Internet Resources 2.1

III. The Board of Directors' Role in Compliance Oversight 2.2

A. An Effective Compliance Program Assists Directors to Discharge Their Fiduciary Duties 2.2

The Duty of Care 2.3

The Board's Decision-Making and Oversight Functions 2.4

B. Patient Safety and Quality of Care 2.5

The Duty of Obedience and Patient Safety/Quality of Care 2.6

C. Considerations for Charitable Organizations 2.6

IV. Some Important Structural Considerations for Effective Compliance Programs 2.7

A. The Hospital's Organizational and Governance Structure 2.7

B. Helping Compliance Committees to be Effective 2.7

Reviewing the Written Charter 2.8

Determining Committee Composition 2.8

Ensuring Accountability to the Board 2.9

C. Considerations Regarding the Roles of General Counsel and the Compliance Officer 2.10

General Counsel Serves as the Compliance Officer 2.11

Compliance Officer Separate, but Reports to General Counsel 2.12

Compliance Officer Separate and Does Not Report to General Counsel 2.12

V. Corporate Compliance Program: The Role of the Compliance Officer 2.13

A. Standards and Procedures, and Identification of Risks 2.13

B. Education and Training 2.14

C. Reporting 2.15

D. Monitoring and Auditing 2.16

E. Enforcement and Discipline 2.16

F. Investigation and Remediation 2.16

VI. Reporting to the Board of Directors 2.17

A. Education and Training 2.17

B. Reporting Mechanisms 2.17

C. Auditing and Monitoring Activities 2.18
D. Annual Report 2.18
E. Potential Areas of Focus for Reports 2.18
Submission of Accurate Claims Information 2.19
Outpatient Procedure Coding 2.19
Admissions and Discharges 2.19
Other Supplemental Payment Considerations 2.19
Compliance With the Self-Referral and Anti-Kickback Statutes 2.19
Substandard Care 2.20
HIPAA Privacy and Security Rules 2.20
Other Risk Areas 2.20

2 Governing Boards

I. INTRODUCTION

Hospitals today operate in a unique regulatory environment with a myriad of ever-changing and expanding compliance issues. The current compliance and enforcement environment has focused a spotlight on the role of the board of directors in overseeing the hospital's compliance program. Compliance officers must understand the responsibilities of the board of directors in order to assist and support the board in meeting its compliance oversight responsibilities.

The first part of this chapter outlines the board's role in compliance oversight and discusses the foundation for the board's compliance obligations. It also explores the increased attention being paid to patient safety and quality of care. The second part of this chapter addresses some important considerations in structuring a compliance program and discusses the roles of the hospital's compliance officer and general counsel. The third part describes the role of the compliance officer in the context of several of the foundational elements to an effective compliance program. This chapter concludes by addressing some considerations for compliance officers when reporting certain compliance-related information.

II. INTERNET RESOURCES

The U.S. Department of Health and Human Services Office of Inspector General (OIG) has worked with the American Health Lawyers Association to produce four documents regarding the compliance responsibilities of health care boards of directors:

1. Corporate Responsibility and Corporate Compliance: A Resource for Health Care Boards of Directors,
2. An Integrated Approach to Corporate Compliance: A Resource for Health Care Boards of Directors,
3. Corporate Responsibility and Health Care Quality: A Resource for Health Care Boards of Directors, and
4. Practical Guidance for Health Care Governing Boards on Compliance Oversight.

These documents and other helpful information may be found at https://oig.hhs.gov/compliance/compliance-resource-material. The first three documents have been combined into one publication, "The Health Care Director's Compliance Duties," which may be found at the same location.

The Health Care Compliance Association (HCCA)-OIG Compliance Effectiveness Roundtable has issued a "Resource Guide" to assist health care organizations in measuring the effectiveness of their healthcare compliance programs. The guide is available at https://oig.hhs.gov/documents/toolkits/928/HCCA-OIG-Resource-Guide.pdf. It suggests metrics for measuring the effectiveness of the various elements of a compliance program.

III. THE BOARD OF DIRECTORS' ROLE IN COMPLIANCE OVERSIGHT

In the compliance context, the ultimate responsibility of the board of directors is to ensure that it receives sufficient information, and makes sufficient inquiry, about compliance matters to ensure that it has met its fiduciary duties to the hospital. Compliance programs provide a mechanism for the board of directors to accomplish this goal. The board of directors, therefore, is ultimately responsible for assuring that the hospital has implemented an effective compliance program. Most effective compliance programs have the following elements:

1. Standards and procedures,
2. Education and training,
3. Reporting,
4. Monitoring and auditing,
5. Enforcement and discipline, and
6. Investigation and remediation.

See chapter 1, "Hospital Compliance Plans," regarding the elements of a compliance program.

The board's role with respect to these elements is to ensure that they are present in the hospital's compliance program, that the compliance program is structured effectively, that adequate resources have been dedicated, and that the board routinely reviews the performance of the compliance program.

A. An Effective Compliance Program Assists Directors to Discharge Their Fiduciary Duties

An essential task for compliance officers is to obtain acknowledgment or "buy-in" from directors that compliance and an effective compliance program are critical to the successful operation of the hospital. A first step to accomplishing this task is to ensure that directors are educated and informed about their fiduciary duty to oversee compliance matters. Compliance programs are an effective tool for hospitals to identify and reduce risks. The failure to have an effective compliance program (including appropriate board oversight) increases the potential for a hospital to fall out of regulatory compliance and suffer adverse consequences, such as governmental investigative and enforcement actions, criminal or civil penalties or sanctions (including exclusion from federal health care programs, such as Medicare), and a loss of reimbursement from government or commercial payers. In addition, failure to maintain an effective compliance program could lead to an individual director being held personally liable for breaching their fiduciary duties to the hospital. While there is no express statutory provision that requires a hospital to have a compliance program, the combination of statutory fiduciary requirements, case law and agency guidance has made an effective compliance program essential for hospitals and their boards of directors. *(See chapter 1 regarding requirements and benefits of maintaining an effective compliance program.)*

Understanding the source of the directors' oversight obligations will enhance the compliance officer's ability to educate the board and implement an effective compliance program. The fiduciary duty most implicated by compliance matters is a director's duty of care. A brief discussion of the fiduciary duty of care and its import to director compliance oversight follows.

The Duty of Care

The duty of care requires a director to act:

1. In good faith,
2. With the level of care, including reasonable inquiry, that an ordinarily prudent person would exercise in like circumstances, and
3. In a manner that the director believes is in the best interest of the corporation.

The "duty of care" is codified in Corporations Code Sections 309(a) (for-profit corporations) and 5231(a) (nonprofit corporations).

Central to satisfying their duty of care is an expectation that directors will exercise "reasonable inquiry" and conduct sufficient due diligence in order to make an informed decision. Directors are entitled to rely upon certain third parties regarding matters which the directors believe are within the expertise of those third parties. Particularly, directors may rely upon the reports, information and opinions prepared or presented by:

1. Officers or employees, whom the directors believe to be reliable and competent,
2. Counsel, independent accountants or other outside advisors, as to matters within their professional competence, or
3. Committees of directors in which the board has confidence, as to matters within their authority.

Thus, the board may rely upon opinions and reports from the compliance officer, general counsel and the board's compliance committee that are generated as part of an effective compliance program, as long as the board believes them to be competent and reliable. Moreover, as a practical matter, receiving regular reports from the compliance officer and committee provides directors the opportunity to review information, ask questions, and demonstrate that they have exercised the requisite reasonable inquiry.

Directors may rely on counsel and other experts only insofar as their opinions warrant confidence. In 2015, the Fourth Circuit upheld the largest False Claims Act (FCA) judgment predicated on the federal anti-self-referral law (Stark Law) violations in *United States ex rel. Drakeford v. Tuomey Healthcare System, Inc.*, 792 F.3d 364 (4th Cir. 2015). Specifically, the court upheld the jury's finding of guilt by a hospital for submitting false claims to Medicare because, the jury found, the hospital knew that its relationships with some referring physicians violated the Stark Law (or acted in deliberate ignorance or reckless disregard of the violation). The hospital received favorable advice from its regular lawyers, its valuation experts, and outside counsel. However, one of the physicians raised compliance concerns, and the hospital and the physician retained other counsel, who advised that the arrangement raised red flags under the Stark Law. The board was apparently aware that legal counsel had expressed concerns about the arrangement, although it was not clear that the board understood the weight and seriousness of these concerns. The hospital took the advice of its regular and outside counsel, and moved forward with the transactions. The court held that the jury properly rejected the hospital's advice-of-counsel defense, because the evidence indicated that the hospital ignored the negative legal advice of the jointly-retained attorney.

This is not a case about the general fiduciary obligations of directors, but rather the FCA defense of good-faith reliance on the advice of counsel. Nevertheless, it illustrates the danger

of opinion shopping, and the importance of the board's engagement where it has reason to believe that an expert's advice may be questionable.

The *Tuomey* case also highlights an area of increasing compliance risk as economic pressures on both hospitals and physicians drive closer alignment. This is an area in which the board needs to rely heavily on management and outside experts in community needs, fair market value and legal compliance. However, the board should approve policies for recruitment assistance, physician compensation and other economic relationships with physicians, and these policies might require board approval of particular arrangements that fall outside the ordinary. A level of review that is focused on the hospital's broader mission and detached from day-to-day financial and operational pressures can be a valuable check for compliance.

The Board's Decision-Making and Oversight Functions

Compliance officers and directors should also understand the context in which the board's duty of care regarding compliance issues is likely to surface. Generally, a director's duty of care with respect to compliance issues will arise in two contexts: the board's decision-making function and the board's oversight function of the hospital.

With regard to the decision-making function, having an effective compliance plan is critical so that directors are kept informed of specific compliance issues or concerns through the plan's reporting, auditing and investigation features.

Directors are not expected to make perfect decisions, and are not held accountable solely because a particular decision resulted in a negative outcome. Rather than concentrating on the outcome, courts have generally considered the process that directors employed when reaching a decision, and whether that process was rational and executed in good faith. A director will usually be considered to be acting in good faith if there is no improper financial benefit to the director or an intent to take advantage of the corporation. In addition, the director must have shown due diligence in making an informed decision. In other words, directors must make a reasonable inquiry into the facts and circumstances surrounding a particular decision. Moreover, the OIG has stressed that a critical element to effective board oversight is directors who actively inquire about the adequacy and effectiveness of the compliance program and the performance of those individuals who develop and execute it. Of course, if a director receives information that puts (or should put) him or her on notice of a possible problem or violation, the director must make further inquiry and take whatever steps are required to address the issue. Having a robust compliance program can help directors focus on the right issues, ask the right questions, and get the right information to make an informed decision.

The seminal judicial decision with respect to a director's oversight obligation is the *Caremark* decision, *In re Caremark International Inc. Derivative Litigation*, 698 A. 2d 959 (Del. Ch. 1996). While the *Caremark* court ultimately declined to find that the board of directors breached its duty of care, it nevertheless provided a framework for compliance oversight against which directors will likely be judged. Specifically, the court held that a director has a duty to act in good faith in attempting to assure that:

1. A hospital has a corporate information and reporting system in place, and
2. This reporting system is adequate to assure that appropriate compliance-related information will come to the board's attention in a timely manner and as a matter of ordinary operations.

In short, the board must assure that there is an effective compliance program in place. Indeed, to benefit from the reduction of fines or penalties under the Federal Sentencing Guidelines for Organizations (FSGO), directors must not only be knowledgeable about the compliance program, but also be able to evaluate and recommend changes to it in light of ongoing risk assessments. *(See chapter 1, "Hospital Compliance Plans," regarding the Federal Sentencing Guidelines for Organizations.)*

B. Patient Safety and Quality of Care

When developing or updating a compliance program, compliance officers (and the board) should keep patient safety and quality of care issues in mind. This is because patient safety and quality of care has been, and will continue to be, an important enforcement priority area for health care regulatory and enforcement agencies. For example, the Medicare and Medicaid conditions of participation require hospitals to monitor quality through credentialing of medical staff and to maintain effective quality assessment and performance improvement programs. State and federal government enforcement agencies have increasingly focused their efforts on recouping payment for substandard care. Hospitals could also be subject to exclusion from federal health care programs for providing medically unnecessary care or services that fail to meet recognized professional standards. *(See chapter 11 regarding exclusion from federal health care programs.)* Indeed, government authorities are closely evaluating quality reporting data (such as data provided by hospitals for annual payment updates, physician-provided data and "sentinel event" data) to identify inconsistencies and evidence of ongoing quality problems that are not being appropriately addressed. Many contractual and financial arrangements commonly used by hospitals to improve patient safety and quality of care, such as gainsharing and pay for performance agreements, also directly raise compliance issues. All of these issues and types of arrangements should be addressed in any compliance program.

The link between patient safety and quality of care, on the one hand, and compliance, on the other, may not be obvious. Consequently, compliance officers should be prepared to educate the board about patient safety and quality of care issues and their relation to compliance and the board's fiduciary duties. As a first step, the compliance officer should assess, and help the board assess, the status of the hospital's patient safety and quality of care initiatives and the current level of reporting to the board. The use of an internal patient safety and quality of care questionnaire or survey can assist compliance officers to identify the status of the hospital's patient safety and quality of care efforts and report this information to the board. The American Health Lawyers Association and the OIG have together developed a sample patient safety and quality of care questionnaire that hospitals may modify to fit their needs. It is available at http://oig.hhs.gov/compliance/compliance-guidance/compliance-resource-material.asp in the document titled, "Corporate Responsibility and Corporate Compliance: A Resource for Health Care Boards of Directors."

The compliance officer can also assist the board in its oversight function as it relates to quality of care and patient safety by educating the board on patient safety procedures, clinical quality measurements and national trends in health care quality. The compliance officer should involve the hospital's patient safety and quality assurance directors, as appropriate. Given the nature of these areas, the directors may wish to consult with outside safety and quality of care experts. Understanding the relevant industry procedures and

clinical care benchmarks will enable directors to better assess the hospital's patient safety, professional competency and quality of care performance, and assist in the hospital's development of assessment tools and performance goals with which to measure adequacy and performance as part of the hospital's compliance program. As part of the regular reporting process, the compliance officer should ensure, through the hospital's reporting structure, that directors are informed of the processes the hospital has in place to monitor the quality of its services. This will enable the board to actively evaluate the effectiveness of the hospital's patient safety and quality assurance efforts and recommend changes for improvement.

It is essential to present patient safety and quality of care data in a manner in which directors can easily understand it and compare it with established clinical care benchmarks. Some thought and care should be given to the means of presenting this information to directors, such as using a scorecard or dashboard report card, so that directors can easily determine how the hospital compares to recognized performance metrics. The compliance officer should seek to provide enough information so that directors have a full and accurate picture of the status of patient safety and quality of care within the hospital, without overwhelming directors or inadvertently burying or obscuring important data or information. A sample dashboard that hospitals may modify to fit their needs may be found at www.ucop.edu/ethics-compliance-audit-services/compliance/ecas-plans-reports-summaries.html.

The Duty of Obedience and Patient Safety/Quality of Care

The duties of directors of nonprofit hospitals with respect to patient safety and quality of care do not originate solely from a director's duty of care, but arise also from the director's duty of obedience — that is, obedience to the hospital's nonprofit purpose or mission. Nonprofit corporations, including nonprofit hospitals, are formed to achieve a specific purpose. This purpose, or mission, is set forth in the corporation's articles of incorporation, and may be amplified in its bylaws. Such a mission could be, for example, "the promotion of the health of the community through the provision of hospital inpatient and outpatient services and the conduct of medical and scientific investigation and research."

Directors are responsible for ensuring that a nonprofit hospital fulfills its charitable mission. It is not difficult to see the link between this duty and ensuring the promotion of patient safety and quality of care. Indeed, a nonprofit organization could be subject to significant adverse consequences for failing to act in conformance with its mission. For instance, the California Attorney General has the right to enforce a nonprofit organization's compliance with its mission, and the Internal Revenue Service may also take action against a nonprofit if it is acting in a manner inconsistent with its charitable purpose. This underscores the importance for the compliance officer to properly educate directors on the need to incorporate patient safety and quality of care performance standards into the hospital's compliance program.

C. Considerations for Charitable Organizations

If the hospital is a charitable organization, the Board of Directors has broad responsibility to oversee compliance with federal laws relating to tax exemption under Section 501(c)(3) of the Internal Revenue Code, and with California laws governing charitable organizations. These responsibilities are explained in detail in Chapter 9. Not all of them will fall under the purview of the compliance officer, but the compliance officer should be aware of the Board's obligations to safeguard the charitable mission and assets of the organization. These

obligations include:

Ensuring that the articles and bylaws of the organization reflect its charitable mission and the dedication of its assets to charitable purposes. The Board may have a governance committee charged with this responsibility.

Monitoring the organization's activities and expenditures, to ensure that they are consistent with the organization's charitable mission, and do not confer more than incidental benefits on private individuals.

Ensuring that the organization conducts a community health needs assessment every three years, and adopts a written plan to meet community needs identified by the assessment.

Ensuring that the organization has a financial assistance policy, an emergency care policy, and a policy on collection actions against individuals who may be eligible for financial assistance.

Monitoring conflicts of interest among Board members and executives. The Board should have a conflicts of interest policy, and Board members and executive employees should submit annual disclosures, which should be reviewed by the chair of the Board and senior management, so that directors' conflicts of interest can be addressed if they are relevant to any action of the Board. Transactions in which a director or a member of management has a financial interest should be dealt with in accordance with the special procedures outlined in Chapter 9.

Adopting a policy on executive compensation, and ensuring that executive compensation is set with reference to comparable market data. Some Boards have a compensation committee charged with this responsibility.

Ensuring that the organization does not engage in prohibited political activities.

IV. SOME IMPORTANT STRUCTURAL CONSIDERATIONS FOR EFFECTIVE COMPLIANCE PROGRAMS

When developing a compliance program from scratch, or assessing a compliance program as part of a periodic review, compliance officers should consider the organizational and governance structures of their hospital. Doing so will greatly improve the likelihood of identifying important areas of structural weakness and allow the opportunity to address these weaknesses before problems arise. This portion of this chapter explores some important structural considerations with respect to compliance committees and the compliance officer's interaction with general counsel.

A. The Hospital's Organizational and Governance Structure

A hospital's organizational and governance structure will affect the approach taken by the board of directors in overseeing the compliance program. Identifying the hospital's structure is an important first step for compliance officers. For example, is the hospital a single, stand-alone entity, or is it part of a larger system with multiple entities? If it is the latter, the compliance officer can help the parent and subsidiary boards identify what compliance information should be reported to each and how best to report it.

B. Helping Compliance Committees to be Effective

Another consideration is whether the hospital board delegates some of its compliance

oversight function to a designated group of directors who serve on a compliance committee. For reasons of economy and efficiency, hospital boards of directors regularly use compliance committees to exercise their compliance oversight function. Compliance officers should have a good understanding of how effective compliance committees should be structured and operated, and should assist the full board to create and maintain effective compliance committees.

When advising the board about the structure of the compliance committee, compliance officers should confirm that the committee has, at a minimum, the following three characteristics:

1. A written charter that contains basic provisions (such as a statement of purpose, responsibilities and authorities, membership requirements and regular reporting obligations),
2. Composition of an appropriate number of members with the right type of qualifications and skill sets, and
3. Ultimate accountability to the board.

These elements are described further below.

In addition, if the board maintains a compliance committee, the compliance officer is likely to be the person assigned the task of regularly reporting compliance information to the committee. However, the compliance officer may or may not be responsible for ultimately reporting compliance information to the full board of directors. That task might fall to another individual, such as the chair of the board's compliance committee or the hospital's general counsel (if there is one). If someone other than the compliance officer reports this information to the full board, the compliance officer should know who the person is and assist him or her to ensure that appropriate compliance information is reported.

Reviewing the Written Charter

The compliance officer should assess whether the compliance committee's written charter sufficiently describes and defines the scope of its authority and responsibilities, as well as the means by which such responsibilities are to be discharged. The charter should address, at a minimum, the committee's membership and qualification requirements (including a requirement that members be independent), the powers and authority of the committee, its ability to obtain independent advice and a process for regular full board review of the committee's performance. The written charter should be approved by the full board of directors and should be reviewed by the compliance officer (and updated if necessary) regularly. If the compliance officer believes the charter is inadequate, or in need of updating, he or she should recommend appropriate changes to the committee, its chair or the full board, as appropriate.

Determining Committee Composition

Optimizing the composition and size of the committee is critical to having a productive compliance committee. The appropriate size of each hospital's compliance committee depends upon a number of factors, which include the size and needs of the board, the hospital's culture and the availability of members. Typically, the compliance committee is a relatively small subset of the full board. Factors to be considered when determining the appropriate size include balancing the need for committee members to represent a

sufficiently diverse set of skills and expertise necessary to solve complex compliance issues with the need for the committee to be efficient, workable and coordinated. The OIG has suggested that the presence of a professional with health care compliance expertise on the board (or compliance committee) will send a strong message about the organization's commitment to compliance issues and provide the other members of the board (or committee) with a valuable resource when evaluating the compliance program or particular compliance issues. Of course, given the subject matter of the committee, all members should be independent and disinterested.

Consideration should also be given to whether the committee should regularly rotate its members. Having a rotation may enhance the full board's understanding of compliance issues and assist it in its oversight functions. However, a constant shuffle of new membership will undoubtedly require the compliance officer to spend additional time educating and orienting new members, and may negatively affect the coordination and efficiency of the committee. Having a rotation should also be weighed against the risk of losing the right balance of expertise.

The compliance officer should be prepared to provide the board specific recommendations in this regard. If the compliance officer believes that improvements can be made to the composition of the committee (such as the addition of an important skill or expertise), he or she should recommend appropriate changes to the committee, its chair, or the full board, as appropriate.

Ensuring Accountability to the Board

Ultimately the responsibility for compliance program oversight falls upon the full board of directors. Consequently, the compliance officer should ensure that there are tangible mechanisms in place to hold the compliance committee accountable to the full board of directors. This is especially important in light of the board's fiduciary duties. A failure by the board to maintain oversight could be seen by outside parties as an improper abdication of its responsibilities, and could place the hospital (and the board) in an unfavorable position with the government in the case of an investigation.

As the person responsible for the operational control of the compliance program, the compliance officer should make sure that appropriate board oversight is in place. This can include ensuring that:

1. Regular compliance reports are made to the full board (perhaps by the committee chair and assisted by the compliance officer),
2. Compliance committee meeting minutes are kept and promptly distributed to the full board after each committee meeting, and
3. The charter requires the compliance committee to defer significant compliance-related decisions to the full board.

The compliance officer can further assist the committee and full board by reviewing and confirming that committee meeting minutes accurately reflect the committee's compliance reports and activities.

C. Considerations Regarding the Roles of General Counsel and the Compliance Officer

The determination of the roles and functions of the general counsel and the compliance officer is a critical decision for the board. The board must decide whether these functions should be combined or separated, and if separated, in what fashion. Before the board can appropriately evaluate this question, it should have a good understanding of the typical functions and responsibilities of both positions.

As noted in chapter one of this manual, the Federal Sentencing Guidelines for Organizations (FSGO) describe the compliance officer as the individual who is assigned the overall responsibility of the compliance program (e.g., the day-to-day operational responsibility for the compliance program). The FSGO expect that the compliance officer will have general control over the compliance program and will have direct reporting access to executive level management and to the board (or its compliance committee).

The U.S. Department of Health and Human Services, Office of Inspector General (OIG), in its Compliance Program Guidance for Hospitals (available at https://oig.hhs.gov/compliance/compliance-guidance/index.asp) has further defined the duties of the compliance officer to include:

1. Developing and implementing policies, procedures, and practices,
2. Overseeing and monitoring the implementation of the program,
3. Updating and revising the program,
4. Developing, coordinating, and participating in a multi-faceted training and education program, as appropriate,
5. Coordinating internal audits,
6. Reviewing, responding to, and investigating reports of non-compliance,
7. Serving as a resource across the organization on substantive compliance questions and issues, and
8. Reporting directly to the board of directors, CEO and president on compliance matters.

In that process, the compliance officer is expected to have a broad knowledge of the organization and operational matters and awareness of relevant laws and regulations.

The role of the compliance officer has often been described as that of an ombudsman who is assigned to oversee the compliance program and identify and prevent misconduct.

Traditionally, the general counsel has also been seen as having the primary responsibility of assuring the implementation of a legal compliance program. Indeed, these responsibilities are consistent with the professional and ethical duties of the general counsel. Therefore, the general counsel will typically also have direct reporting access to top-level management and the board.

However, it has been observed that the general counsel also has a supervisory role over the legal defense of the hospital, and consequently, could be responsible at the same time for defending it against claims of non-compliance, on the one hand, and ensuring its

compliance, on the other. While it is not impermissible to combine these functions (or to have the compliance officer subordinate to the general counsel), the board should know that the government disfavors such an arrangement, and has a strong preference for the complete separation of the legal and compliance functions, where feasible. Specifically, the OIG has stated:

> The OIG believes that there is some risk to establishing an independent compliance function if that function is subordinate to the hospital's general counsel, or comptroller or similar hospital financial officer. Freestanding compliance functions help to ensure independent and objective legal reviews and financial analyses to the institution's compliance efforts and activities. By separating the compliance function from the key management positions of general counsel or chief hospital financial officer (where the size and structure of the hospital make this a feasible option), a system of checks and balances is established to more effectively achieve the goals of the compliance program.

The following discussion addresses a few of the potential compliance officer/general counsel structures that the compliance program (and board) could use and some key considerations of each.

General Counsel Serves as the Compliance Officer

As previously noted, one way to structure the general counsel and compliance officer functions is to have these functions performed by the same individual. Indeed, in its previous guidance, the OIG expressly acknowledged that a hospital could have one individual serve as both the general counsel and the chief compliance officer. Hospitals may wish to combine these functions for reasons of economic efficiency, or to increase their ability to preserve or claim the attorney-client privilege. While having the same person perform both functions will certainly prevent failures of communication between the compliance officer and general counsel, it also creates the appearance that the compliance officer lacks independence and increases the potential for conflicts to arise, particularly with respect to the monitoring, audit, and investigative functions of the compliance officer position.

If a hospital combines the general counsel and compliance officer positions, directors should be clearly advised that this structure is not viewed favorably by the government, and may be detrimental should the hospital ever become the subject of a government investigation. Indeed, the OIG has released survey results in the past indicating that a minority of hospitals use a combined general counsel/compliance officer structure. To mitigate some of the risks raised by a combined arrangement, the OIG recommends that the individuals serving a dual role be given the ability to execute each function separately, including through reporting opportunities with the board of directors and executive management.

The OIG has also provided additional suggestions that directors should consider regarding separating the two functions in certain circumstances — for example, if the subject matter of a compliance investigation involves the general counsel/compliance officer. In such a case, the OIG suggests that the compliance program include procedures for the recusal of the general counsel/compliance officer, in which case there should also be a procedure for identifying an alternative investigator (perhaps outside counsel). The OIG also suggests that compliance programs have procedures that implement periodic third-party independent reviews of the compliance program to identify those situations in which outside counsel is appropriately retained. These third-party reviews should also explore other ways to enhance the independence of the compliance officer function.

It may be difficult to distinguish when the general counsel is acting as a compliance officer and when he or she is acting as the organization's attorney. This is particularly important for purposes of determining when and whether communications and work product will be privileged. The difficulty of keeping track of which hat the general counsel is wearing weighs in favor of having a separate compliance officer apart from the general counsel, or bringing in outside counsel when the hospital needs to address an issue in a privileged environment.

Compliance Officer Separate, but Reports to General Counsel

Another way to structure the roles of the general counsel and the compliance officer is to have these functions performed by different individuals, but have the compliance officer report to the general counsel. Again, this structure is not optimal in the government's view because it raises concerns about the compliance officer's independence and ability to report compliance matters to directors without undue influence. Even if these concerns reflect only perception, and not reality, the government is likely to view the structure with skepticism, particularly since it does not appear to be necessary. Directors should be advised that this structure is not viewed favorably by the government and that OIG survey results indicate that a minority of hospitals use it.

Nevertheless, the OIG has also suggested procedures that it believes will help reduce the actual or perceived lack of independence of the compliance officer or the compliance officer's potentially reduced access to the board. For example, the OIG suggests that the compliance program include alternate reporting lines that permit the compliance officer to report to another member of hospital management (or directly to the directors) periodically, or when the compliance officer believes it is prudent or necessary. The OIG also suggests that the compliance program include procedures to allow another person (such as a member of the compliance committee) to authorize the compliance officer to pursue compliance investigations and hire outside counsel under certain circumstances. However, the OIG also suggests balancing this authority by requiring notice and consultation with the general counsel. Finally, the OIG suggests having periodic direct reports by the compliance officer to the board after prior notice and consultation with the general counsel.

Compliance Officer Separate and Does Not Report to General Counsel

The OIG recommends structures that completely separate the compliance officer and general counsel functions as the best way to create a system of appropriate checks and balances in the compliance program. While these structures solve the issue of compliance officer independence, they raise questions about how the responsibilities, coordination, communication, and reporting relationship between the two positions are divided so that the compliance program does not become fragmented and the board does not lose the benefit of advice from the general counsel.

If a hospital uses this structure, directors should be advised to ensure, at a minimum, that:

1. The job descriptions of both positions are sufficiently clear and identify the compliance-related duties and responsibilities of each position,
2. The compliance officer has sufficient stature within the hospital's organizational hierarchy to permit the compliance officer to meet their responsibilities effectively,
3. A direct reporting relationship between executive management, the board and the compliance officer is established and maintained, and

4. A collaborative and coordinated communication procedure between the general counsel and the compliance officer is developed and maintained.

To ensure that the board does not lose the benefit of its general counsel's expertise, when designing or assessing the compliance program, the compliance officer should consider the areas in which the board relies upon the general counsel's advice and ensure that the compliance program implements appropriate procedures to ensure that it will retain this input. Recommendations from the compliance officer and general counsel will be useful in this regard.

The OIG has suggested that areas in which input from the general counsel will benefit the board include:

1. Periodic risk assessments,
2. Review of proposed policies and reports on compliance processes,
3. Conducting investigations, and
4. Devising remedial measures to address violations of the law.

The OIG also suggests that general counsel should routinely review matters reported to the board by the compliance officer, and that prior notice and consultation with the general counsel should be required where the compliance officer has the authority to retain outside counsel or consultants.

V. CORPORATE COMPLIANCE PROGRAM: THE ROLE OF THE COMPLIANCE OFFICER

The rest of this chapter focuses on some of the important aspects of the role of the compliance officer as the individual charged with the day-to-day operation of the compliance program. To provide effective oversight of the compliance program, the compliance officer should ensure that directors have a good working understanding of the structure of the program. The compliance officer should keep in mind that oversight of the compliance program is but one of many duties of directors, and that not all directors will have a background in health care. Accordingly, the compliance officer should ensure that directors receive, as part of their orientation, an overview of the basic framework of the compliance program, which should include the structure of the compliance program as well as the substantive laws and requirements that drive the program. A good place for compliance officers to start with directors is an overview of the elements set forth in the OIG's compliance program guidance *(described in C. "Considerations Regarding the Roles of General Counsel and the Compliance Officer," page 2.10)*.

A. Standards and Procedures, and Identification of Risks

The OIG believes that an effective compliance program should have written policies and procedures to document the hospital's commitment to the program. Written policies and procedures also provide a means to communicate the hospital's expectations and standards for conduct by all employees, management, directors and contractors.

Policies and procedures will typically include a code of conduct (see chapter 1), policies related to the goals and operation of the compliance program, and policies that specifically address the regulatory risks of the organization.

The compliance officer should oversee the development and implementation of the policies and procedures and should be prepared to educate directors on their content as well as the content of the organization's code of conduct. The volume of policies and procedures may preclude an in-depth explanation of every single policy, but the compliance officer should ensure that directors have at least a general knowledge of the policies. If the full board of directors has appointed a compliance committee, it may be advisable to give the committee additional, more in-depth education on the compliance program policies and procedures. A solid review of the policies and procedures will communicate to the board of directors how the compliance program operates as well as the expectations the hospital has with regard to the actions of its employees and managers.

Reviewing compliance policies and procedures will also enhance director understanding of the hospital's principal compliance risks. Compliance officers should be prepared to outline for directors how the hospital's principal risks are identified. This is likely to include an overview of the OIG strategic plan, work plans, fraud alerts, known enforcement actions, and any other relevant guidance.

The compliance officer should also be prepared to provide the board with an overview of:

1. How often the policies and procedures are reviewed,
2. How the compliance program monitors the hospital's adherence to the policies and procedures,
3. How the compliance program monitors changes or developments in relevant laws and guidance, and
4. How the policies and procedures are updated to respond to these changes.

A healthy understanding of the compliance-related policies and procedures will not only make directors aware of the goals and objectives of the compliance program, it will also lead to better compliance plan oversight.

B. Education and Training

An effective compliance program must have ongoing education and training for all employees as well as directors. The compliance officer should look for opportunities to provide directors with regular in-house and outside educational opportunities with respect to industry regulatory and compliance risks. Education and training will also benefit the hospital by ensuring that all employees understand the hospital's policies and procedures and expectations regarding compliant conduct. Education and training also assists the hospital in demonstrating to outside third parties (such as the government) its commitment to compliance. The compliance officer should design and implement an education and training program that meets these goals.

The education and training program should also be tailored to the audience. For example, training for employees involved in the organization's billing and collections department should be different from the training for an employee negotiating contracts with payers. Similarly, the compliance officer should design an appropriate training program for directors, keeping in mind the board's duty of oversight of the compliance program.

Director training should, at a minimum, provide an overview of the compliance program and the fiduciary duties of directors as they relate to compliance. This training may also

involve an overview of the major laws that affect compliance, and any consequences of the hospital's failure to abide by these laws (for both the hospital organization and, if applicable, for individual directors). These laws would likely include, but not necessarily be limited to, the laws described throughout this manual (the False Claims Act, the Stark Law, anti-kickback laws, community health needs assessment and charity care laws, screening for excluded providers and related state laws), as well as licensing requirements, EMTALA, and the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and state health information privacy laws. If the board has appointed a compliance committee, the compliance officer may choose to go into greater detail with the members of the committee.

Developing and maintaining documentation of completed training is important to ensure that it actually happens, and to demonstrate a commitment to compliance to the outside world. The compliance officer should document the training provided to the board of directors (as well as to other employees), and should ensure that new board members receive timely orientation and compliance training. Additionally, the compliance officer may want to consider incorporating some element of education into each meeting of the board or relevant subcommittee in order to keep directors apprised of new developments in health care regulations that are relevant to the organization. This education will, in turn, assist directors to meet their responsibility to ensure that the compliance program is appropriately identifying and responding to the regulatory environment. It will also put the board in a better position to recommend and assess modifications to the compliance program when necessary.

C. Reporting

The compliance officer should make it a priority to develop ways for employees at all levels of the organization to report compliance concerns. Hospitals that encourage employees to report suspected wrongdoing improve their chances of having an effective compliance program, because internal reporting often permits the hospital to investigate and address possible problems at an early stage. Further, directors are responsible for ensuring that adequate processes are in place to facilitate the reporting of compliance concerns. This is a fundamental pillar of a successful compliance program, as it is an effective means to identify possible misconduct.

In fulfillment of their oversight duties, directors should inquire whether the hospital has developed systems for the reporting of compliance-related concerns. The compliance officer can help the board meet this obligation by educating directors on the processes in place to encourage open communication across all levels of employees and management.

The compliance officer should review reports, and determine the appropriate response, including when to initiate an investigation. The compliance officer should develop a means for tracking reports made through the hospital's reporting mechanisms and the response made to each report. The methods that are needed to document, respond to and monitor this information will vary from hospital to hospital. The compliance officer will need to determine the information that needs to be reported to the board of directors, such as trends, possible areas of risk, corrective actions being taken and ongoing oversight of any problems identified. The compliance officer may want to consider partnering with the general counsel when developing mechanisms for reporting and determining what information to report to the board of directors.

D. Monitoring and Auditing

An essential element to any compliance program is the development of monitoring and auditing processes by which the compliance officer and compliance staff assess the hospital's adherence to internal policies and procedures as well as relevant laws. A hospital's compliance risk can be greatly mitigated by the development of an ongoing auditing and monitoring program.

It is generally the compliance officer's duty to establish the auditing and monitoring plan based on the hospital's principal risks. Areas of risk can be identified from both internal sources (such as employee reports to an internal hotline) and external sources such as OIG guidance, consultants, industry guidance and competitor issues. The compliance officer should also ensure that the hospital makes appropriate responses to adverse audit findings. The compliance officer must have sufficient authority and resources to conduct effective monitoring and auditing activities.

For instance, the compliance officer must have the authority to review all records and documentation relevant to monitoring adherence to the hospital's policies and procedures. The compliance officer should communicate to the board of directors the resources required and authority necessary for these activities. In doing so, the compliance officer should keep in mind the nature of the hospital's business as well as compliance issues flagged during prior audits so that directors can ensure the compliance officer is able to perform the necessary monitoring and auditing functions.

The board of directors must review audit findings in a timely manner. The compliance officer may want to work with the general counsel when reporting results of the compliance program's auditing and monitoring activities and, if necessary, developing action plans in response to such results.

E. Enforcement and Discipline

Adequate enforcement and discipline is also a necessary component to an effective compliance program. Without it, the compliance program will lack credibility. Enforcement and discipline helps to ensure that employees are held accountable for their actions and are appropriately disciplined for misconduct. It also serves as an important notice to employees of the hospital's expectations and should help deter future misconduct. Finally, it demonstrates the hospital's commitment to its compliance program. The compliance officer should also ensure that effective records are kept that document disciplinary actions taken by the hospital and ensure that such information is reported to the board.

F. Investigation and Remediation

The investigation and remediation function is one of the most important functions that the compliance officer fulfills. The compliance officer is likely to be the senior management official primarily responsible for overseeing the hospital's investigation and response activities. The compliance officer should assist the board in adopting policies and procedures for investigating compliance concerns. These procedures should, at a minimum:

1. Describe how and when investigations are triggered,
2. Identify the person responsible for conducting and overseeing the investigation, and
3. Describe when the general counsel should be involved.

After an event, the compliance officer should also initiate corrective and monitoring measures to prevent future misconduct. The policies should also say what actions should be taken following an investigation to ensure that similar violations do not recur. While the types of measures that a compliance officer can take are many, some of the steps a compliance officer should consider include:

1. Identifying deficiencies in the hospital's existing policies and procedures,
2. Providing additional education and/or training to affected employees, and
3. Creating new or revising existing procedures to prevent future events.

Of course, the compliance officer should report results of significant investigations to key management and the board of directors.

Finally, there may be circumstances in which a compliance investigation is initiated outside the hospital, such as a government investigation. The hospital's compliance program should have procedures in place to ensure that it responds appropriately.

VI. REPORTING TO THE BOARD OF DIRECTORS

One of the most important ways in which the compliance officer can assist the board of directors in meeting its compliance-related duties is to ensure that the board receives ongoing compliance information. This duty spans multiple elements of an effective compliance program. The compliance officer needs to ensure that directors receive sufficient information to be able to assess the efficacy of the compliance program (and identify problems in a timely fashion), but not so much information that directors get lost in the details. It is the job of the compliance officer to identify the key components of the compliance program and to organize the data so that it is easily understood. The frequency of reports may vary depending on the particular compliance program component, with some components reported quarterly, and others annually. In its guidance, the OIG has suggested that scheduling regular executive compliance sessions (without senior management) will encourage more open communication with the board on compliance issues generally (and not just when an issue arises), and could help avoid creating suspicion among senior management as to why a special board session has been called.

When determining what information to report to the board, the compliance officer may wish to start with the seven basic compliance program elements developed by the OIG *(see chapter 1)*, and supplement them where necessary. A few of the compliance program elements, and suggestions for ways to report on them, are highlighted below.

A. Education and Training

The compliance officer should provide the board of directors a summary report of all training completed so that the board can confirm that the necessary training is being provided to the hospital's directors, management, employees and others. The board of directors can use this report to determine whether the training should be modified because of changes in laws or newly identified risk areas.

B. Reporting Mechanisms

The compliance officer should regularly report on the status of compliance-related issues and concerns raised through the hospital's reporting mechanisms. These reports may include the

number of reports, the nature of the concerns raised, and a discussion of any investigation or action taken in response to the issues reported. The report may also include any significant violations or material risks identified through the reporting process. The compliance officer should determine the best way to organize the information received through the reporting process so that the board can identify any trends in the information. This will allow the board not only to identify material areas of risk, but also to determine whether the information demonstrates that the hospital is improving in areas previously flagged as raising compliance concerns. Often these reports will come in the form of a dashboard report — a relatively short, easy to read chart or graphic presentation that describes the hospital's performance in key compliance areas. Dashboard reports can be an effective tool for the board of directors to assess the hospital's current compliance performance in comparison to its historical performance and against the performance of its peers.

C. Auditing and Monitoring Activities

The board of directors should receive reports of findings from the hospital's auditing and monitoring activities. The compliance officer should prioritize the results in order of importance, and include the plans of action that have been developed to address any failures. This will help the board of directors meet its duty of being reasonably informed of the hospital's business. This will also give the board the opportunity to assess the hospital's response to instances of non-compliance, and to make an independent determination of whether further action is needed for the board to meet its duty of reasonable inquiry. Given the possible legal implications of auditing or monitoring activity, the compliance officer may want to work with the general counsel in this area.

D. Annual Report

The compliance officer should prepare an annual report for the board of directors summarizing the activities and actions of the compliance program for that year. This report should, at a minimum, concentrate on the hospital's performance within each of the seven elements of an effective compliance program developed by the OIG *(see chapter 1)*. The annual report may also touch on topics such as audit review findings and the status of action plan implementation, changes to the code of conduct or policies and procedures, patient safety and quality of care, and enforcement and discipline efforts. The information should be presented in a way that allows directors to understand the overall efficacy of the compliance program. The annual report is also useful as an easy resource to share with outside auditors or government enforcement agencies to demonstrate the robustness of the hospital's compliance program. Lastly, it is a tool for the compliance officer to use to build a relationship with the board of directors and assist the board in meeting its compliance program oversight responsibility.

E. Potential Areas of Focus for Reports

The compliance officer will need to determine (or assist the board in determining) the topics or areas to be focused upon in reports to the board. These topics should include the hospital's performance in areas previously identified by the board or compliance officer as important to the hospital's compliance efforts. Topics will, of course, vary depending upon the compliance needs of the hospital, and are likely to change over time. The OIG has provided two guidance documents that describe compliance areas that it considers to

be important. The compliance officer and board may wish to start with this guidance as a beginning tool when developing (or supplementing) reporting topics for the board:

1. Compliance Program Guidance for Hospitals, and
2. Supplemental Compliance Program Guidance for Hospitals.

These documents and other helpful information may be found at https://oig.hhs.gov/compliance/compliance-guidance/index.asp. A brief summary of the significant areas of concern identified by the OIG, and published in the Supplemental Compliance Program Guidance For Hospitals (Supplemental Guidance), follows.

Submission of Accurate Claims Information

The OIG makes clear its position that "[p]erhaps the single biggest [compliance] risk area for hospitals is the preparation and submission of claims or other requests or erroneous claims." The OIG identifies many different areas of concern, including inaccurate or incorrect coding, upcoding, unbundling of services, billing for medically unnecessary services, duplicate billing, providing insufficient documentation, and filing false or fraudulent cost reports. Ensuring that compliance activity in these areas is identified and reported is an important first step. The OIG further identifies the following areas as evolving areas of risk.

Outpatient Procedure Coding

In the Supplemental Guidance, the OIG identifies risk areas such as using incorrect procedure code modifiers for outpatient coding, billing on an outpatient basis for procedures that are only reimbursed on an inpatient basis, submitting incorrect claims due to an outdated charge description master, using improper codes to describe evaluation and management services, and improperly billing for observation services.

Admissions and Discharges

The OIG also identifies risk areas with respect to the admission and discharge process, including failing to follow the "same-day rule," abusing partial hospitalization payments for certain behavioral and mental health services, same-day discharge and readmissions (which could indicate premature discharges, unnecessary readmissions or improper coding), violating post-acute care transfer policies and the "churning" of long-term care patients that are co-located within an acute care hospital.

Other Supplemental Payment Considerations

Under certain circumstances, hospitals may claim supplemental payment for services provided to Medicare patients. The OIG identifies a number of risk areas in the Supplemental Guidance, including improper reporting of costs of pass-through items, abuse of DRG outlier payments, improper claims due to the incorrect designation as a provider-based clinic, and improper claims for organ acquisition costs and cardiac rehabilitation services.

Compliance With the Self-Referral and Anti-Kickback Statutes

Another significant compliance area identified by the OIG in its Supplemental Guidance is compliance with the federal Stark Law and Anti-Kickback Statute. *(See chapters 6 and 7 for a discussion of the requirements and considerations of these laws.)* Areas for scrutiny identified by the OIG include physician joint ventures, compensation arrangements with physicians (such as medical director agreements, personal services agreements, space or equipment leases, management agreements and recruitment agreements), the conditioning

of medical staff privileges on referrals, and the subsidization of malpractice insurance premiums. Compliance with these statutes will likely continue to be a major concern given the anticipated increase of new forms of reimbursement methodologies that seek to incentivize the collective improvement of the population's health through global and bundled payments — the bundling of services and payment with the aim of maintaining and improving the health of the patient at a lower cost.

Substandard Care

The OIG also notes that it has the authority to exclude any provider who provides unnecessary items or services, or items or services of a quality that fails to meet appropriate standards of care. Accordingly, hospitals are expected to continually measure their performance against comprehensive standards.

HIPAA Privacy and Security Rules

Another major compliance area, enforced by the Office for Civil Rights ("OCR") of the Department of Health and Human Services, is privacy and security of patient information, including compliance with HIPAA and other federal and state privacy and security laws. These laws, among other things, require hospitals to implement privacy and security policies and procedures, conduct periodic risk assessments to assist with a security management plan, and report privacy breaches to patients and regulatory authorities. OCR and the California Department of Public Health have levied substantial penalties on hospitals that have suffered breaches of privacy and security.

HIPAA requires a hospital to have a privacy official, who is responsible for developing and implementing the hospital's health information privacy policies and procedures, and a contact person or office for privacy complaints and information. The privacy official may be the compliance officer, but these roles may be separate. HIPAA also requires a hospital to have a security official charged with developing and implementing comprehensive health information security policies and procedures. The security official is typically an information technology specialist. It is important that the privacy official and the security official are in close communication to deal appropriately with security incidents that may require notification to patients and regulatory authorities.

The compliance officer should track issues affecting privacy and security compliance, such as breaches or other security incidents, patient complaints, and significant risks, and ensure that they are dealt with appropriately. For example, given the recent rise in ransomware attacks on hospitals, it is critical that security measures include implementing procedures to guard against and detect malicious software. In recent years, OCR has been vigorously enforcing patients' right to access their medical records under HIPAA as part of its Right of Access Initiative, so prioritizing responses to patient access requests in a compliant manner is also important. CHA publishes the *California Health Information Privacy Manual*, which describes all state and federal health information privacy and breach laws.

Other Risk Areas

Topics discussed above are, of course, illustrative and the compliance officer should tailor and supplement their reports to include other compliance topics affecting the hospital depending upon circumstances. These topics can include reporting on compliance with EMTALA, maintenance of tax exemption status under federal and state laws, requirements of a corporate integrity agreement (if applicable), compliance with applicable bond requirements,

compliance with conflicts of interest and self-dealing policies, employment matters (such as wage and hour rules), waste management and other environmental issues, etc. Finally, and as noted previously in this chapter, the compliance officer should take care to educate their board on emerging patient safety and quality of care compliance issues, and ensure that such issues are adequately addressed in the hospital's compliance program and regularly reported upon to the board of directors.

3 Federal and State False Claims Acts

I. Introduction 3.1

II. Federal False Claims Act 3.3

A. Overview of the Law 3.3

B. Elements of FCA Claims 3.4

Liability for a False Claim 3.4

The Definition of a Claim Under the FCA 3.5

False or Fraudulent Claims Under the FCA 3.5

Materiality 3.8

"Presenting" a Claim Under the FCA 3.8

"Knowingly" Making Claims Under the FCA 3.10

"Conspiracy" Under the FCA 3.11

The Statute of Limitations on FCA Actions 3.11

C. Conduct That May Trigger a False Claims Action 3.12

Risks for Allegations of False Claims in Billing 3.12

Risks for Allegations of False Claims in Cost Reports 3.13

Other Risks for Allegations of False Claims 3.14

D. Procedures for FCA Actions 3.14

Step 1: The FCA Complaint is Filed 3.14

Step 2: The Government Chooses Whether to Intervene 3.16

Step 3: The FCA Complaint is Served on the Defendant 3.18

E. Remedies for Violations of the FCA 3.18

Remedies for Civil Liability 3.18

Relator's Share of the Recovery 3.20

Civil Monetary Penalties, Exclusion, and Enrollment Revocation 3.20

III. Criminal Liability for False Claims Under Other Federal Laws 3.23

A. Crimes Against Federally-Funded Health Care Programs 3.23

Penalties 3.23

B. Crimes Against Both Private and Government Health Care Programs ... 3.24

C. Statute of Limitations 3.24

IV. California's False Claims Act 3.25

A. Elements of California FCA Claims 3.25

The Legal Standard for a California FCA Claim 3.25

The Definition of a Claim Under the California FCA 3.26

The Definition of an Obligation Under the California FCA 3.26

The Statute of Limitations on California FCA Actions 3.26

B. Procedures for California FCA Actions 3.27

Limitations on Subject Matter of California FCA Actions 3.27

The Government Chooses Whether to Intervene 3.28

C. Remedies for Violations of the California FCA 3.28

Parties' Shares of the Recovery 3.29

Additional Liability for False Statements Concerning Medi-Cal Claims 3.30

D. Protections for Whistleblowers 3.30

Employers May Not Prohibit Whistleblowing 3.30

Employers May Not Retaliate Against Whistleblowers 3.30

V. California Insurance Fraud Laws 3.32

A. Civil Actions 3.32

Civil Action to Recover on False or Fraudulent Claims, Including Claims Resulting from Referrals 3.32

Statute of Limitations 3.33

The District Attorney or Insurance Commissioner Decides to Intervene 3.33

B. Civil Penalties 3.34

Parties' Shares of the Recovery 3.34

C. Employers May Not Retaliate Against Whistleblowers 3.35

VI. California Criminal Penalties 3.36

3 Federal and State False Claims Acts

I. INTRODUCTION

This chapter discusses the federal civil False Claims Act (FCA) and California's false claims laws as they relate to hospitals, and the potential civil money penalties and other civil liability for fraud related to these laws. In recent decades, it has become more important than ever for hospital employees to understand the FCA and the related criminal Disclosure Statute (discussed in chapter 15), so that the severe potential penalties and expenses associated with responding to criminal fraud investigations or civil FCA lawsuits can be minimized or avoided altogether. Almost all hospitals in California are now required to have detailed and documented policies and procedures regarding compliance with the FCA's prohibition on false claims to federal health care programs, including the Medicare and Medi-Cal programs. With the Medicare Fraud Strike Force created by the Department of Justice (DOJ) and increased attention on health care fraud, prosecutions for FCA violations by hospitals and other health care providers will only increase.

Congress originally passed the FCA, 31 U.S.C. Section 3729 *et seq.*, during the Civil War to combat rampant fraud by contractors that billed the government for inferior or nonexistent products, such as artillery shells filled with sawdust rather than gunpowder. The FCA authorizes DOJ or a whistleblower — known as the "relator" — to initiate lawsuits on behalf of the government against individuals or companies that submit, or cause the submission of, false and fraudulent claims.

In 1986, the FCA was amended to further facilitate whistleblower lawsuits, as explained below. Since that time, there has been an explosion in civil and criminal false claim actions in the health care arena, including against almost every major hospital system. As a result, the federal government has recovered billions of dollars in civil FCA and fraud settlements and judgments, with approximately 80 percent of those cases involving health care services. Since 2009, the Justice Department has recovered more than $31.3 billion from FCA cases, with more than $17.9 billion of that amount recovered in cases involving fraud against federal health care programs. In fiscal year 2016 alone, the federal government won judgments or negotiated settlements of over $2.5 billion in health care fraud cases.[1] With the government recovering approximately $7-$15 dollars for every dollar invested in health care fraud enforcement, hospitals and other health care providers continue to be ripe targets for both whistleblowers and the government because of the significant financial returns available from successful civil and criminal false claim actions.

As part of the Fraud Enforcement and Recovery Act of 2009 (FERA), Congress again amended the FCA to make investigations, litigation and recovery easier for DOJ and *qui tam* relators. The law extends liability to any person who, among other things:

1 Department of Health & Human Services and Department of Justice, Health Care Fraud & Abuse Control Program, Annual Report for Fiscal Year 2016, p. 1, 71 (Jan. 2017). *See also Press Release, Department of Justice, Justice Department Recovers Over $4.7 Billion from False Claims Act Cases in Fiscal Year 2016 (Dec. 14, 2016)*

1. Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
2. Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; or
3. Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the government.

(See full definition under B. "Elements of FCA Claims," page 3.4.)

[31 U.S.C. Section 3729(a)]

In addition, FERA:

1. Expands liability for "reverse" false claims by imposing liability for knowingly or recklessly retaining overpayments from the government, even in the absence of any false statement;
2. Allows the government's complaint to "relate back" to the filing of the relator's complaint, enabling the DOJ to conduct longer investigations and bring higher dollar-value actions; and
3. Expands the anti-retaliation provisions to cover contractors and agents, in addition to employees.

[31 U.S.C. Sections 3729(b)(3) and 3731(c)]

Also, the 2010 Dodd-Frank Wall Street Reform and Consumer Protection Act and the Whistleblower Protection Enhancement Act of 2012 reinforced whistleblower protections under the FCA, by expanding protected conduct to include employees' lawful efforts to investigate or stop fraud and other FCA violations.

In light of these changes that make it easier and more lucrative to bring false claims cases, FCA filings have increased approximately 50 percent since 2009.

These recent amendments to the FCA impact hospital and health care providers with special force, and have also contributed to an increase in FCA filings in health care. For example, with FERA, Congress amended the FCA's definition of "obligation" to include liability for "knowingly and improperly" retaining an overpayment. In 2010, the Affordable Care Act (ACA) defined an "obligation," under the FCA, as an overpayment retained more than 60 days after it was "identified" as being past due for the corresponding cost report. As such, hospitals and other health care providers could face FCA liability for failing to disclose and return overpayments in the specified time frame. An overpayment has been "identified" for purposes of starting the 60-day deadline when a hospital or other entity "has or should have, through the exercise of reasonable diligence, determined that the [entity] has received an overpayment and quantified the amount of the overpayment." 42 C.F.R. Section 401.305. This obligation has a lookback period of six years. *(See chapter 15, "Repayment and Self-Disclosure.")* FERA also clarifies that violations of anti-kickback statutes serve as predicates to FCA claims. *(See 42 U.S.C. Section 1320-7b(g) (A "claim that includes items or services resulting from a violation of" the anti-kickback statute "constitutes a false or fraudulent claim" for purposes of the FCA.))*

Hospitals can reduce the risk of criminal and civil litigation by conducting risk-based training, monitoring and auditing to ensure that all governmental submissions are factually and legally accurate, and completing a thorough and credible investigation if any potential violations of the FCA are detected. When hospital employees understand their individual responsibilities in ensuring that only accurate claims are submitted for reimbursement and that overpayments are properly divulged, they can identify and report systemic billing and reporting errors. In turn, the hospital can swiftly reverse or correct improper claims before they become a significant financial liability or basis for FCA litigation.

II. FEDERAL FALSE CLAIMS ACT

This section provides an introduction to the federal False Claims Act — an area of law that hospitals must understand, as its application to the health care industry has expanded rapidly in recent years and continues to be a top area of government enforcement. This section also provides an overview of the statute, numerous examples of the types of conduct that may lead to false claims allegations, a discussion of the types of conduct that make up a false claim under the FCA, and a discussion of the procedure for an FCA action that includes advice for hospitals that find themselves under investigation. This section concludes with a discussion of the remedies and damages awarded for successful FCA actions, as well as a brief look at the criminal penalties that may be attached to making false and fraudulent claims, should they be prosecuted under applicable federal criminal statutes.

A. Overview of the Law

The FCA imposes liability on any person who:

1. Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
2. Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
3. Conspires to commit a violation of subparagraph 1, 2, 4, 5, 6 or 7;
4. Has possession, custody, or control of property or money used, or to be used, by the government and knowingly delivers, or causes to be delivered, less than all of that money or property;
5. Is authorized to make or deliver a document certifying receipt of property used, or to be used, by the government and, intending to defraud the government, makes or delivers the receipt without completely knowing that the information on the receipt is true;
6. Knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the government, or a member of the Armed Forces, who lawfully may not sell or pledge property; or
7. Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the government.

[31 U.S.C. Section 3729(a)(1)]

Defendants found liable under the FCA may be subject to treble damages — defined as three times the amount of the false claims — and a mandatory civil penalty of as much as $22,363 per false claim.[2] The FCA provides an incentive for a relator to initiate an FCA lawsuit — also known as a *"qui tam"*[3] action — by allowing the relator to share in a percentage of the recovery that is ultimately obtained in the case. In fiscal year 2019, the government recovered more than $2.1 billion related to lawsuits filed under the *qui tam* provisions of the FCA.[4]

Conduct in the health industry that traditionally has given rise to FCA liability includes submitting claims for services not rendered or for services rendered by an unlicensed practitioner or tainted by improper kickbacks. However, a series of court decisions culminating in a Supreme Court decision issued in 2016 has broadened the scope of FCA liability by finding that a provider submits a false claim any time the claim is the result of the provider's violation of, or false certification of compliance with, a law or regulation that is material to the government's decision to pay for those services. The Centers for Medicare & Medicaid Services (CMS) has taken advantage of these court decisions by requiring providers to sign an increasing number of express certifications of compliance with various laws and regulations. Accordingly, the FCA has become an effective, and often draconian, remedy used by the government to combat fraud in the health care industry.

The following section describes the legal elements of the FCA and the conduct for which health care providers have faced FCA liability. It also includes a brief summary of the procedures followed in an FCA action and the potential damages and federal civil penalties.

B. Elements of FCA Claims

This section covers the key elements of an FCA claim, including the legal standard such claims must meet, the question of who is liable for false claims, the definition of false claims, whether they are "knowingly" made, and what constitutes "presenting" a claim. Finally, this section describes the statute of limitations on FCA violations — that is, the deadline to bring an action against a violator.

Liability for a False Claim

The FCA imposes liability not only on a person who submits a false claim (or makes a false statement in support of a false claim), but also on a person who causes the submission of a false claim. Thus, a person may be liable under the FCA even if the person does not contract with or receive funding from the government and does not submit any claims to the government. For example, a manufacturer that knowingly sells defective medical devices to a hospital that uses them on Medicare patients can be liable for the hospital's resulting false claims, and a hospital administrator can be personally liable under the FCA for knowingly directing the billing department to submit false claims to the government.

2 The minimum and maximum civil penalty amounts occasionally are adjusted for inflation. Recently, the amounts were increased dramatically pursuant to federal budget legislation. *See Final Rule, Civil Monetary Penalties Inflation Adjustment for 2017, 82 Fed. Reg. 9131, 9133 (Feb. 3, 2017)* (increasing minimum per-claim penalty from $10,781 to $10,957, and maximum per-claim penalty from $21,563 to $21,916, pursuant to the Bipartisan Budget Act of 2015, Pub. L. No. 114-74, Section 701, 129 Stat. 584, 599). The current applicable civil penalty may be found at 28 C.F.R. Section 85.5.

3 ***Qui tam*** is an abbreviation of the Latin phrase "qui tam pro domino rege quam pro si ipso in hac parte sequitur," which means "who sues on behalf of the King as well as for himself."

4 Press Release, Department of Justice, Justice Department Recovers Over $3 Billion from False Claims Act Cases in Fiscal Year 2019 (Jan. 9, 2020).

The word **"person"** includes corporations and other entities. Thus, a corporation can be liable under the FCA. However, in *Vermont Agency of Natural Resources v. United States ex rel. Stevens*, 529 U.S. 765 (2000), the U.S. Supreme Court held that a state is not a "person" subject to FCA liability. Thus, state agencies generally are immune from FCA liability. The Ninth Circuit, however, has held that state officials can be sued for violations of the FCA in their personal capacities.[5]

Although some division exists among federal courts across the country, federal courts in California have generally found that counties and local governments, as well as their employees, are "persons" subject to FCA liability.

The Definition of a Claim Under the FCA

A **"claim"** is defined as any request or demand, whether under a contract or otherwise, for money or property to which the United States may or may not have title to the money or property, that:

1. Is presented to an officer, employee, or agent of the United States; or
2. Is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the government's behalf or to advance a government program or interest, and if the United States government:
    a. Provides or has provided any portion of the money or property requested or demanded; or
    b. Will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded; but
    c. Does not include requests or demands for money or property that the government has paid to an individual as compensation for federal employment or as an income subsidy with no restrictions on that individual's use of the money or property.

[31 U.S.C. Section 3729(b)(2)]

"Obligations" are "an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment." [31 U.S.C. Section 3729(b)(3)]

The FCA defines **"material"** as anything "having a natural tendency to influence, or being capable of influencing, the payment or receipt of money or property." [31 U.S.C. Section 3729(b)(4)]

False or Fraudulent Claims Under the FCA

According to the law, a claim is considered "false or fraudulent" if it is "factually false" or "legally false."

Factually False

A claim is **"factually false"** if it requests payment for goods or services not actually provided as claimed. Examples of factually false claims that arise in the health care industry include, but are not limited to:

5 *Stoner v. Santa Clara Cnty. Office of Educ.*, 502 F.3d 1116, 1125 (9th Cir. 2007)

1. Claims for items or services that were not provided or were billed at a code for a higher level of care than that which was actually provided (i.e., upcoding);
2. Claims for services by an individual who is not licensed or did not provide the services personally or at his/her direction; or
3. Claims billed under the "borrowed" provider number of another physician or entity.

Legally False

A claim is **"legally false"** if it includes either an express or an implied false certification of compliance with a contract term or statutory or regulatory requirement that is a condition of payment. An express certification is a signed statement indicating that a particular requirement has been or will be met. For example, the UB-04 (CMS Form 1450), which is used for Medicare inpatient claims, includes an express certification that the items and services identified in the claim were medically necessary. A person submits a false claim based on an express false certification if he or she submits a signed UB-04 claim form for items and services that were not medically necessary.

Implied Certification. Under the implied certification theory, the submission of a claim itself represents a certification that all of the conditions required for payment of the claim by contract, law, regulation, or other rule have been met. Both the Medicare and Medi-Cal programs have increasingly required providers to certify their compliance with what were traditionally conditions of *participation* as a condition of *payment*, thereby eliminating the distinction drawn by the courts between such conditions. As a result, it is well established that certain legal and regulatory violations will be deemed material to payment and lead to FCA liability.

For example, the Stark Law prohibits any Medicare claim for a "designated health service" by a hospital where the service was furnished pursuant to a prohibited referral by a physician who has a financial relationship with the hospital. As a result, a hospital can be charged with submitting a false claim based on an implied false certification theory if it knowingly submits a UB-04 claim form for items and services that were the result of Stark Law violations. Such a violation occurs even if the hospital makes no written representation or express certification about its compliance with that statute as part of its claim. *(See chapter 6 regarding the Stark law.)* Because the Stark law conditions payment on compliance, violations support FCA liability.[6]

Likewise, the Anti-Kickback Statute (AKS) expressly provides that any claim "resulting" from a violation of the statute is a false claim for purposes of the FCA. *(See chapter 7 regarding the Anti-Kickback Statute.)*

Importantly, the United States Supreme Court upheld the validity of the implied certification theory in *Universal Health Services, Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016). In doing so, the Supreme Court held that a statutory, regulatory, or contractual requirement does not have to be expressly designated a condition of payment for its violation to serve as the potential basis for a false claim. At the same time, however, the Supreme

6 See, e.g., ***Ebeid ex rel. United States v. Lungwitz***, 616 F.3d 993, 1000 (9th Cir. 2010) (observing that "the Stark Act may provide a valid basis from which to imply certification, because it expressly conditions payment on compliance."). In July 2015, the Court of Appeals for the Fourth Circuit upheld a jury verdict imposing more than $237 million in damages and civil penalties under the FCA against a hospital for submitting more than 22,000 false claims resulting from violations of the Stark law [***United States ex rel. Drakeford v. Tuomey Healthcare System, Inc.***, 792 F.3d 364 (4th Cir. 2015)].

Court cautioned that just because a government official could deny payment based on the underlying violation does not necessarily mean that the underlying violation renders a claim false (e.g., if evidence shows that a government agency routinely pays claims even if it knows a provider failed to comply with a particular requirement). The Supreme Court also ruled that just because a requirement is expressly labeled a condition of payment does not mean that its violation renders a claim false under the FCA. Instead, DOJ or the relator must prove that, in fact, the underlying requirement is material to the government's decision to pay a claim.

Escobar expressly held that not every violation by a hospital of a law, regulation, or rule will create false claims liability under an implied certification theory. Counsel can help identify the factual and legal weaknesses in an FCA allegation. Counsel can also help stem FCA actions by demonstrating the absence of an underlying violation of the law related to the submission of the claims at issue. Sub-Regulatory Guidance. There are legal arguments against Medicare's use of sub-regulatory guidance, including CMS's Internet Only Manuals and LCDs, to form the basis of an enforcement action. Providers should consult legal counsel if they are subject to an enforcement action based on noncompliance with sub-regulatory guidance.[7]

Statistical Sampling. When determining the number of potentially false claims, the government may try to use statistical sampling to extrapolate a single false claim to a wider set of submitted claims. The courts that have allowed the use of statistical sampling in FCA cases generally have limited its use to determining damages, rather than as a method to proving liability. In *United States ex rel. Martin v. Life Care Centers of America, Inc.*, Case No. 1:08—cv—251, 2014 WL 4816006 (E.D. Tenn. Sept. 29, 2014), the defendant argued that the use of statistical sampling to prove the number of false claims and the losses associated with those claims was improper and insufficient for the government to establish its burden of proof. The court acknowledged the splits in authority where some courts have allowed, while others have prohibited, the use of statistical sampling in FCA cases, with most courts approving extrapolations for damages purposes. This court ultimately found that the use of sampling for both liability and damages was acceptable as it would not impermissibly shift the burdens of proof or violate the defendant's rights to due process.

In *United States ex rel. Michaels v. Agape Senior Community Inc.*, Case No. 12-3466, 2015 WL 3903675 (D.S.C. June 25, 2015), the court rejected the use of statistical sampling and extrapolation as a method of proving liability or damages in an FCA case involving the submission of more than 50,000 allegedly false claims for hospice services. Though it declined to intervene, the government objected to a settlement reached by the parties after the government extrapolation method resulted in a potential recovery amount significantly greater than the parties' agreed-upon settlement. Significantly, before the government's objection, the court had ruled that it would not allow the plaintiff-relators to use statistical sampling to determine liability and damages. The Fourth Circuit initially agreed to decide whether statistical sampling may be used to prove liability or damages under the FCA. However, the Fourth Circuit ultimately declined to decide the issue, finding that it was not a "pure question of law" and, thus, not appropriate for interlocutory review by the Court. To date, the disagreement among the district courts as to whether and how the government may use statistical sampling to establish damages or liability in FCA cases continues.[8]

It is likely that more FCA prosecutions will be attempted on the basis of a subset of allegedly

7 ***Azar v. Allina Health Svcs.***, 139 S. Ct. 1804 (2019); HHS-OIG, Kelly M. Cleary & Brenna E. Jenny, Memorandum Regarding Impact of ***Allina*** on Medicare Payment Rules, October 31, 2019; HHS-OGC, Advisory Op. 20-05 on Implementing ***Allina*** (Dec. 3, 2020), ***available at*** https://www.hhs.gov/sites/default/files/allina-ao.pdf.

8 In addition to ***LifeCare*** and ***Agape***, see ***United States ex rel. Wall v. Vista Hospice Care, Inc.***, No. 3:07-cv-00604-M, 2016 U.S. Dist. LEXIS 80160, at *42 (N.D. Tex. June 20, 2016) (refusing to allow extrapolation).

false claims, which the government will argue should be extrapolated to a greater number of claims and greatly increase the available penalties. Nonetheless, hospitals and other health care providers will have grounds to object to the attempted extrapolation of a few false claims to their entire practice. For example, health care providers may challenge the need for statistical sampling, the validity of the sampling technique and the findings, as well as the admission of statistical sampling evidence at trial.

Materiality

Not every false or fraudulent statement or action gives rise to FCA liability, even where the other elements of the claim are otherwise satisfied. Courts require that the government prove that the defendant's false statement or conduct was "material" to the government's payment decision. Prior to FERA, courts in some circuits were requiring the government or relator to meet a higher standard of materiality that focused on whether the false statement was a "prerequisite to payment," rather than merely "capable of influencing" the government payment. With FERA, the FCA broadly defines "material" to mean "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." Under this definition, a defendant's false or fraudulent statement or conduct will generally be considered "material" to the government's payment decision if it had any relevance to the claimed service, without any showing by the government that it, in fact, would not have paid the claim had it known the truth. However, the Supreme Court's recent decision in *Escobar* indicates that the more robust definition of materiality still applies in determining whether a payment claim is "false."

In *United States ex rel. Harman v. Trinity Industries Inc.*, 872 F. 3d 645 (5th Cir. 2017), the Court of Appeals for the Fifth Circuit surveyed and summarized the holdings of its "sister circuits," including the First Circuit, regarding the impact of the government's continuing payment action in FCA cases in light of *Escobar's* characterization of the materiality requirement as being "demanding" and "rigorous."

The *Harman* court stated the "lesson we draw from these well-considered opinions is that, though not dispositive, continued payment by the federal government after it learns of the alleged fraud substantially increases the burden on the relator in establishing materiality." In *Harman*, the Fifth Circuit overturned a jury verdict in favor of the relator because the evidence showed that the government continued paying claims notwithstanding its actual knowledge of alleged deficiencies.

"Presenting" a Claim Under the FCA

Under the FCA, a person is liable for "knowingly" presenting a false claim or causing another individual to present a false claim to:

1. An officer, employee or agent of the United States government; or
2. Any person or entity if the claim is for money to be spent or used on the government's behalf or to advance a government program or interest, and the government provides or will reimburse any portion of the claimed money.

[31 U.S.C. Section 3729(b)(2)]

The law establishes that a person may be liable under the FCA for submitting a false claim

not only to a federal agency, but also to a state or private company that contracts with or is funded in part by the federal government. Thus, a party may be liable under the federal FCA for the submission of a false Medicare claim to a private company, which acts as a Medicare administrative contractor or administers a Medicare Advantage plan[9] because the federal government provides funding for the claims paid by such company. Similarly, a party may be liable under the federal FCA for the submission of a false Medi-Cal claim to the California Department of Health Care Services because the Medi-Cal program receives federal funding.

Even more broadly, a person may also be liable under the FCA for knowingly making, using, or causing to be made or used, a false record or statement that is material to a false or fraudulent claim regardless of whether the person knew or intended that the claim would be paid by the federal government. Rather, FCA liability attaches if the false statement or record had a tendency to influence the payment of the claim even if the person had no idea that the claim would be paid or reimbursed, in whole or in part, by the government or with government funds. For example, FCA liability would exist for a hospital employee who creates a false medical record to support the admission of a patient who is believed to be covered by private insurance, but turns out to be a Medicare beneficiary for whom the hospital later submits a claim.

Because liability under the FCA is established when a party submits a false claim "for approval," a person may face liability for statutory penalties even where the government suffered no damages because it did not pay or reimburse any money on the claim. Liability also may attach when the party violated a technical condition of payment (such as maintaining sufficient supporting documentation), but that violation did not cause the government to pay more money than was due for the claimed services.

Reverse False Claim/Overpayment

The FCA establishes liability for a **"reverse false claim"** — that is, where a person makes or uses a false record to avoid paying or underpaying money to the government that the person rightfully owes. Specifically, a person is liable under the FCA for knowingly making, using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the government. Under this provision, for example, a hospital would be liable for knowingly submitting a cost report that falsely stated that the hospital owed only $100,000 to Medicare, when an accurate cost report would show that $200,000 was due.

Similarly, a hospital would also be liable for failing to disclose and repay a known overpayment to Medicare resulting from an innocent billing error because the FCA defines an **"obligation"** as being a legal duty arising from a contract, statute, regulation, or "the retention of any overpayment." In addition, a hospital's failure to report and refund a Medicare or Medicaid overpayment to the applicable payer within the regulatory deadline of the later of "60 days after the date on which the overpayment was identified" or "the date any corresponding cost report is due" can also create FCA liability. *(See chapter 15, "Repayment and Self-Disclosure.")*

"Knowingly" Making Claims Under the FCA

9 But see *United States ex rel. Martinez v. Orange Cty. Global Med. Ctr., Inc.*, No. 8:15-cv-01521-JLS-DFM, 2017 U.S. Dist. LEXIS 221085 (C.D. Ca. Sept. 14, 2017) (holding that the relator had not sufficiently pled that a hospital's alleged regulatory violations were material to the government's decision to pay the Medicare Advantage plan.

"Knowingly" is defined to mean that a person, with respect to information:

1. Has actual knowledge of the information;
2. Acts in "deliberate ignorance" of the truth or falsity of the information; or
3. Acts in "reckless disregard" of the truth or falsity of the information.

[31 U.S.C. Section 3729(b)(1)]

Mere negligence, innocent mistakes, scientific errors, or reasonable differences in opinion or judgment do not give rise to FCA liability. However, the government or relator does not need proof of specific intent to defraud. [31 U.S.C. Section 3729(b)(1)(B)]

The FCA's definition of "knowingly" means that a person may be liable under the FCA even if he or she did not specifically intend to defraud the government, but knew that he or she was making, or causing another to make, a false claim or false statement material to such a claim. For example, the statute's broad definition means that the government can always contend that any claim violating a payment regulation or rule is "false" because the hospital acted in "reckless disregard" of that regulation or rule, even though most people associate a "false claim" with an intentional lie.

The "deliberate ignorance" standard is intended to prevent the "ostrich defense," where an individual intentionally avoids learning facts that would reveal the falsity of the claim.

The "reckless disregard" standard is sometimes called "gross negligence-plus." For example, a physician acts with reckless disregard when submitting claims for services that total more than 24 hours in any 24-hour period, regardless of whether the physician actually knew that any of the individual claims submitted were false. [*United States v. Krizek*, 111 F.3d 934 (D.C. Cir. 1997)]

Although division exists among courts nationwide, some courts (including federal courts in California) have found that the government's full knowledge of the defendant's alleged wrongdoing precludes a finding that the defendant knowingly submitted a false or fraudulent claim in violation of the FCA.[10] In such cases, the defendant often engages in an open dialogue with the government regarding the defendant's performance and any difficulties it faces, or the positions it will take with respect to cost reporting, for example. In some cases, the government and the defendant negotiate new or different contract requirements or applicable rules. Overall, when the defendant is open and honest about the goods and services it is providing to the government, courts are more likely to conclude that the defendant was not out to defraud the government. Furthermore, when there is evidence about the honest exchanges with government entities, the evidence may be used to help defeat a potential complaint in certain circumstances.[11] Note, however, that a hospital can waive its attorney-client privilege if it argues advice of counsel or good faith compliance as a defense.[12]

In other cases, courts have found that the FCA defendant did not act knowingly in submitting

10 These facts also undermine a finding that the issue was material, as addressed above.

11 See, e.g., ***Gonzalez v. Planned Parenthood of Los Angeles***, 759 F.3d 1112 (9th Cir. 2014) (affirming dismissal of FCA complaint for failure to plausibly allege the knowing submission of false statements where the defendant showed prior communications with the government about the defendant's plans and no objection from the government in response)

12 See, e.g, ***United States ex rel. Barker v. Columbus Regional Healthcare System, Inc.***, No. 4:12-cv-108 (CDL), 2014 WL 4287744 (M.D. Ga. Aug. 29, 2014) (finding waiver of attorney-client privilege where health care organization asserted a defense in its answer to an FCA complaint that it believed its conduct was legal, even though it did not assert any advice of counsel defense directly).

false or fraudulent claims because the defendant was diligent in investigating potential fraud and monitoring its compliance with applicable statutes, regulations and other rules and requirements. In some cases, the fact that a defendant voluntarily disclosed the allegedly fraudulent conduct was a factor that weighed in favor of the court's finding that the defendant did not knowingly violate the FCA.

In summary, it is important for health care providers to operationalize and maintain an effective compliance program and to take timely action to resolve and prevent the recurrence of any compliance issue of which they become aware.

"Conspiracy" Under the FCA

A person may violate the FCA by conspiring to engage in any of the conduct prohibited by the statute [42 U.S.C. Section 3729(a)(1)(C)]. A conspiracy exists when a defendant reaches an agreement with one or more other persons to engage in conduct that violates the FCA. For example, a conspiracy exists if two persons agree to make a false claim, statement, or record that is material to the government's payment of a claim, even if the conspirators had no specific intent to defraud the government, did not know that the claim would be paid by the government or with government funds, or were entirely ignorant that the false statement or record was material to a claim payment. A corporation can engage in a conspiracy, but cannot conspire with its own employees or subsidiaries.

In addition, a conspiracy participant is liable under the FCA for all acts by other conspirators if the acts further the conspiracy, including any false claims. Interestingly, in order to be liable for conspiracy, no actual false claim, statement, or record has to be made by any conspirator. Instead, most courts have ruled that conspirators are liable so long as a conspirator commits some "overt act" (which can be entirely legal) in furtherance of the conspiracy.

Although a defendant can be held liable for "knowingly" violating any of the other FCA provisions [42 U.S.C. Section 3729(a)(1)(A), (B), (D), (E), (F), (G)], the conspiracy provision does not adopt the knowing standard [42 U.S.C. Section 3729(a)(1)(C)]. At least some courts have interpreted this to mean that the general rule for mental state in conspiracy cases — that the defendant must have specific intent to conspire — applies in the FCA context.[13]

The Statute of Limitations on FCA Actions

General Rule

A **"statute of limitations"** is the period of time within which a lawsuit must be filed — in other words, a deadline. If the statute of limitations has "run," then it is too late for a person to bring a lawsuit. An FCA action may not be brought more than six years after the date on which the violation was committed, or more than three years after the date when facts material to the right of action were known or reasonably should have been known by the official of the United States charged with responsibility to act in the circumstances, but in no event more than 10 years after the date on which the violation was committed, whichever occurs last. [31 U.S.C. Section 3731(b)]

This means that, generally, a government or a relator may bring an FCA action against a defendant based on false claims submitted up to six years before the filing of the FCA complaint in federal court.

Typically, an FCA violation is committed, and the statute of limitations begins to run, when the

13 *United States v. Murphy*, 937 F.2d 1032, 1038-39 (6th Cir. 1991) (holding a defendant cannot be liable under 42 U.S.C. Section 3729(a)(1)(C) for "deliberate ignorance" or "reckless disregard"); *United States ex rel. Johnson v. Shell Oil*, 183 F.R.D. 204, 208 (E.D. Tex. 1998) ("Indeed, the conspiracy provision of the Act seems to require the specific intent to defraud, unlike the other provisions which merely require knowledge.")

government pays on the false claim or, if the government never paid on the claim, when the defendant submitted the false claim or the false statement in support of the false claim.

Delayed Discovery

However, a longer period is possible in the case of **"delayed discovery."** This means that if the government can show that, within the last three years and for the first time, it discovered or had reason to suspect the submission of false claims that occurred up to 10 years before the complaint was filed in federal court, the defendant may be liable for false claims submitted within this longer 10-year statute of limitations period. This rule applies to both intervened and non-intervened *qui tam* actions.[14]

C. Conduct That May Trigger a False Claims Action

As amended by FERA, the FCA captures conduct that leads to a payment or overpayment from the government. Many types of conduct by hospital employees may expose the hospital to FCA liability. This section provides a number of illustrative examples. Note, however, that CMS and state governments continue to introduce new health care statutes, regulations, and other program requirements, and relators continue to bring FCA actions based on novel theories of liability. Therefore, these examples cannot be considered a comprehensive statement of the law.

Compliance Tip: The law surrounding the False Claims Act is developing rapidly, especially in the courts. To ensure compliance, periodically check with legal counsel or another expert to determine if new case law has expanded the law's scope.

Risks for Allegations of False Claims in Billing

Hospitals may be at risk for allegations of false claims if they bill Medicare, Medicaid or other federally-funded health programs (e.g., CHAMPUS or TRICARE) for the following types of services or products:

1. Services or products that were not medically necessary.
2. Services or products that were not provided.
3. Services that have been "upcoded" (e.g., billed using a DRG code for a higher level of care than that which is justified by the patient's medical records) or services where the prices were otherwise inflated.
4. Services or products provided to dead or discharged patients, or services billed to government health programs for which the patient was not eligible.
5. Services or products billed without the necessary, properly completed documentation, such as the certificate of medical necessity, physician's order, or delivery receipt.
6. Services or products billed under the wrong provider number (that is, the physician/provider whose provider number was used did not provide the service personally or provide the supervision required for the performance of the service by other personnel).
7. Services provided by an unlicensed physician, unlicensed provider or nonphysician.

14 *Cochise Consultancy, Inc. v. United States ex rel. Hunt*, 139 S. Ct. 1507, 1510 (2019).

8. Services that were performed so deficiently that they were effectively worthless (which is distinct from services that are "worth less" than the billed price).
9. Services billed without complying with average length of stay classification criteria for long-term hospital stays, including improper early discharges, interrupted stays, outlier payments, or level of service.
10. Services resulting from or "tainted by" violations of the Anti-Kickback Statute *(see chapter 7, "Federal and State Anti-Kickback Laws")* or Stark Law *(see chapter 6, "Physician Self-Referral Laws")*.
11. Services or products payable by primary insurers (rather than by the government program that was billed).
12. Services or products provided to inmates.
13. Services billed in violation of specific billing rules, such as the 72-hour rule for emergency room care and inpatient hospital stays *(see "Three-Day Payment Rule," page 4.14)* or Medicare Secondary Payer rules *(see VII. "Medicare Secondary Payer," page 4.43)*.
14. Unbundling services.
15. Billing for multiple or repeat procedures and global surgeries.
16. Claiming "inpatient only" services performed in an outpatient setting.
17. Billing for unnecessary, extended services to increase outlier payments or the TEFRA rate.
18. Billing for prescriptions or devices, including any related procedures, knowing that they were ordered and performed for "off-label" uses (that is, uses not approved by the FDA), but concealing or failing to disclose that fact.
19. Billing for, or selling, prescription drugs in violation of "best price" regulations *(see Title 22, California Code of Regulations, Section 51501)*.
20. Billing for free samples.
21. Billing for products that were discounted or subject to rebates without disclosing the discount or rebate.
22. Retaining overpayments to which the provider is not entitled.

Compliance Tip: FCA liability can be based on any false statements in requests for payment submitted to the government. The first line of FCA defense is strict compliance with the regulations and any contracts that govern the goods or services being reimbursed.

Risks for Allegations of False Claims in Cost Reports

Cost reports are a second area in which hospitals may expose themselves to allegations of false claims. Practices that may give rise to such allegations include:

1. Making false certifications of compliance with federal and state laws and regulations in Medicare and Medicaid cost reports.

2. Claiming false or inflated costs in a Medicare or Medicaid cost report, including:
    a. Bad debt amounts claimed when the provider routinely waived Medicare beneficiaries' copayments and deductibles;
    b. Employee retirement or pension contributions not actually made;
    c. Improper management fees to hospital owners.
3. Improperly shifting post-transplant costs and costs from other cost centers to an organ acquisition cost center or making unreasonable payments to organ procurement agencies.
4. Improperly using inpatient capital payments for unintended purposes.
5. Making improper claims for "new" hospital devices and technology otherwise inadequately reimbursed under DRGs.
6. Making unreasonable costs claims for hospital-operated nursing and allied health (NAH) education programs.
7. Inflating claims for reimbursement of medical equipment, supplies and drugs by failing to pass on discounts or rebates received.

(See chapter 5, "Proper Cost Reporting Practices," for more information.)

Other Risks for Allegations of False Claims

Outside of direct patient care, a third area in which hospitals are at risk for allegations of false claims is making false representations in applications for federally-funded grants and programs. These include, for example, research grants from the Department of Health and Human Services and construction grants from the Federal Emergency Management Agency. Finally, another risk area involves making false representations regarding disproportionate-share funding.

D. Procedures for FCA Actions

This section discusses the procedures by which a relator or the government files an FCA action, how the government may respond if a relator filed the lawsuit, and when the action is served on the defendant. The Compliance Tip at the end of this section presents key do's and don'ts for hospitals that find themselves under investigation for FCA violations.

Step 1: The FCA Complaint is Filed

An FCA action can be initiated by the government itself or by a relator (i.e., a whistleblower) who files the FCA action on behalf of the government.

To initiate an FCA action, a relator must file a complaint in a federal district court. The FCA requires that the relator file the initial complaint with the federal district court **"under seal."** This means that the names of the relator and the defendant are not available to the public. After filing the FCA complaint under seal, the relator must serve the government with a copy of the complaint and a written disclosure of substantially all material evidence and information the relator possesses regarding the alleged false claims.

The FCA complaint will remain under seal for a minimum of 60 days to enable the government to investigate the relator's allegations. If necessary, the government may request that the complaint remain under seal longer to enable it to continue its investigation. Often,

the complaint remains under seal for a year or even several years. During this time, the government may or may not notify the defendant of its investigation or the existence of the FCA complaint. However, the complaint will not be served on the defendant until the court orders the government or relator to do so.

Allegations of an FCA violation are required to be set forth in a complaint "with particularity," pursuant to Federal Rule of Civil Procedure 9(b). This is a heightened pleading standard, which is applied to fraud-related causes of action. This generally means that the complaint must describe the "who, what, where, when, and how" in sufficient detail so as to notify the defendant of the particular misconduct on which the FCA claim is based, to the extent such information is not solely within the defendant's knowledge and control. Upon a challenge by the defendant, a court may dismiss a complaint that does not describe the alleged FCA violation in sufficient detail.

Currently, there is a split of authority regarding the level of detail required, with the majority of federal circuit courts holding that FCA complaints need not identify specific false claims to satisfy the pleading standard. Instead, in the First, Third, Fifth, Eighth, and Ninth Circuits, relators may rely on allegations that create an "indicia of reliability" and a "strong inference" that fraudulent claims must have been submitted to plead a valid cause of action at the pleading stage. Now, the majority of circuits do not require FCA complaints to identify specific false claims.[15] In those districts, defendants will have the opportunity to disprove the inference at the summary judgment and trial stages, but will not be able to dismiss the complaints outright on those grounds. In the Ninth Circuit, where California sits, the lower courts require "particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted," [including] "the who, what, when, where, and how" of the scheme. [*Ebeid ex rel. U.S. v. Lungwitz*, 616 F.3d 993, 998-1000 (9th Cir. 2010) (internal quotation marks omitted) (citing *U.S. ex rel. Grubbs v. Ravikumar Kanneganti*, 565 F.3d 180, 190 (5th Cir.2009).] Although the United States Supreme Court may eventually weigh in on the characteristics of the allegations required to satisfy this heightened pleading standard in FCA cases, it has declined to do so on multiple occasions in recent years.

Limitations on Subject Matter of FCA Actions

Special requirements are placed on relators if the facts on which the FCA action is based have been "publicly disclosed" before the relator filed the complaint. In such cases, the FCA statute requires that the relator prove that he or she is the "original source" of the factual information on which the false claims allegations are based.

A public disclosure occurs when facts regarding the allegations or transactions on which the FCA claim is based appear in a federal criminal, civil, or administrative hearing in which the federal government or its agent is a party; in a congressional, administrative, Government Accounting Office, or other federal report, hearing, audit, or investigation; or from the news media.

An individual is an original source if:

1. Prior to the public disclosure, he or she voluntarily disclosed to the government the information regarding the allegations or transactions on which his FCA claim is based, or

15 See, e.g., *United States ex rel.* ***Thayer v. Planned Parenthood***, 765 F.3d 914 (8th Cir. 2014) (setting forth circuit split regarding level of detail required to satisfy Rule 9(b) in FCA cases and adopting rule that reliable indicia is required).

2. He or she has knowledge that is independent of, and materially adds to, the publicly-disclosed allegations and voluntarily provided the information to the government before filing his FCA action.

Only when a public disclosure has occurred must a relator prove that he or she is the "original source." If the relator is not able to do so, then the district court must dismiss the FCA action unless the government opposes dismissal of the action, in which case the relator will be permitted to maintain the action on behalf of the government even if he or she is not an "original source." If the FCA action is dismissed, however, the relator is not permitted to share in any recovery, even if the government elects to prosecute the case on its own.

A relator is not permitted to bring an FCA action based on allegations or transactions that are the subject of a civil suit or an administrative civil money penalty proceeding in which the government is a party.

Compliance Tip: Encourage open communication with employees who may be in positions to detect or report improper billing practices and have your attorney document the facts uncovered by any subsequent investigation or remediation.

Step 2: The Government Chooses Whether to Intervene

After the FCA complaint is filed and material disclosures are made, the government decides whether to intervene in the action. In a majority of cases, the government does not intervene and the case proceeds through the efforts of the relator and his and her counsel.

If the Government Intervenes

If the government decides to intervene, then it will take primary responsibility for prosecuting the case. However, the relator has the right to continue as a party to the FCA action, subject to the following limitations.

First, the government may dismiss an FCA action, despite the relator's objections, by submitting a motion to dismiss to the court. However, in such circumstances, the FCA requires that the relator receive notice of the motion to dismiss and an opportunity for a hearing on the relator's objections. In 2018, a memorandum from Michael D. Granston, the Director of the Fraud Section of DOJ's Commercial Litigation Branch (the Granston memo),[16] encouraged DOJs to exercise their authority to dismiss frivolous FCA actions and listed factors for evaluating dismissal. DOJ has been hesitant to exercise the Granston memo, but famously did by seeking dismissal in a series of cases brought by a company that was formed for the purpose of filing *qui tam* actions.[17]

Second, the government may settle the action with the defendant, despite the relator's objections, if the court determines that the proposed settlement is fair, adequate, and reasonable under all the circumstances. Again, the FCA requires that the relator have an opportunity for a hearing on his objections to the proposed settlement. Upon a showing of

16 Memorandum from Michael D. Granston, Director of Commercial Litigation Branch, Fraud Section of the Department of Justice, "Factors for Evaluating Dismissal Pursuant to 31 U.S.C. 3730(c)(2)(A)," (Jan. 10, 2018).

17 See, e.g., United States v. UCB, Inc., 970 F.3d 835, 838 (7th Cir. 2020), cert. denied sub nom. Cimznhca, LLC v. United States, 141 S. Ct. 2878 (2021); *U.S. ex rel. Health Choice Alliance, LLC v. Eli Lilly & Co.*, No. 5:17-cv-123 (E.D. Tex.); *Health Choice Group LLC v. Bayer Corporation et al*, 5:17-cv-126 (E.D. Tex.); *U.S. ex rel. SMSPF, LLC v. EMD Serono, Inc.*, No. 16-cv-5594 (E.D. Pa.).

good cause, the hearing may be held "in-camera," which means in a private court hearing that is closed to the public.

Finally, the government may obtain a court order limiting the relator's participation in the FCA action upon a showing that the relator's unrestricted participation would interfere with, or unduly delay, the government's prosecution of the case, or would be repetitious, irrelevant, or for purposes of harassment. The defendant may also obtain a court order limiting the relator's participation upon a showing that the relator's unrestricted participation would cause the defendant undue burden or unnecessary expense. In such circumstances, the court has discretion to place limitations on the relator's participation including, but not limited to, the number of witnesses called, the length of the witnesses' testimony, and the length of the cross-examinations.

If the government decides to pursue its claims through an alternate remedy other than an FCA action, such as an administrative proceeding for civil monetary penalties, the relator has the same rights in the other proceeding as it would have had if the government elected to proceed in the FCA action.

If the Government Declines to Intervene

If the government declines to intervene in the FCA action, then the relator can continue to prosecute the case on the government's behalf. The relator bears the costs of pursuing the case on his own, though the FCA includes a fee-shifting provision such that the defendant must pay for the attorneys' fees for a successful relator. Unless the relator himself is a licensed attorney, the relator must obtain legal representation after the government declines to intervene (if he or she has not done so already), because an individual who is not an attorney is not authorized to represent the government's interests in court. Relators may be able to obtain legal assistance on a contingency basis or with outside funding that enables him or her to pursue the litigation without out-of-pocket expenses.

When a relator proceeds with an FCA action on his own, the government can request that it continue to be served with copies of all pleadings filed in the action and to receive, at the government's expense, copies of all deposition transcripts. The government can also request a court order staying, or delaying, discovery in the FCA action to prevent interference with any government investigation or prosecution of any civil or criminal matter arising out of the same facts. An order for a discovery stay will initially be for a period of not more than 60 days, but can be extended upon a showing of good cause. The government is entitled to present to the court the grounds for its request for the initial order staying discovery, and its request for any extension of the stay, in-camera. Additionally, the government can request to intervene in the case at a later time upon a showing of good cause.

When the government declines to intervene in the FCA action, and the relator continues to prosecute the FCA action, the defendant may be awarded, and the relator will be liable for, the defendant's reasonable attorneys' fees and expenses. Such a scenario occurs if the defendant prevails in the action and the court finds the relator's claims to be frivolous, vexatious, or brought for purposes of harassment.

Step 3: The FCA Complaint is Served on the Defendant

Once the government decides whether it will, or will not, intervene in the FCA action, the court will issue an order unsealing the complaint. After this order is entered, the complaint must be served on the defendant within a certain number of days (i.e., 60 or 90 days,

depending on the court's rules and the court's order). If the complaint is not served on the defendant within the time period ordered by the court, the FCA action can be dismissed by the court for lack of prosecution.

Compliance Tip: What to Do When You Are Being Investigated for False Claims. If the government notifies your hospital that it is under investigation in an FCA action (or otherwise), contact legal counsel immediately to ensure that you take appropriate actions. If you are under investigation:

- DO preserve relevant written and electronic documents, so that you do not inadvertently destroy evidence. This is essential both to enable you to defend against the allegations in the FCA action and to avoid any allegations of obstruction of justice, which could potentially lead to criminal charges.
- DO have your attorney communicate with the government to reach a settlement or otherwise resolve the issues raised by an FCA lawsuit before the complaint is unsealed and thus before litigation gets fully underway.
- DO NOT fire or take other disciplinary action against an employee who is, or who you suspect may be, a whistleblower, without speaking with an experienced attorney. Federal and state law prohibits retaliation against whistleblowers.
- DO have your attorney review any agreements signed by the qui tam relator if he or she is a current or former employee. Qui tam relators may still be bound to confidentiality agreements, which he or she may have violated based on the information disclosed in the complaint, and you may want to consider the potential of a countersuit.[18]

E. Remedies for Violations of the FCA

The damages, penalties and fees that a defendant may be required to pay for violations of the FCA can be severe and, because relators are generally entitled to a share of them, constitute an incentive for bringing an action. In addition to civil liability, the federal government may file criminal charges for false claims or fraud under a number of statutes. This section discusses both civil liability and possible criminal penalties.

Remedies for Civil Liability

A defendant found liable under the FCA must generally pay three times the amount of damages the federal government sustained because of the defendant's conduct. In addition, the defendant is currently liable for a mandatory civil penalty of as much as $21,563 per false claim. Moreover, the defendant is liable to the government for the costs of bringing the FCA action or other civil remedy and, as discussed above, may be liable to the relator for his reasonable expenses, attorneys' fees, and costs.

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18 See, e.g., *United States ex rel. Wildhirt v. AARS Forever, Inc.*, No. 1:09-cv-01215, 2013 WL 5304092 (N.D. Ill. Sept. 19, 2013) (rejecting relator's argument that confidentiality agreement was unenforceable on public policy grounds and denying motion to dismiss counterclaims for violation of agreements through disclosures to government and public). See also *Siebert v. Gene Sec. Network, Inc.*, No. 11—1987, 2013 WL 5645309, at *8 (N.D. Cal. Oct.16, 2013) (holding that the confidentiality agreement was unenforceable as a matter of public policy, but also holding the counterclaim should not be dismissed in its entirety because it was possible that the plaintiff took confidential documents unrelated to his FCA claim).

A defendant may decrease his liability under the FCA from treble damages to double damages if the court finds that:

1. The defendant furnished officials of the United States responsible for investigating false claims violations with all information known to the defendant about the violation within 30 days after the date on which the defendant first obtained the information;
2. The defendant fully cooperated with any government investigation; and
3. At the time the defendant furnished the United States with the information about the violation, no criminal prosecution, civil action, or administrative action had commenced with respect to the violation and the defendant did not have actual knowledge of the existence of an investigation into such violation.

DOJ released guidance concerning individual accountability for corporate wrongdoing in 2015. Called the "Yates Memo," it directs DOJ employees, including all United States Attorneys, to target individuals for both civil and criminal prosecutions.[19] The Yates Memo formalizes DOJ policy to focus on individual employees and senior management as part of broader investigations of corporate wrongdoing, and directs that the U.S. Attorneys' Manual (USAM) be revised accordingly. On Nov. 16, 2015, the revised USAM was released. Significantly, the revised USAM and the Yates Memo itself make clear that to be eligible for *any* cooperation credit at all, corporations must identify the individuals involved in the corporate wrongdoing and disclose to DOJ all relevant facts concerning their misconduct. Corporate providers that fail to carry out thorough investigations in the face of fraud and abuse allegations and disclose all relevant facts about potentially culpable individuals to the government will not obtain cooperation credit under the U.S. Attorneys' Manual Guidelines, the U.S. Sentencing Guidelines, or the FCA's "reduced damages" provision. [31 U.S.C. Section 3729(a)(2)]

In a speech in 2018, Deputy Attorney General Rod Rosenstein announced some softening in the Yates approach, particularly in the civil context. Rosenstein indicated that a corporation need not admit civil liability on the part of all individuals for the corporation to receive cooperation credit. DOJ will instead focus on those who played significant roles. Partial credit will be available for less fulsome disclosures in civil cases, but a corporation cannot conceal involvement of senior management. Importantly, Rosenstein indicated that DOJ had restored the discretion to DOJ attorneys to release individuals civilly. Subsequently, in 2019, DOJ amended the U.S. Attorney Manual (at 4-4.112) to provide guidance on when cooperation credit might be available and what the credit might look like. The guidance continues to place some weight on whether the company identifies individuals "substantially involved" in the corporate wrongdoing.

The Biden administration appears to have changed course. In a speech in October of 2021, Deputy Attorney General Lisa O. Monaco announded a renewed focus on individual accountability. She announced that she had directed the DOJ to restore the guidance from the Yates memo.[20]

19 Department of Justice: Sally Quillian Yates, Memorandum Regarding Individual Accountability for Corporate Wrongdoing. Sept. 9, 2015. Available at http://bit.ly/justice-dag.

20 Department of Justice: Deputy Attorney General Lisa O. Monaco Gives Keynote Address at ABA's 36th National Institute on White Collar Crime. Oct. 28, 2021. Available at https://www.justice.gov/opa/speech/deputy-attorney-general-lisa-o-monaco-gives-keynote-address-abas-36th-national-institute.

Relator's Share of the Recovery

Relators are entitled to a share of the recovery that the government obtains as a result of the FCA action. The percentage of the relator's recovery depends on the circumstances of the case. When the government has intervened in the FCA action, the relator is entitled to 10-25 percent of the recovery that the government obtains. This sum includes any alternative remedies, such as civil penalties in an administrative action, which the government pursues based on the conduct that formed the basis of the FCA action. The court determines the percentage of the recovery to which the relator is entitled based on the relator's contributions to the case. A relator is entitled to no more than 10 percent of the government's recovery if the court finds that the action is based primarily on disclosures of specific information, other than the information provided by the relator, relating to allegations or transactions in a criminal, civil or administrative hearing; in a congressional, administrative or Government Accounting Office report, hearing, audit or investigation; or from the news media.

When the government does not intervene in the FCA action, the relator is entitled to 25-30 percent of the recovery that is obtained on behalf of the government. The court determines the percentage of the recovery to which the relator is entitled based on the relator's contributions to the case.

Moreover, if either the government or the relator is successful in obtaining a recovery based on any of the relator's FCA allegations, the defendant is also obligated to pay the relator's reasonable expenses, attorneys' fees, and costs.

The court may reduce the relator's recovery if the relator planned and initiated the FCA violation. Additionally, the relator is prohibited from receiving any share of the recovery if convicted of a crime arising from participation in the FCA violation.

Civil Monetary Penalties, Exclusion, and Enrollment Revocation

Even if no FCA action is filed, the Office of Inspector General (OIG) for the U.S. Department of Health Human Services may still assess significant civil monetary penalties (CMPs) against providers pursuant to the Civil Monetary Penalties Law. Such providers include those who submit claims to a federal health care program that the person knows or should know is for an item or service that was not provided as claimed or is otherwise false or fraudulent.

CMPs may be assessed for, among others, the following types of misconduct:

1. Billing for items or services that were not provided as claimed, including the use of a code that the person knows or should know will result in a greater payment to the person than the code the person knows or should know is applicable to the item or service actually provided;
2. Billing for items or services provided by a physician or other provider who was not licensed, not a medical specialist as certified to the patient, or had obtained his or her license through misrepresentation of material fact;
3. Retaining an interest in an entity participating in government health care programs after being excluded from participation;
4. Offering or providing remuneration to individuals eligible for benefits (i.e., patients) in order to influence provider choice;
5. Failing to report and return an overpayment of which the individual is aware;
6. Employing or contracting with an excluded individual;

7. Failing to grant OIG timely access to records, upon reasonable request; and
8. Knowingly making a false record or statement material to a claim for payment or services to a federal health plan.

[42 U.S.C. Section 1320a-7a]

Recently, the OIG has imposed CMPs for a wide range of alleged misconduct by health care providers, including the use of excluded or unqualified providers, upcoded or otherwise fraudulent Medicare claims, and kickbacks.

In the case of false or fraudulent claims, the OIG may seek a penalty of up to $10,000 for each item or service improperly claimed, an assessment of up to three times the amount improperly claimed, and a penalty of up to $50,000 for each false statement or record material to a false or fraudulent claim. [42 U.S.C. Section 1320a-7a(a)]

On Dec. 7, 2016, the OIG issued a final rule clarifying a provider's or supplier's liability under the CMP statute for violating the 60-day refund rule established by the ACA, as well as for ordering or prescribing items or services while excluded from participation in federal health care programs [81 Fed. Reg. 88334 (Dec. 7, 2016)]. For such violations, the OIG will impose the default penalty amount in the CMP statute, which is up to $10,000 plus an inflation adjustment, for each item or service [45 C.F.R. Section 102.3 (setting forth inflation-adjusted civil monetary penalties for these violations)]. Additionally, the final rule clarifies the aggravating and mitigating factors the OIG considers in assessing CMPs and exclusions. These factors include:

1. The nature and circumstances of the violation;
2. The person's degree of culpability, including whether the person had actual knowledge and whether the person took timely and appropriate corrective action in response to the violation, which must include self-disclosure to the OIG or CMS, as appropriate;
3. The person's or entity's history of prior offenses;
4. Other wrongful conduct; and
5. Other matters, as justice may require.

The OIG emphasized that it will weigh these factors on a "case-by-case" basis, but the presence of "any single aggravating factor" may justify a penalty at or near the maximum regardless of the presence of one or more mitigating factors. OIG changed the threshold for when the loss amount may be considered aggravating from "substantial" to $50,000 or more. In determining the CMP amount, the OIG will consider a person's ability to pay the penalty or assessment. Absent extraordinary mitigating circumstances, the amount of the penalty and assessment should not be less than double the approximate amount of damages and costs sustained by the United States, or any state, as a result of the violation. [42 C.F.R. Part 1003]

The final rule also codifies revisions to the definition of "remuneration" and exceptions to that definition. Under the final rule, the following discounts and waivers are among the exceptions to the prohibition on beneficiary inducements and are not considered "remuneration" subject to the Civil Monetary Penalties Law:

1. Copayment reductions for certain hospital outpatient services;

2. Arrangements that promote access to care and pose a low risk of harm;
3. Coupons, rebates, and other retailer reward programs that are made available to the general public regardless of health insurance status and are not tied to the provision of other items or services reimbursable by a state or federal health care program;
4. Offer or transfer of items (other than cash or cash equivalents) or services for free or less than fair market value to financially needy individuals, provided certain requirements are met; and
5. Copayment waiver by a Part D Plan sponsor for the first fill of a generic drug if the sponsor discloses such waiver in its benefit plan package submitted to CMS.

Though many of these exceptions seem broad on their face (e.g., arrangements that promote access to care and free items to financially needy individuals), the regulatory requirements to fall into each exception make them much narrower. The preambulatory guidance further narrows them. In addition, the OIG has the discretionary authority to exclude any individual or company from participation in federal health care programs if it determines that:

1. The company or individual submitted false claims to a federal health care program or violated the Anti-Kickback Statute;
2. The individual was an owner or controlled a company that was convicted of health care fraud or excluded and knew or should have known of the conduct underlying the conviction or exclusion, or was an officer or managing employee of such a company; or
3. The company was owned, controlled, or managed by an individual who was excluded or convicted or assessed a CMP for health care fraud.

[42 U.S.C. Section 1320a-7a(b)]

The OIG has mandatory exclusionary authority for certain health care-related crimes, including felony convictions for patient abuse. For the conduct outlined above, the authority is permissive and gives the OIG discretion to evaluate the facts and circumstances of each case. The OIG has proposed expanding its permissive exclusionary authority to reach a broader range of false statements, conduct that obstructed an audit of a federally-funded health care provider, and failures to provide payment information required by Medicare. While, historically, the OIG has not barred executives of excluded or convicted companies for FCA-related misconduct, the agency has recently expressed its intent to examine whether the owner, officer, or managing employee of a convicted or excluded company should be prohibited. Unless mitigating factors exist, the OIG has also expressed interest in such exclusion if the evidence supports a finding that the individual should have known of the underlying conduct.

Lastly, CMS has issued regulations granting it the authority to revoke a hospital's enrollment in Medicare regardless of the action, if any, OIG takes with respect to CMPs and exclusion. For example, CMS may revoke a hospital's Medicare enrollment if CMS determines that a hospital has engaged in a "pattern or practice of submitting claims that fail to meet Medicare requirements. [42 C.F.R. Section 424.535(a)(8)(ii)]

III. CRIMINAL LIABILITY FOR FALSE CLAIMS UNDER OTHER FEDERAL LAWS

In addition to civil liability, making false and fraudulent claims can be a federal crime. It is impossible to compile a complete list of federal criminal statutes that could apply to individuals or entities within the health industry that submit false or fraudulent claims. However, some examples of laws with criminal penalties that are often asserted in such cases by federal authorities are described below.

A. Crimes Against Federally-Funded Health Care Programs

Several federal statutes establish criminal penalties for the submission of false claims and other fraudulent activities specifically involving federally-funded health care programs, such as Medicare, Medicaid, CHAMPUS and TRICARE. Specifically, a person commits a federal crime if he or she:

1. Knowingly and willfully makes or causes to be made any false statement or representation of a material fact in any application for any benefit or payment under a federal health care program [42 U.S.C. Section 1320a-7b(a)(1)];
2. At any time knowingly and willfully makes or causes to be made any false statement or representation of a material fact for use in determining rights to such benefit or payment [42 U.S.C. Section 1320a-7b(a)(2)];
3. Having knowledge of the occurrence of an event affecting:
    a. His initial or continued right to any benefit or payment, or
    b. The initial or continued right to any such benefit or payment of any other individual on whose behalf he or she has applied for, or is receiving, such benefit or payment, conceals or fails to disclose such event with an intent to fraudulently secure such benefit or payment either in a greater amount or quantity than is due or when no such benefit or payment is authorized [42 U.S.C. Section 1320a-7b(a)(3)];
4. Having made application to receive any such benefit or payment for the use and benefit of another, and having received it knowingly, willfully converts such benefit or payment or any part thereof to a use other than for the use and benefit of such other person [42 U.S.C. Section 1320a-7b(a)(4)]; and
5. Presents, or causes to be presented, a claim for a physician's service for which payment may be made under a federal health care program and knows that the individual who furnished the service was not licensed as a physician. [42 U.S.C. Section 1320a-7b(a)(5)]

Penalties

A person who commits any of the prohibited conduct described above, by making a statement, representation, concealment, failure, or conversion, in connection with that person's furnishing of items or services for which payment is, or may be, made under a federal health care program, is guilty of a felony. As such, he or she may be subject to a $250,000 fine per offense and imprisonment for not more than five years or both.

A person who commits any of the prohibited conduct described above, by making a statement, representation, concealment, failure, or conversion, or providing counsel or

assistance in connection with another person's furnishing of items or services for which payment is or may be made under a federal health care program, is guilty of a misdemeanor. In such instance, he or she may be subject to a $10,000 fine per offense and imprisonment for not more than one year or both.

B. Crimes Against Both Private and Government Health Care Programs

The offenses described below are not limited to government-funded programs; they apply to private insurance plans, as well. It is a crime to do the following:

1. Execute a scheme to defraud any health care benefit program or to obtain any money or property of a health care benefit program by false or fraudulent pretenses, representations or promises. [18 U.S.C. Section 1347]
2. Knowingly and willfully, in any matter involving a health care benefit program, falsify, conceal, or cover up by any trick, scheme, or device a material fact in connection with the delivery of or payment for health care benefits, items, or services. [18 U.S.C. Section 1035(a)(1)]
3. Knowingly and willfully, in any matter involving a health care benefit program, make any materially false, fictitious, or fraudulent statements or representations, or make or use any materially false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry in connection with the delivery of or payment for health care benefits, items, or services. [18 U.S.C. Section 1035(a)(2)]

It is also a crime:

1. To receive or conceal property, including money, with the value of $5,000 or more, which a party knows has been stolen, unlawfully converted, or taken [18 U.S.C. Section 2315]; and
2. For "two or more persons [to] conspire either to commit any offense against the United States, or to defraud the United States, or any agency thereof in any manner or for any purpose." [18 U.S.C. Section 371]

Such conduct may be subject to a felony or misdemeanor conviction.

Also, more recently, the federal government has pursued criminal actions under the Travel Act for conduct that violates state law but would not otherwise implicate federal law (for example, because the claims at issue are for worker's compensation).[21]

C. Statute of Limitations

A **"statute of limitations"** is the period of time within which a lawsuit must be filed — that is, a deadline. The government generally must prosecute an individual for violation of a federal statute which is not subject to the death penalty — a category that includes the federal criminal fraud statutes — within five years of the date the violation occurred, unless a more specific statute of limitations period applies [18 U.S.C. Section 3282(a)].

21 See, e.g., *U.S. v. Payne*, No. 8:17-cr-00053-JLS (C.D. Cal. April 25, 2018); *U.S. v. Tantuwaya*, No. 8:18-cr-00040-JLS (C.D. Cal. Feb. 23, 2018); *U.S. v. Gross*, No. 8:18-cr-00014-JLS (C.D. Cal. Jan. 23, 2018); *U.S. v. Drobot*, No. 8:14-cr-00034-JLS (C.D. Cal. Jan. 16, 2018); *U.S. v. Beauchamp, et al.*, No. 3:16-cr-00516-JJZ-3 (N.D. Tex. Aug. 18, 2018).

IV. CALIFORNIA'S FALSE CLAIMS ACT

California has its own False Claims Act (the California FCA), which creates civil liability for the submission of false claims to the state or political subdivisions (such as counties and cities) [Government Code Section 12650 *et seq.*]. The California FCA is modeled on the federal False Claims Act described in II. "Federal False Claims Act," page , and, thus, many of the same legal standards, such as the requirement that the defendant "knowingly" submit a false claim, apply. California courts will take guidance from federal FCA case law.

The California legislature recently amended the California FCA to make the state law conform to some of the changes brought by FERA. Such changes include imposing liability for so-called reverse false claims in retaining overpayments and expanding liability to "claims" that include submissions to government contractors and agents. The changes also made it easier for employees, who violate the Act themselves, to file suit against an employer based on the employee's prohibited conduct and, as a result, obtain a share of the recovery.

However, the California FCA differs from the federal law in a number of ways. For example, a California FCA action requires that the minimum amount in controversy for one or more claims be $500 or more, and also follows a different procedure for initiating a case. [Government Code Section 12651(d)] The procedure for initiating a California FCA action is described below.

While many governmental agencies participate in the enforcement of the California FCA and other laws described below, violations of the California FCA involving the Medi-Cal program are typically investigated and prosecuted by the Attorney General's Bureau of Medi-Cal Fraud & Elder Abuse.

A. Elements of California FCA Claims

The Legal Standard for a California FCA Claim

The California FCA imposes liability on any person who:

1. Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
2. Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
3. Conspires to commit a violation of the statute;
4. Has possession, custody, or control of public property or money used or to be used by the state or by any political subdivision and knowingly delivers, or causes to be delivered, less than all of that property;
5. Is authorized to make or deliver a document certifying receipt of property used, or to be used, by the state or by any political subdivision and knowingly makes or delivers a receipt that falsely represents the property used or to be used;
6. Knowingly buys, or receives as a pledge of an obligation or debt, public property from any person who lawfully may not sell or pledge the property;
7. Knowingly makes, uses, or causes to be made or used a false record or statement material to an obligation to pay or transmit money or property to the state or to any political subdivision;

8. Knowingly conceals or knowingly and improperly avoids, or decreases an obligation to pay or transmit money or property to the state or to any political subdivision; or

9. Is a beneficiary of an inadvertent submission of a false claim, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the state or the political subdivision within a reasonable time after discovery of the false claim.

[Government Code Section 12651(a)]

The Definition of a Claim Under the California FCA

A **"claim"** is defined as:

> Any request or demand, whether under a contract or otherwise, for money, property, or services, and whether or not the state or a political subdivision has title to the money, property, or services that meets either of the following conditions:
>
> (A) Is presented to an officer, employee, or agent of the state or of a political subdivision.
>
> (B) Is made to a contractor, grantee, or other recipient, if the money, property, or service is to be spent or used on a state or any political subdivision's behalf or to advance a state or political subdivision's program or interest, and if the state or political subdivision meets either of the following conditions:
>
> (i) Provides or has provided any portion of the money, property, or service requested or demanded.
>
> (ii) Reimburses the contractor, grantee, or other recipient for any portion of the money, property, or service that is requested or demanded ...

[Government Code Section 12650(b)(1)]

Like the federal FCA, the California FCA does not apply to workers' compensation claims or tax returns.

The Definition of an Obligation Under the California FCA

For purposes of the California FCA's "reverse claim" liability, an **"obligation"** is defined as:

> An established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment.

[Government Code Section 12650(b)(5)]

The Statute of Limitations on California FCA Actions

A California FCA action may not be brought more than six years after the date on which the California FCA violation was committed, or three years after the date when facts regarding the California FCA violation were known, or reasonably should have been known, by the Attorney General or other prosecuting authority with jurisdiction to act under the California FCA, but in no event more than 10 years after the date on which the California FCA violation was committed [Government Code Section 12654(a)].

B. Procedures for California FCA Actions

A California FCA action may be initiated by the California Attorney General, or by the prosecuting authority of a political subdivision, such as a city district attorney's office. A

relator — referred to as the "*qui tam* plaintiff" under California law — may also initiate an action by filing a California FCA action on behalf of the state or a political subdivision (if the political subdivision's funds are exclusively involved).

To initiate a California FCA action, a *qui tam* plaintiff must file the complaint under seal. A California FCA claim may be filed in a state superior court. The California FCA complaint will remain under seal for a minimum of 60 days to enable the California Attorney General and local prosecuting authority to investigate the *qui tam* plaintiff's allegations. The California Attorney General and local prosecuting authority may request extensions of time, during which the complaint remains under seal upon a showing of good cause and is not served on the defendant. Like in federal FCA cases, extensions are typically granted.

On the same day that the *qui tam* plaintiff files a California FCA complaint, he or she must serve on the California Attorney General a copy of the complaint and a written disclosure of substantially all material evidence and information he or she possesses. The California Attorney General is required to forward the complaint and the written disclosure to an appropriate local prosecuting authority, if applicable.

Limitations on Subject Matter of California FCA Actions

A person may not bring a California FCA action that is based upon allegations or transactions that are already the subject of another *qui tam* plaintiff's California FCA action or of a civil suit or an administrative civil money penalty proceeding in which the state or political subdivision is already a party [Government Code Section 12652(c)(10) and (d)(2)].

Additionally, similar to the public disclosure bar for federal claims, if the facts on which the California FCA action is based have been "publicly disclosed" before the *qui tam* plaintiff discloses those facts to the California Attorney General or local prosecuting authority, the California FCA statute requires that the *qui tam* plaintiff prove that he or she is the "original source" of the factual information on which the false claims allegations are based [Government Code Section 12652(d)(2)-(3)]. A public disclosure occurs when facts regarding the allegations or transactions on which the California FCA claim is based were disclosed in a criminal, civil, or administrative hearing in which the state or political subdivision was a party; in a report, hearing, audit, or investigation of the California Legislature, the state, or governing board of a political subdivision; or in the news media. An individual is an original source when he or she has knowledge of information that is independent of, and materially adds to, the publicly disclosed allegations or transactions and has voluntarily provided such information to the state or political subdivision before filing his California FCA action.

Only when a public disclosure has occurred must a *qui tam* plaintiff prove that he or she is the "original source." If the *qui tam* plaintiff is not able to do so, then the court must dismiss the *qui tam* plaintiff's California FCA action and bar his share in any recovery, even if the California Attorney General or local prosecuting authority elects to prosecute the case on its own. However, if the California Attorney General or local prosecuting authority opposes the dismissal, then the *qui tam* plaintiff will be permitted to maintain the California FCA action even if he or she is not an "original source."

Generally, a government employee cannot serve as a *qui tam* plaintiff if he or she gained the information on which the California FCA action is based through his position as a public employee, unless he or she exhausted internal reporting procedures and the state or political

subdivision failed to act within a reasonable time. However, this limitation on a government employee does not apply if the California FCA action alleges false claims involving the Medi-Cal program. [Government Code Section 12652(d)(4)]

The Government Chooses Whether to Intervene

After the FCA complaint is filed and material disclosures are made, the government decides whether to intervene in the action.

If the Government Intervenes

If the California Attorney General, local prosecuting authority, or both, decide to intervene in a California FCA action initiated by a *qui tam* plaintiff, then they will take primary responsibility for prosecuting the case. A *qui tam* plaintiff may continue to participate in the California FCA action. However, upon a showing by the Attorney General or local prosecuting authority that the *qui tam* plaintiff's unrestricted participation in the litigation would interfere with or delay the prosecution of the case, or would be repetitious, irrelevant or for purposes of harassment, the court may, in its discretion, limit the *qui tam* plaintiff's participation. The court may limit the number of witnesses the *qui tam* plaintiff may call, limit the length of the witnesses' testimony, limit cross-examination of the witnesses, or order other restrictions. [Government Code Section 12652(i)]

For purposes of the statute of limitations described above, if the Attorney General or other prosecuting authority intervenes and files an amended California FCA complaint, the date of the amended complaint relates back to the filing date of the *qui tam* plaintiff's original complaint to the extent that the claim of the state or political subdivision arises out of the same conduct, transactions, or occurrences alleged in the original complaint. [Government Code Section 12654.5] In other words, the filing of a California FCA complaint by a *qui tam* plaintiff tolls or suspends the statute of limitations for purposes of the Attorney General's or the local prosecuting authority's intervention unless new and unrelated claims are asserted by the government agency.

If the Government Declines to Intervene

If neither the California Attorney General and local prosecuting authority decides to intervene, then the *qui tam* plaintiff has the right to conduct the action on his own. However, the *qui tam* plaintiff may not dismiss the action without the written consent of the California Attorney General, local prosecuting authority and the court.

C. Remedies for Violations of the California FCA

A defendant found liable under the California FCA generally must pay three times the amount of damages the state or political subdivision sustained because of the defendant's conduct. In addition, the defendant is liable to the state or political subdivision for the costs of bringing the California FCA action, and for a civil penalty of not less than $5,500 and not more than $11,000 for each violation under the current law. [Government Code Section 12651(a)] If the state, political subdivision or *qui tam* plaintiff prevails in or settles a California FCA action, then each of them is entitled to an award of reasonable expenses necessarily incurred, plus reasonable costs and attorneys' fees [Government Code Section 12652(g)(8)].

A defendant may decrease his liability under the California FCA from treble damages to double damages and avoid any civil penalty if the court finds that:

1. The defendant furnished officials of the state or the political subdivision responsible for investigating false claims violations with all information known to him about the violation within 30 days after the date on which the defendant first obtained the information.
2. The defendant fully cooperated with any investigation by the state or the political subdivision of the violation.
3. At the time the defendant furnished the state or the political subdivision with information about the violation, no criminal prosecution, civil action, or administrative action had commenced with respect to the violation, and the defendant did not have actual knowledge of the existence of an investigation into the violation.

However, if the defendant prevails in the California FCA action and the court finds that the claim was clearly frivolous, clearly vexatious or brought solely for purposes of harassment, the court may award the defendant his reasonable attorney's fees and expenses against the party (including the state or political subdivision) who initiated the action.

Parties' Shares of the Recovery

If the California Attorney General initiates or intervenes in a California FCA action, the Attorney General is entitled to 33 percent of any recovery. This money is required by law to be used to support the Attorney General's ongoing efforts to investigate and prosecute false claims. [Government Code Section 12652(g)(1)(A)]

If a local prosecuting authority initiates and conducts a California FCA action, the local prosecuting authority is entitled to 33 percent of any recovery. This money is required by law to be used to support the local prosecuting authority's ongoing efforts to investigate and prosecute false claims. [Government Code Section 12652(g)(1)(B)]

If a local prosecuting authority intervenes in a California FCA action initiated by the California Attorney General, the local prosecuting authority is entitled to share in some portion of the Attorney General's 33 percent of the recovery. The local prosecuting authority's share is determined by the role it played in prosecuting the action. [Government Code Section 12652(g)(1)(C)]

If the California Attorney General or local prosecuting authority intervenes in a California FCA action initiated by a *qui tam* plaintiff, the *qui tam* plaintiff receives 15-33 percent of any recovery obtained. [Government Code Section 12652(g)(2)] If neither the California Attorney General nor local prosecuting authority intervenes, the *qui tam* plaintiff receives 25-50 percent of any recovery. [Government Code Section 12652(g)(3)].

However, if a public employee acts as a *qui tam* plaintiff, the court is not required to award the public employee any of the recovery, although the court has the discretion to do so based on the same award provisions governing any *qui tam* plaintiff [Government Code Section 12652(g)(4)]. Similarly, if a *qui tam* plaintiff planned and initiated the fraudulent activity giving rise to the California FCA claim, the court may reduce the award to the *qui tam* plaintiff, taking into account the significance of the information she provided, her role in advancing the case to litigation, the scope of her involvement in the fraudulent activity, her attempts to avoid or resist the activity, and all other circumstances surrounding the activity. Unfortunately, there is no prohibition against alleged wrongdoers becoming *qui tam* plaintiffs. [Government Code Section 12652(g)(5)]

Additional Liability for False Statements Concerning Medi-Cal Claims

California law prohibits any person or entity from presenting a false Medi-Cal claim with the intent to defraud or knowingly submitting false information for the purpose of obtaining greater Medi-Cal compensation than such person is legally entitled to obtain [Welfare and Institutions Code Section 14107].

The following acts may lead to criminal liability under the Welfare and Institutions Code:

1. A person knowingly submits false information for the purpose of obtaining greater compensation than that to which he or she or she is legally entitled for furnishing services or merchandise to the Medi-Cal program [Welfare and Institutions Code Section 14107(b)(2)].
2. A person knowingly and willfully executes, or attempts to execute, a scheme or artifice to do either of the following:
    a. Defraud the Medi-Cal program or any other health care program administered by the Department of Health Care Services (DHCS) or its agents or contractors.
    b. Obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, the Medi-Cal program or any other health care program administered by DHCS or its agents or contractors, in connection with the delivery of or payment for health care benefits, services, goods, supplies or merchandise. [Welfare and Institutions Code Section 14107(b)(4)]

Violations of this law may be punished by imprisonment for 3-5 years, a fine of up to three times the amount of the fraud or improper reimbursement, or both.

D. Protections for Whistleblowers

As with the federal laws prohibiting retaliation against whistleblowers, California law contains special provisions protecting whistleblowers, which are described below.

Employers May Not Prohibit Whistleblowing

California law prohibits an employer from establishing policies to prevent an employee from disclosing information to a government agency or law enforcement agency regarding potential false claims [Government Code Section 12653(a); see also Labor Code Section 1102.5]. An employer is also prohibited from establishing policies to prevent an employee from acting in furtherance of a California FCA action, including investigating, initiating, testifying for, or assisting in an action that is or will be filed.

Employers May Not Retaliate Against Whistleblowers

California law prohibits an employer from retaliating against an employee for performing lawful acts in furtherance of a California FCA action brought by the employee or another person. Protected **"whistleblowing"** activities include disclosing information to a government agency or law enforcement agency, and investigating, initiating, testifying for, or assisting in the action. Specifically, an employer cannot retaliate against an employee by discharging, demoting, suspending, threatening, harassing, denying a promotion to or in any other manner discriminating against an employee in the terms and conditions of employment. [Government Code Section 12653(a); see also Labor Code Section 1102.5] California

recently strengthened these protections to prevent retaliation by a person working on the employer's behalf against any employee who discloses information to another employee with the authority to investigate and correct the violation. [Labor Code Section 1102.5] Thus, internal reporting is also a covered whistleblowing activity. An employee may bring a lawsuit against an employer that violates these prohibitions.

An employer found to have retaliated against an employee for engaging in protected whistleblowing activities is liable for "all relief necessary to make the employee whole, including reinstatement with the same seniority status that the employee would have had but for the discrimination, two times the amount of back pay, interest on the back pay, compensation for any special damage sustained as a result of the discrimination, and, where appropriate, punitive damages." [Government Code Section 12653(b)] In addition, the employer is required to pay the employee's litigation costs and reasonable attorneys' fees.

Even more broadly, California law prohibits a health care facility from discriminating or retaliating against any patient, employee, member of the medical staff, or any other health care worker because that person has:

1. Made a complaint or report to the facility, the facility's medical staff, an accreditation organization, or a government entity; or
2. Initiated, participated, or cooperated in an investigation or administrative proceeding relating to the quality of care, services, or conditions at the facility that is carried out by an accreditation organization or a government agency.

[Health and Safety Code Section 1278.5]

Discriminatory treatment includes, but is not limited to, discharge, demotion, suspension, or any unfavorable changes in, or breach of, the terms or conditions of a contract, employment, or privileges, or the threat of any of these actions.

A health care facility that willfully violates Health and Safety Code Section 1278.5 is guilty of a misdemeanor punishable by a fine of up to $20,000. A violation of this law may also be punished by a civil monetary penalty of up to $25,000. In addition, any employee, member of the medical staff, or any other health care worker who has been discriminated against is entitled to reinstatement, reimbursement for lost wages, income or other work benefits caused by the acts of the facility, reimbursement of the legal costs associated with pursuing the case, or to any other remedy warranted by the court.

The California Labor Code also provides protection for any employee against whom an employer is retaliating for disclosing information to a government or law enforcement agency where the employee has reasonable cause to believe that the information discloses a violation of state or federal statute or regulation. The law provides that, "[i]n addition to other penalties, an employer that is a corporation or limited liability company is liable for a civil penalty not exceeding $10,000 for each violation of this section." [Labor Code Section 1102.5(f)]

V. CALIFORNIA INSURANCE FRAUD LAWS

In addition to the California FCA, which deals specifically with false or fraudulent claims presented to the state or political subdivisions of the state, several other California statutes

cover other types of fraudulent conduct and false claims in the health care arena. These include both civil and criminal laws prohibiting insurance fraud. This section covers these laws.

A. Civil Actions

California law seeks to prevent the commission of fraud upon both public and private insurers, including workers' compensation insurers. Thus, California law allows interested parties, such as insurance companies, to file a civil claim under the Insurance Fraud Prevention Act ("IFPA") to recover damages and civil penalties against individuals who engage in a range of fraudulent conduct, including the submission of false or fraudulent claims to insurers or preparation of writings in support of such false or fraudulent claims.[22]

California law also permits civil actions against individuals who pay for referrals of patients. Specifically, Insurance Code Section 1871.7 prohibits the employment of "runners, cappers, steerers, or other persons to procure clients or patients to perform or obtain services or benefits ... under a contract of insurance or that will be the basis for a claim against an insured individual or his or her insurer." [Insurance Code Section 1871.7(a)]

Civil Action to Recover on False or Fraudulent Claims, Including Claims Resulting from Referrals

Any interested party, including an insurer, may bring a civil action for violation of Insurance Code Section 1871.7 on behalf of itself and the state of California.[23] To initiate the civil action, the interested party, or *qui tam* plaintiff, must file a complaint under seal, and then must serve on the district attorney and the Insurance Commissioner a copy of the complaint and a written disclosure of substantially all material evidence and information that the person possesses. The complaint remains under seal, and may not be served on the defendant, for a minimum of 60 days, during which time the district attorney and Insurance Commissioner must decide whether to intervene.

Once an IFPA case is initiated, it may be dismissed only if the court and the district attorney or the Insurance Commissioner gives written consent to the dismissal and their reasons for consenting.

Limitations on Subject Matter of IFPA Actions

Like the rules for FCA *qui tam* plaintiffs, if the facts on which the IFPA action is based have been "publicly disclosed" before the interested party filed the complaint, the interested party must prove that he or she is the "original source" of the factual information on which the false claims allegations are based. A public disclosure occurs when the allegations or transactions on which the action is based appear in a criminal, civil, or administrative hearing; in a legislative or administrative report, hearing, audit, or investigation; or from the news media. An individual is an original source when he or she has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the district attorney or Insurance Commissioner before filing the action based on that information. [Insurance Code Section 1871.7(h)(2)] Note that, though the

22 See California Insurance Code Section 1871.7(a) and (b), and Penal Code Sections 549, 550 and 551 for a complete list of conduct giving rise to a civil Insurance Fraud Action.

23 A District Attorney and the Insurance Commissioner are specifically authorized to bring a civil action against anyone who has employed a runner or other person in violation of Insurance Code Section 1871.7. Before filing such a claim, the Insurance Commissioner must present the evidence obtained to the local district attorney for possible criminal or civil prosecution. The Insurance Commissioner may file an action if the district attorney elects not to proceed.

California FCA and the federal FCA have been amended such that the public disclosure bar is no longer jurisdictional, there has been no update to the IFPA. As a result, the bar remains jurisdictional.

Only if a public disclosure has occurred must the interested party prove that he or she is the "original source." If the interested party is not able to do so, then he or she will not be permitted to maintain the claim on behalf of the state, or share in any recovery, even if the state elects to prosecute the case on its own.

An interested party is not permitted to bring an IFPA case at all based on allegations or transactions that are the subject of a civil suit or an administrative civil money penalty proceeding in which the Attorney General, district attorney, or Insurance Commissioner is already a party. [Insurance Code Section 1871.7(h)(1)]

Statute of Limitations

A **"statute of limitations"** is the period of time within which a lawsuit must be filed — that is, a deadline. A claim under the IFPA may not be filed more than three years after discovery of the facts constituting the grounds for commencing the action. [Insurance Code Section 1871.7(l)(1)] Additionally, no action may be filed more than eight years after the commission of the act constituting a violation of Insurance Code Section 1871.7 or criminal provisions against insurance fraud. [Insurance Code Section 1871.7(l)(2) (citing Penal Code Sections 549, 550 and 551)]

The District Attorney or Insurance Commissioner Decides to Intervene

If the district attorney or Insurance Commissioner decides to intervene, the interested party may continue to participate in the litigation. However, the court may limit the interested party's participation upon a showing by the district attorney or Insurance Commissioner that unrestricted participation would interfere with or unduly delay prosecution of the case, or would be repetitious, irrelevant or for purposes of harassment. Additionally, the court may limit the interested party's participation upon a showing by the defendant that it would be for purposes of harassment or would cause the defendant undue burden or unnecessary expense.

The district attorney or Insurance Commissioner may settle the action with the defendant despite the objections of the interested party if the court determines, after a hearing, that the proposed settlement is fair, adequate, and reasonable under the circumstances. The district attorney or Insurance Commissioner may also elect to pursue the claim through any alternative remedies available.

If the district attorney and the Insurance Commissioner elect not to proceed, the interested party has the right to conduct the action. However, the district attorney and the Insurance Commissioner may request that they be served with copies of all pleadings filed in the action and deposition transcripts. Additionally, the court may permit the district attorney and the Insurance Commissioner to intervene at a later date upon a showing of good cause.

B. Civil Penalties

In addition to any other civil or criminal penalties, a person who submits a false or fraudulent claim or prepares a writing in support of a false or fraudulent claim under a contract of insurance, or violates the prohibition on payments for patient referrals set forth in Insurance Code Section 1871.7 is subject to a civil penalty of between $5,000 and $10,000, plus

an assessment of not more than three times the amount of each claim presented to an insurance company. The court also has authority to grant other equitable relief, including temporary injunctive relief to prevent the transfer, concealment, or dissipation of illegal proceeds, or to protect the public. [Insurance Code Section 1871.7(b)]

Parties' Shares of the Recovery

If the district attorney intervenes in an IFPA action filed by an interested party, the interested party is entitled to 30-40 percent of the proceeds of the action or settlement of the claim, depending on the interested party's contribution to the prosecution of the action [Insurance Code Section 1871.7(g)(1)(A)(i)].

In an action in which the Insurance Commissioner has intervened, the interested party who originally filed the action and the Insurance Commissioner can stipulate to an allocation of the proceeds between them, if the court finds that the allocation is in the interest of justice. The district attorney has the opportunity to object to the allocation. [Insurance Code Section 1871.7(g)(1)(A)(ii)]

If the Insurance Commissioner has intervened, and the parties have not stipulated to an allocation of the judgment or settlement, the court will determine the allocation according to the following criteria:

1. The interested party bringing the action will receive an amount that the court determines reasonable for attorney's fees, costs, and expenses that the court determines were necessarily incurred. The interested party is entitled to these amounts regardless of whether it was involved in the acts that violated Insurance Code Section 1871.7. [Insurance Code Section 1871.7(g)(1)(A)(iii)(I)]
2. The Insurance Commissioner will receive the amount that the court determines for reasonable attorney's fees and costs [Insurance Code Section 1871.7(g)(1)(A)(iii)(II)].
3. If the interested party bringing the suit has paid money to the defendants as part of the acts alleged in the complaint, that party will receive the amount paid to the defendants [Insurance Code Section 1871.7(g)(1)(A)(iii)(III)].
4. At least 30 percent, but no more than 40 percent, of the remaining amounts of the judgment or settlement will be allocated to the interested party who brought the action, depending upon the extent to which the party substantially contributed to the prosecution of the action. [Insurance Code Section 1871.7(g)(1)(A)(iii)(IV)]
5. Any remaining undistributed funds will be paid to the state and, upon appropriation by the state legislature, apportioned between the California Department of Justice and the California Department of Insurance for enhanced fraud investigation and prevention efforts [Insurance Code Section 1871.7(g)(1)(A)(iii)(V)].

If the court finds that the case is based primarily on disclosures of specific information, other than information provided by the interested party bringing the action, relating to allegations or transactions in a criminal, civil, or administrative hearing; in a legislative or administrative report, hearing, audit, or investigation; or from the news media, the court may award those sums that it considers appropriate not exceeding 10 percent of the proceeds, taking into account the significance of the information and the role of the interested party in advancing the case to litigation. [Insurance Code Section 1871.7(g)(1)(B)]

In any case in which the district attorney or Insurance Commissioner intervenes, in addition to any portion of the judgment, the interested party bringing the action will receive an amount that the court determines is reasonable for attorney's fees, costs, and expenses that the court determines were necessarily incurred. The defendant must pay these amounts. [Insurance Code Section 1871.7(g)(1)(C)]

If the district attorney and Insurance Commissioner decline to intervene, the interested party bringing the action or settling the claim will receive an amount that the court determines reasonable for collecting the civil penalty and damages. This amount will not be less than 40 percent and not more than 50 percent of the proceeds of the action or settlement. The interested party will also receive an amount that the court determines is reasonable for attorney's fees, costs, and expenses that were necessarily incurred. The interested party and defendant must serve any proposed settlement agreement on the local district attorney and the Insurance Commissioner at least 10 days before filing a motion for allocation with the court. The district attorney and Insurance Commissioner may object to the terms of the settlement. After ruling on these objections, the court may allocate the funds pursuant to the settlement if it finds that it is in the interests of justice to do so. [Insurance Code Section 1871.7(g)(2)(A)]

As a result of a violation of the statute, if the interested party bringing the IFPA claim paid money to the defendant or an attorney acting on behalf of the defendant in the underlying claim, then the interested party is entitled to up to double the amount paid to the defendant or the attorney if that amount is more than 50 percent of the proceeds. The interested party will also receive an amount that the court determines is reasonable for attorney's fees, costs, and expenses that the court determines were necessarily incurred. [Insurance Code Section 1871.7(g)(2)(B)]

If the court finds that an interested party bringing the case planned and initiated the violation of Insurance Code Section 1871.7, that interested party must be dismissed from the civil action and will not receive any share of the proceeds of the action. However, the district attorney or Insurance Commissioner may continue to prosecute the action on behalf of the state. [Insurance Code Section 1871.7(g)(4)]

If the district attorney and Insurance Commissioner decline to intervene, and the interested party continues to prosecute the case, the court may award the defendant, and the interested party will be liable for, the defendant's reasonable attorneys' fees and expenses, if the defendant prevails in the action and the court finds the interested party's claim was clearly frivolous, clearly vexatious or brought primarily for purposes of harassment. [Insurance Code Section 1871.7(g)(5)]

C. Employers May Not Retaliate Against Whistleblowers

California law prohibits an employer from retaliating against an employee for performing lawful acts in furtherance of an IFPA action brought by that employee or another person. Protected "whistleblowing" activities include disclosing, investigating, initiating, testifying for, or assisting in an action that is filed or will be filed. Specifically, an employer cannot retaliate against an employee by discharging, demoting, suspending, threatening, harassing, denying a promotion to, or in any other manner discriminating against the employee in the terms and conditions of employment. An employee may bring a lawsuit against an employer that violates this prohibition.

An employer found to have retaliated against an employee for engaging in protected whistleblowing activities is liable for "all relief necessary to make the employee whole," including:

> Reinstatement with the same seniority status the employee would have had but for the discrimination, two times the amount of backpay, interest on the backpay, and compensation for any special damage sustained as a result of the discrimination, including litigation costs and reasonable attorney's fees. [Insurance Code Section 1871.7(k)]

These remedies are in addition to any other remedies provided by existing law, including any other anti-retaliatory protections for whistleblowers.

VI. CALIFORNIA CRIMINAL PENALTIES

Under California Penal Code Section 550, "[i]t is unlawful to do any of the following, or to aid, abet, solicit, or conspire with any person to do any of the following":

1. Knowingly present, or cause to be presented, any false or fraudulent claim for the payment of a loss or injury, including payment of a loss or injury under a contract of insurance [Penal Code Section 550(a)(1)].
2. Knowingly present multiple claims for the same loss or injury, including presentation of multiple claims to more than one insurer, with an intent to defraud [Penal Code Section 550(a)(2)].
3. Knowingly prepare, make, or subscribe to any writing, with the intent to present or use it, or to allow it to be presented in support of any false or fraudulent claim [Penal Code Section 550(a)(5)].

The commission of any of these crimes is a felony punishable by two, three, or five years in prison, and a fine of up to $50,000 or double the amount of the fraud, whichever is more [Penal Code Section 550(c)(1)].

It is also "unlawful to do any of the following, or to aid, abet, solicit, or conspire with any person to do any of the following":

1. Knowingly make, or cause to be made, any false or fraudulent claim for payment of a health care benefit [Penal Code Section 550(a)(6)].
2. Knowingly submit a claim for a health care benefit which was not used by, or on behalf of, the claimant [Penal Code Section 550(a)(7)].
3. Knowingly present multiple claims for payment of the same health care benefit with an intent to defraud [Penal Code Section 550(a)(8)].
4. Knowingly present for payment any undercharges for health care benefits on behalf of a specific claimant unless any known overcharges for health care benefits for that claimant are presented for reconciliation at that same time [Penal Code Section 550(a)(9)].

The rules set forth above that address "health care benefits" also apply to workers' compensation claims [Penal Code Section 550(a)(10)]. If the claim at issue is more than $950, the conduct described above is punishable by:

1. Two, three or five years in state prison, a fine of the greater of up to $50,000 or double the amount of the fraud or both, or
2. Up to one year in county jail, a $10,000 fine or both.

[Penal Code Section 550(c)(2)(A)]

If the claim at issue is $950 or less, unless the aggregate amount of claims in a twelve month period is more than $950, the conduct described above is punishable by up to six months in county jail, a $1,000 fine or both [Penal Code Section 550(c)(2)(B)].

California Penal Code Section 550(b) further prohibits a person from doing, knowingly assisting or conspiring with any person to do any of the following:

1. Presenting, or causing to be presented, any written or oral statement as part of, or in support of or opposition to, a claim for payment or other benefit pursuant to an insurance policy, knowing that the statement contains any false or misleading information concerning any material fact [Penal Code Section 550(b)(1)].
2. Preparing or making any written or oral statement that is intended to be presented to any insurer or any insurance claimant in connection with, or in support of or opposition to, any claim or payment or other benefit pursuant to an insurance policy, knowing that the statement contains any false or misleading information concerning any material fact [Penal Code Section 550(b)(2)].
3. Concealing, or knowingly failing to disclose the occurrence of, an event that affects any person's initial or continued right or entitlement to any insurance benefit or payment, or the amount of any benefit or payment to which the person is entitled [Penal Code Section 550(b)(3)].

A violation of California Penal Code Section 550(b) is punishable by:

1. Two, three or five years in state prison, a fine of the greater of up to $50,000 or double the amount of the fraud or both, or
2. Up to one year in county jail, a $10,000 fine or both.

[Penal Code Section 550(c)(3)]

Finally, a person who commits any of the state law crimes described above must make restitution to the victim of the crime [Penal Code Section 550(c)(4)]. Moreover, the person is subject to a two- to five-year penalty enhancement for certain prior convictions [Penal Code Section 550(e) and (f)].

(See California Insurance Code Section 1871.7(a) and (b), and Penal Code Sections 549, 550 and 551 for a complete list of conduct giving rise to a civil IFPA liability.)

4 Submission of Accurate Claims Information

I. Introduction 4.1

II. Resources 4.1

A. Where to Find the Medicare Manuals 4.1

B. Program Memoranda/Transmittals 4.2

C. National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs) 4.2

D. Where to Find the Medi-Cal Manuals 4.2

E. Provider Bulletins 4.2

III. Coding Integrity 4.2

A. Coding Systems 4.2

B. The Importance of Medical Record Documentation 4.3

Evaluation and Management (E/M) Visit Coding 4.4

IV. Inpatient Billing 4.4

A. Medicare Inpatient Billing 4.4

Inpatient Prospective Payment System 4.5

Transfer Versus Discharge 4.5

Post-Acute Transfers 4.6

Repeat Admissions and Leaves of Absence 4.7

Readmissions Reduction Program 4.7

Same-Day Acute Care Readmissions 4.8

Canceled Surgical Procedures 4.9

Hospital-Acquired Conditions 4.9

Extent of Inpatient Coverage 4.10

Definitions 4.13

Three-Day Payment Rule 4.14

Claims Submission 4.14

Elimination of the Inpatient Only (IPO) List Halted 4.15

"Two-Midnight" Rule 4.15

Value-Based Purchasing 4.18

B. Medi-Cal Inpatient Billing 4.19

Claims Submission 4.19

Medicare/Medi-Cal Crossover Claims 4.20

Administrative Days 4.21

Treatment Authorization Requests (TARs) 4.21

Provider-Preventable Conditions 4.24

V. Outpatient Billing 4.25

A. Medicare Outpatient Billing 4.25

Introduction 4.25

Availability of OPPS Reimbursement for Services in an Off-Campus Hospital Outpatient Department 4.25

Partial Hospitalization 4.26

Observation Days 4.28

Physician Supervision of Therapeutic Services 4.30

Same-Day Rule 4.31

Billing For Outpatient Procedures When Only Inpatient Service Provided 4.32

Payment for Interpretation of Diagnostic X-Rays in Emergency Department 4.33

National Correct Coding Initiative Edits 4.33

Laboratory Issues 4.34

Medicare Referrals by Physicians Not Enrolled in Medicare 4.37

B. Medi-Cal Outpatient Billing 4.37

Introduction 4.37

Medicare/Medi-Cal Crossover Claims 4.38

Treatment Authorization Requests and Appeals 4.38

Supplies and Drugs for Outpatient Services 4.39

Medi-Cal Observation Days 4.39

VI. Advance Beneficiary Notice of Noncoverage (ABN) 4.39

A. Purpose 4.39

B. ABN Standards 4.41

Proper Notice Documents 4.41

General Notice Preparation Requirements 4.41

Delivery Requirements 4.41

Retention Requirements 4.42

Period of Effectiveness 4.42

Other Considerations During ABN Completion 4.42

VII. Medicare Secondary Payer 4.43

A. Purpose 4.43

B. Determining Who is the Primary or Secondary Payer 4.44

VIII. Credit Balances 4.44

A. Purpose 4.44

B. The Medicare Credit Balance Report — Form CMS-838 ..... 4.45

Completing and Submitting Form CMS-838 ..... 4.45

When to Repay Credit Balances Owed to Medicare 4.47

Records Necessary to Support CMS-838 Data 4.47

4 Submission of Accurate Claims Information

I. INTRODUCTION

The importance of submitting accurate claims information to the Medicare and Medi-Cal programs cannot be overstated. The submission of accurate claims information is necessary to receive prompt and accurate payment and to avoid potential overpayment and False Claims Act liability. *(See chapter 3, "Federal and State False Claims Acts," and chapter 16, "Responding to Government Audits and Investigations," for further information.)* As such, hospitals must be aware of shifting federal and state policies and requirements regarding billing and must incorporate any changes into their regular coding and billing operations.

This chapter discusses several topics related to submission of claims to the Medicare and Medi-Cal programs for both inpatient and outpatient services. This chapter also identifies issues related to advance beneficiary notices, Medicare as a secondary payer, credit balances and coding integrity.

II. RESOURCES

There are several resources available for hospitals to ensure accurate submission of claims to the Medicare and Medi-Cal programs. These resources are discussed below.

A. Where to Find the Medicare Manuals

The Medicare Manuals (e.g., *Benefit Policy Manual, Claims Processing Manual, Financial Management Manual, Secondary Payer Manual*) provide guidance related to the Medicare program, and include CMS program issuances, day-to-day operating instructions, and policies and procedures. The CMS program components, contractors, Medicare Advantage organizations and state survey agencies use the Medicare Manuals to administer CMS programs. They provide much more detail than found in the regulations and statutes that govern the Medicare program, and thus they are a good source of information for hospitals. The Medicare Manuals can be accessed online at www.cms.gov/manuals.

The Medicare Payment Advisory Committee (MedPAC) produces a Payment Basics series of brief overviews of how Medicare's payment systems function. Twenty separate overviews, updated in November 2021, describe how Medicare reimburses for services provided by ambulatory surgical centers, critical access hospitals (CAHs), clinical laboratory services, hospices, etc. The documents may be found at https://www.medpac.gov/document-type/payment-basic/.

CMS also produces "Medicare Learning Network" (MLN) educational publications that are educational resources for health care professionals. These publications include articles, fact sheets, booklets and educational tools on a wide variety of subjects. They are available online at www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNGenInfo/index.html.

B. Program Memoranda/Transmittals

CMS issues program transmittals to communicate new or changed policies and/or procedures that are being incorporated into a specific CMS program manual. CMS transmittals may be reviewed online at www.cms.gov/transmittals.

C. National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs)

Decisions regarding whether the Medicare program will cover a major new technology or procedure are made by CMS through NCDs. Local Medicare contractors, fiscal intermediaries or Medicare Administrative Contractors (MACs) may evaluate new technologies and procedures through LCDs, which are valid only in the area covered by the contractor. The Medicare Coverage Database (MCD) contains all NCDs and LCDs, local policy articles, and proposed NCD decisions. The MCD may be accessed online at www.cms.gov/medicare-coverage-database.

D. Where to Find the Medi-Cal Manuals

The Medi-Cal Manuals (e.g., Medi-Cal Provider Manuals), maintained by the California Department of Health Care Services, provide useful detailed information regarding the Medi-Cal program. Specifically, the Medi-Cal Provider Manuals provide guidance regarding reimbursement and billing requirements for various services and provider types. The Medi-Cal Manuals may be reviewed online at http://files.medi-cal.ca.gov/pubsdoco/manuals_menu.aspx.

E. Provider Bulletins

The California Department of Health Care Services issues Provider Bulletins to update Medi-Cal beneficiaries and providers about the most recent Medi-Cal policies. Provider Bulletins may be reviewed online at http://files.medi-cal.ca.gov/pubsdoco/Bulletins_menu.aspx.

III. CODING INTEGRITY

A. Coding Systems

Government health care programs and private insurers use a series of coding rules for the submission of claims for payment. The process of coding requires the assignment of codes or numbers to represent clinical information and services rendered. For example, the International Classification of Diseases (ICD) codes describe a patient's primary and secondary diagnoses.

The Healthcare Common Procedure Coding System (HCPCS) codes describe procedures and other medical services for health claims involving, among other things, physician services, physical therapy, clinical laboratory tests, and other diagnostic procedures. Finally, the Current Procedural Terminology (CPT) codes, which comprise Level I of the HCPCS coding system, are five-digit codes that identify procedures and services performed that are consistent with current medical practice (e.g., evaluation and management (E/M) codes).

Hospitals are reimbursed based on the codes they submit to payers for payment. Coding for services that were not provided, or coding for a higher level of service than was provided ("upcoding"), may result in an improper level of reimbursement and constitute a false claim

(see e.g., U.S. ex rel. Bledsoe v. Community Health Systems*, 501 F3d 493, 497-98 (6th Cir. 2007) (relator alleged hospital engaged in upcoding practices);* United States v. Larm*, 824 F 2d 780, 783-84 (9th Cir. 1987), cert. denied, 484 U.S. 1078 (1988) (physician liable under false claims statute for billing state Medicaid program with higher code than justified by services performed))*.

Given the complexity of the governmental reimbursement systems and the constantly changing rules and regulations, hospitals must develop internal systems to ensure the accurate submission of claims. In general, the hospital's system of checks and balances should include the use of proper forms and methods to submit claims, a quality assurance program to monitor efficiency of the hospital's claims submissions, and a process for implementing immediate corrective action should problems be identified.

Most importantly, the hospital must utilize coders sufficiently trained in coding techniques and familiar with current coding requirements to ensure that the codes selected accurately depict the procedure or service performed. The hospital's coders should be provided with the current CPT, HCPCS, ICD-10-CM and ICD-10-PCS manuals, which are published on an annual basis. Coders should not utilize outdated resources.

As of Oct. 1, 2015, all providers are required to update to the new ICD-10 coding system for medical diagnosis and inpatient procedure coding. *(For information, news and annual updates to the ICD-10 coding tables, see the official CMS industry resource page at* https://www.cms.gov/Medicare/Coding/ICD10/index*.)*

In addition, the hospital should review ongoing updates from government payers and private insurers to ensure that changes to the coding requirements are implemented timely.

B. The Importance of Medical Record Documentation

Codes for payment must correlate with the documentation in the patient's medical record and comply with the particular rules associated with billing those codes. Payment disputes often require a review of the medical record to support the codes billed. Medical record documentation should be legible and contain a description of the patient's condition(s) and the services provided, including the reason for the patient's admission, the ongoing care and services rendered, and the rationale for procedures performed.

For example, the admission history and physical should reflect the patient's chief complaint, any significant past medical or surgical history, a review of systems, the basis for the services provided, the patient's vital signs and physical findings, and any other information that supports the reason for the hospital admission.

CMS' "two-midnight" rule, discussed under ""Two-Midnight" Rule," page 4.15, requires additional documentation for inpatient hospital admissions. The orders for care should reflect the level of care and services provided. Progress notes should include the status of the patient, noting changes in the patient's condition and actions taken. Discharge summaries should include the patient's status at the time of discharge, patient instructions and plans for follow-up care.

Finally, hospitals should develop policies and procedures that address documentation requirements before the services are coded. Claims should be submitted only when there is documentation available for review to support the codes billed. Hospitals must work

with physicians and other health care providers to ensure that appropriate documentation guidelines are met. Hospitals must also establish an ongoing oversight process to monitor compliance.

Evaluation and Management (E/M) Visit Coding

Physicians and other practitioners paid under the Physician Fee Schedule (PFS) bill for E/M services on the basis of coding levels determined by the complexity of the service, site of service, and whether the patient is new or established. Historically, the documentation required for each level of E/M code included three components: History of Present Illness, Physician Examination, and Medical Decision Making (MDM). The American Medical Association's Current Procedural Terminology (CPT) Editorial Panel issued a new coding, prefatory language, and interpretive guidance framework for the outpatient and office E/M visit code set (CPT codes 99201 through 99215), effective Jan. 1, 2021, which was generally adopted by CMS [84 Fed. Reg. 62844-62860 (Nov. 15, 2019)]. Under this policy, practitioners coding and billing for E/M services must use either the level of MDM or the total time personally spent by the reporting practitioner on the day of the visit. History and exam are no longer used to select the level of code, and practitioners may no longer use the 1995 or 1997 E/M Documentation Guidelines. [84 Fed. Reg. 62568 (Nov. 15, 2019)] CMS also finalized adoption of add-on code G2211, which describes visit complexity Inherent to E/M associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition [84 Fed. Reg. 62856 (Nov. 15, 2019)]. For CY 2021, CMS also created new HCPCS code G2212, which is used in lieu of CPT code 99417 and describes each additional 15 minutes of prolonged office or other outpatient E/M service(s) beyond the maximum required time of the primary procedure which has been selected using total time on the date of the primary service [85 Fed. Reg. 85866 (Dec. 28, 2020)].

Additionally, CMS has reduced requirements that were leading to redundant documentation. As of Jan. 1, 2019, the billing practitioner is no longer required to re-document any part of the chief complaint or history that is recorded by ancillary staff or the patient. Rather, the billing practitioner may simply review and update or supplement as needed. *(See CMS Evaluation and Management (E/M/) FAQs, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/E-M-Visit-FAQs-PFS.pdf; 83 Fed. Reg. 59635 (Nov. 23, 2018).)*

IV. INPATIENT BILLING

A. Medicare Inpatient Billing

Hospitals generally are reimbursed for inpatient services rendered to Medicare beneficiaries based on the Inpatient Prospective Payment System (IPPS), which delineates prospectively set rates. There are various types of hospitals and hospital units, such as psychiatric and rehabilitation hospitals and units, long-term care hospitals, cancer hospitals, and CAHs, which are not reimbursed under IPPS and have their own unique billing issues.[1] This section focuses on billing under IPPS.

1 Hospitals also excluded from PPS include children's hospitals that have inpatients predominantly under the age of 18, hospitals participating in a CMS-approved demonstration project or state payment control system, nonparticipating hospitals furnishing emergency services, and hospitals located outside of the 50 states and Puerto Rico [42 C.F.R. Sections 412.22 and 412.23]

Inpatient Prospective Payment System

The IPPS system classifies each case into a diagnosis-related group (DRG), which has a payment rate assigned based on the national average costs incurred to treat the particular medical condition. A case is assigned to a DRG based upon information contained in each beneficiary's bill, including principal diagnosis, up to 24 additional diagnoses, and up to 25 procedures performed during the stay, as well as age, sex and discharge status. [42 C.F.R. Section 412.60(c)(1); *Medicare Claims Processing Manual*, Pub. 100-04, chapter 3, Section 20.2.2] The amount of payment a hospital receives is generally calculated by multiplying the DRG weight by a "standardized amount." The standardized amount accounts for basic hospital costs, adjusted for geographic location, and usually adjusted annually for inflation. The DRG assignment determines the payment the hospital receives for the inpatient stay. Payment under IPPS may also be adjusted if the hospital:

1. Serves a high percentage of low-income patients, known as the "disproportionate share hospital" (DSH) adjustment;
2. Is an approved teaching hospital, known as the "indirect medical education" (IME) adjustment[2];
3. Treats outlier cases where the hospital's actual costs for caring for a patient exceed the total DRG payment plus a fixed dollar amount; and/or
4. Treats cases that involve certain new approved medical services and technologies.

Further adjustments may be made to the IPPS rate under the value-based incentive purchasing program *(see "Value-Based Purchasing," page 4.18)* and the readmissions reduction program *(see "Readmissions Reduction Program," page 4.7)*.

In 2008, CMS introduced a revised list of DRGs, called Medicare Severity DRGs (MS-DRGs), to better account for a patient's severity of illness.

Transfer Versus Discharge

In addition to adjustments to the IPPS payment made for the foregoing reasons, Medicare distinguishes between patient transfers and discharges, with different rules for acute care transfers and, in some circumstances, for post-acute transfers. When a patient is transferred to another acute care hospital, full payment is made to the final discharging hospital and each transferring hospital is paid a per diem rate for each day of the stay, not to exceed the full DRG payment that would have been made if the patient had been discharged without being transferred.

Medicare considers a patient to be **"discharged"** when the patient is formally discharged from the hospital, expires while in the hospital, or is transferred to an "excluded" hospital (i.e., certain hospitals not subject to IPPS) or a distinct-part unit (subject to the Post-Acute Transfer policy discussed below). The release of a patient to another IPPS hospital or a patient's leave of absence from the hospital does not qualify as a "discharge." [42 C.F.R. Section 412.4(a); *Medicare Claims Processing Manual*, Pub. 100-04, chapter 3, Sections 20.1.2.4 and 40.2.6]

A patient is considered **"transferred"** when the patient is readmitted the same day to:

1. Another IPPS hospital;

2 Such hospitals will also receive separate graduate medical education (GME) payments, the amount of which depends, in part, on the number of resident physicians and the number of available hospital beds.

2. A hospital excluded from the Prospective Payment System (PPS) because of a statewide cost-control program or demonstration project;
3. An acute care hospital that would otherwise be eligible to be paid under the IPPS, but does not have an agreement to participate in the Medicare program; or
4. A CAH.

[42 C.F.R. Section 412.4(b); *Medicare Claims Processing Manual*, Pub. 100-04, chapter 3, Section 20.1.2.4]

Transfers include all patients who are admitted to another PPS hospital on the same day that the patient is discharged from a PPS hospital, unless the first hospital can demonstrate that the patient's treatment was completed at the time of discharge. This is true even where the patient left the first hospital against medical advice. [42 C.F.R. Section 412.4(b); 69 Fed. Reg. 48916, 49070 (Aug. 11, 2004)]

A hospital that claims a patient as a discharge when the patient is actually transferred to another acute care setting may be considered to have billed inappropriately for a "discharge in lieu of transfer."

Post-Acute Transfers

The discharge of a hospital inpatient is considered to be a **"post-acute transfer"** when the patient's discharge is assigned to one of a group of qualifying DRGs and the discharge is made to:

1. A hospital or distinct-part hospital unit excluded from IPPS;
2. A skilled nursing facility;
3. Home under a written plan of care for the provision of home health services from a home health agency, and those services begin within three days after the date of discharge; or
4. For discharges occurring on or after Oct. 1, 2018, hospice care provided by a hospice program.

[42 C.F.R. Section 412.4(c); *Medicare Claims Processing Manual*, Pub. 100-04, chapter 3, Section 40.2.4(C)]

Payment to the transferring hospital is subject to a statutory limit. For qualifying DRGs, the transferring hospital is paid a graduated per diem rate for each day of the patient's stay in that hospital, not to exceed what would have been paid if the patient had been discharged to another setting. However, specific transfer cases qualify for payment under an alternative methodology. These include transfer cases in which the patient's discharge is assigned to one of the qualifying Special Pay MS-DRGs referenced in Table 5 of the applicable Fiscal Year IPPS *Federal Register*. For these cases, the transferring hospital is paid 50 percent of the appropriate inpatient prospective payment rate and 50 percent of the appropriate transfer payment. [42 C.F.R. Section 412.4(f)]

In prior years, Office of Inspector General reviews have identified Medicare overpayments to hospitals that did not comply with Medicare's post-acute care transfer policy. In May 2014, the OIG concluded that non-compliance with this policy resulted in approximately $12.2 million in overpayments. In August 2018, the OIG announced that its Work Plan includes

whether Medicare appropriately paid hospitals' inpatient claims subject to the post acute care transfer policy when:

1. Patients resumed home health services after discharge, or
2. Hospitals applied conditions codes to claims to receive a full DRG payment.

Repeat Admissions and Leaves of Absence

When a patient's readmission is expected, and the patient does not require hospital level care during the interim period (such as if a surgery cannot be immediately scheduled, a specific surgery team is not available, bilateral surgery is planned, or further treatment cannot begin immediately), a hospital may place the patient on a leave of absence. A leave of absence is considered a single discharge for which one DRG payment is made. Providers must submit only one bill for covered days and days of leave when the patient is ultimately discharged. The leave of absence billing procedure must not be used if a second readmission is unexpected. The hospital's A/B MAC may review such claims, which will be referred to the Quality Improvement Organization (QIO). The QIO may review acute care hospital admissions occurring within 30 days of a discharge from an acute care hospital in the same QIO jurisdiction if it appears that the two admissions could be related. However, the QIO's authority is not limited to just the 30-day readmission period. [*Medicare Claims Processing Manual*, Pub. 100-04, chapter 3, Section 40.2.5]

Readmissions Reduction Program

To improve care and lower costs, the Affordable Care Act established the Hospital Readmissions Reduction Program, which requires CMS to reduce payments to IPPS hospitals with excessive readmissions, effective for discharges beginning on Oct. 1, 2012.

In the FY 2012 IPPS final rule [76 Fed. Reg. 51476 (Aug. 18, 2011)], CMS implemented the Readmissions Reduction Program. A **"readmission"** is defined as an admission to a subsection (d) hospital within 30 days of a discharge from the same or another subsection (d) hospital.[3] [42 C.F.R. Section 412.152] It excludes certain readmissions, such as transfers to another IPPS hospital, and readmissions classified by CMS as "planned," such as chemotherapy or rehabilitation. For the first two years (FYs 2013 and 2014), the program applied to readmissions of Medicare patients ages 65 and older with diagnoses of Acute Myocardial Infarction (AMI), Heart Failure (HF) and Pneumonia (PN). [76 Fed. Reg. 51476, 51666 (Aug. 18, 2011)] In addition, CMS expanded the list of the applicable conditions for FY 2015 to include:

1. Patients admitted for an acute exacerbation of chronic obstructive pulmonary disease (COPD); and
2. Patients admitted for elective total hip arthroplasty (THA) and total knee arthroplasty (TKA).

[78 Fed. Reg. 50496, 50657 (Aug. 19, 2013)]

CMS then expanded the list of the applicable conditions for FY 2017 to include patients admitted for coronary artery bypass graft (CABG) surgery [79 Fed. Reg. 49854, 50034 (Aug. 22, 2014)].

3 A subsection (d) hospital is a general, acute care, short-term hospital, as defined in Section 1886(d)(1)(B) of the Social Security Act [42 U.S.C. 1395ww(d)(1)(B)]. Examples of non-subsection (d) hospitals include psychiatric hospitals, rehabilitation hospitals, long term care hospitals, children's hospitals and cancer hospitals.

CMS established a methodology to calculate the excess readmission ratio for each applicable condition, which is used, in part, to calculate the readmission payment adjustment. A hospital's excess readmission ratio for the applicable conditions is a measure of a hospital's readmission performance compared to the national average for the hospital's set of patients with that applicable condition. CMS is also using the risk adjustment methodology endorsed by the National Quality Forum (NQF) for the readmissions measures for the applicable conditions to calculate the excess readmission ratios, which includes adjustment for factors that are clinically relevant including patient demographic characteristics, co-morbidities, and patient frailty. The payment adjustment is calculated using a complex formula based on the amount of Medicare payments received by the hospital for the excess readmissions. The penalties are collected from the hospitals through a percentage reduction in their base Medicare inpatient claims payments, up to a cap. The penalty cap was set at one percent of aggregate IPPS base payments for FY 2013, 2 percent for FY 2014, and 3 percent for each year thereafter. [42 C.F.R. Section 412.154(c)]

In FY 2019, CMS implemented a socioeconomic adjustment approach, in which CMS will assess penalties based on a hospital's performance relative to other hospitals with a similar proportion of patients who are dually eligible for Medicare and Medicaid [82 Fed. Reg. 38205 (Aug. 14, 2017)].

Same-Day Acute Care Readmissions

The issue of same-day acute care readmission has been the subject of GIG initiatives for a number of years. Same-day readmissions raise a number of concerns, including:

1. Premature discharges;
2. Additional services that should have been billed as part of the first stay;
3. Medically unnecessary readmission;
4. Lack of documentation; and
5. DRG upcoding.

Effective January 2004, CMS established common working file edits to ensure payment compliance for beneficiaries who are readmitted the same day to the same PPS hospital. As detailed in the *Medicare Claims Processing Manual*, Pub. 100-04, chapter 3, Section 40.2.5, for a beneficiary who is discharged/transferred from an acute PPS hospital and subsequently readmitted to the same hospital on the same day for symptoms related to the prior stay's medical condition (or to evaluate and manage the prior stay's medical condition(s)) the hospital is required to adjust the original claim from the original stay to combine the original and subsequent claim into one single claim. It should be noted that services rendered by other institutional providers during a combined stay must be paid by the acute care PPS hospital, in accordance with usual Medicare practice. In those situations where the beneficiary is admitted to the same PPS hospital on the same day for symptoms unrelated to the prior stay (or evaluation/management of a medical condition that is not related to the prior stay), the hospital must place a condition code "B4" on the claim which contains the admission date that is the same as the prior stay's discharge date. The hospital must be prepared to submit the medical records related to the readmission to the Part NB MAC upon request.

Canceled Surgical Procedures

In its FY 2013 work plan, the GIG noted that it would look into the issue of billing for cancelled surgical procedures. In August 2013, the GIG issued a report *(see* http://oig.hhs.gov/oas/reports/region1/11200509.pdf*)*, finding that most (80 out of 100 sample claims) inpatient admissions related to short-stay hospital claims involving canceled elective surgeries were not reasonable and necessary. The OIG estimated that in CYs 2009 and 2010, Medicare made $38.2 million in Part A inpatient hospital payments for short-stay canceled elective surgery admissions that were not reasonable and necessary (noting, however, that hospitals may bill Part B for services related to the incorrectly billed Part A admissions, thus reducing this estimate). The OIG determined that these payments occurred because:

1. The hospitals were unclear about the Medicare requirements for billing canceled inpatient surgeries;
2. CMS' billing requirements are too restrictive, particularly with regard to changing a beneficiary's status from inpatient to outpatient after discharge; and
3. Hospitals did not always have adequate utilization review controls to confirm whether admissions were reasonable and necessary after elective surgeries had been canceled.

The OIG recommended that CMS adjust the sample claims it found to be incorrectly billed; strengthen guidance to better explain the Medicare rule that a clinical condition requiring inpatient care must exist for hospitals to bill for Part A prospective payments for elective surgeries that were canceled; work with the OIG to resolve the unsampled claims that may be incorrectly billed; and instruct MACs to emphasize the need for better utilization review controls for claims that include surgeries that were canceled. CMS responded, stating that it believed the "two-midnight" rule, discussed under ""Two-Midnight" Rule," page 4.15, might solve this issue.

Hospital-Acquired Conditions

As part of its ongoing efforts to improve the quality of hospital care, the Medicare program has instituted payment provisions regarding those conditions that are high in cost and/or volume, that result in a higher DRG payment when present as a secondary diagnosis, and that are reasonably believed to have been preventable through the use of evidence-based guidelines. These conditions are known as **"hospital-acquired conditions"** (HACs).

Additional reimbursement will not be made to a hospital for these conditions when they were not present on admission, nor may a hospital bill the beneficiary for any associated charges. Pursuant to 42 U.S.C. Section 1395ww(d)(4)(D), and CMS Change Request 5679 [Pub. 10020, One-Time Notification, Transmittal 289], IPPS hospitals are required to determine and to submit information pertaining to the patient's condition on admission (known as a POA indicator) for all primary and secondary diagnoses. Claims that do not contain POA data will not be processed for payment until the information is received.

Pursuant to 42 U.S.C. Section 1395ww(d)(4)(D)(iv), CMS must identify HACs and may revise the list of HACs. CMS has identified the following 14 categories of HACs:

1. Foreign object retained after surgery;
2. Air embolism;

3. Blood incompatibility;
4. Stage III and IV pressure ulcers;
5. Falls and trauma (fractures, dislocations, intracranial injuries, crushing injuries, burns, and other injuries);
6. Manifestations of poor glycemic control (diabetic ketoacidosis, nonketotic hyperosmolar coma, hypoglycemic coma, secondary diabetes with ketoacidosis, secondary diabetes with hyperosmolarity);
7. Catheter-associated urinary tract infection;
8. Vascular catheter-associated infection;
9. Surgical site infection following coronary artery bypass graft (mediastinitis);
10. Surgical site infection following certain orthopedic procedures (spine, neck, shoulder, elbow);
11. Surgical site infection following bariatric surgery for obesity (laparoscopic gastric bypass, gastroenterosomy, laparoscopic gastric restrictive surgery);
12. Surgical site infection following Cardiac Implantable Electronic Device (CIED);
13. Deep Vein Thrombosis (DVT)/Pulmonary Embolism (PE) following a total knee or hip replacement; and
14. Iatrogenic Pneumothorax with venous catheterization.

Information regarding HACs may be viewed online at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/Hospital-Acquired_Conditions.html.

In its recent work plans, the OIG identified this issue as an area of concern and will review Medicare inpatient hospital claims to identify the number of beneficiary stays associated with HACs and determine their impact on reimbursement. The OIG will also verify the accuracy of POA indicators, which are used for identifying HACs. *(See the December 2008, "Office of Inspector General, Adverse Events in Hospital Overview of Key Issues," found at https://oig.hhs.gov/oei/reports/oei-06-07-00470.pdf.)*

Separately, the HAC Reduction Program is a Medicare pay-for-performance program that was adopted in the Patient Protection and Affordable Care Act (ACA) of 2010 and effective FY 2015. It is distinct from the Hospital-Acquired Conditions Present on Admission Indicator program described above. Under the HAC Reduction Program, Medicare payments for all discharges will be reduced by one percent for those hospitals in the top quartile with respect to national rates for HACs. CMS sends confidential hospital-specific reports to hospitals and gives 30 days for hospitals to review their HAC Reduction Program data, submit questions about the calculation of their results, and request corrections to the scoring. [42 U.S.C. Section 1395ww(p)]

Extent of Inpatient Coverage

The Medicare Hospital Insurance Program, "Medicare Part A," pays for hospital, nursing home, home health and hospice services. The Medicare Supplemental Medical Insurance Program, "Medicare Part B," covers physicians' services and a variety of other items and services including outpatient hospital services, home health care, physical and occupational therapy, prosthetic devices, durable medical equipment, and ambulance services.

Inpatient coverage under Part A is available for each day of inpatient hospital care up to a maximum of 150 days in any single "spell of illness" [42 U.S.C. Section 1395d(a)(1)]. With limited exceptions, services provided to a hospital inpatient must be treated as an inpatient hospital service to be paid for under Part A, if Part A coverage is available for the stay and the beneficiary qualifies. Payment may be made under Part B for certain services when they are reasonable and necessary and when they are furnished by a participating hospital either directly or under arrangements to an inpatient of the hospital, but only if payment for these services cannot be made under Part A. In PPS hospitals, this means that Part B payment may be made for services if:

1. No Part A prospective payment is made at all for the hospital stay because the patient exhausted his or her Part A benefit days before admission;
2. The admission was denied as not reasonable and necessary, and waiver of liability payment was not made;
3. The day or days of the otherwise covered stay during which the services were provided were not reasonable and necessary, and no payment was made under waiver of liability; or
4. The patient was not otherwise eligible for, or entitled to, coverage under Part A.

In non-PPS hospitals, Part B payments may be made for the covered services listed above delivered on any day for which Part A is denied, due to:

1. Exhaustion of Part A benefit days,
2. The patient or the services were not at the hospital level of care, or
3. The patient was not otherwise eligible for, or entitled to, payment under Part A.

If no Part A payment is made, Part B payment may be made for:

1. Diagnostic X-ray tests, diagnostic laboratory tests, and other diagnostic tests;
2. X-ray, radium, and radioactive isotope therapy, including materials and services of technicians;
3. Acute dialysis of a hospital inpatient with or without end stage renal disease (ESRD).
4. Screening pap smears;
5. Influenza, pneumococcal pneumonia, and hepatitis B vaccines;
6. Colorectal screening;
7. Bone mass measurements;
8. Prostate screening;
9. Hemophilia clotting factors for hemophilia patients competent to use these factors without supervision;
10. Immunosuppressive drugs;
11. Oral anti-cancer drugs;
12. Oral drug prescribed for use as an acute anti-emetic used as part of an anti-cancer chemotherapeutic regimen;
13. Epoetin Alfa (EPO);

14. Surgical dressings, and splints, casts, and other devices used for reduction of fractures and dislocations;
15. Prosthetic devices (other than dental) which replace all or part of an internal body organ (including contiguous tissue), or all or part of the function of a permanently inoperative or malfunctioning internal body organ, including replacement or repairs of such devices;
16. Leg, arm, back and neck braces, trusses, and artificial legs, arms and eyes including adjustments, repairs and replacements required because of breakage, wear, loss or a change in the patient's physical condition;
17. Outpatient physical therapy, outpatient speech pathology services, and outpatient occupational therapy;
18. Ambulance services; and
19. Screening mammography services.

[*Medicare Benefit Policy Manual*, Pub. 100-02, chapter 6, Section 10]

When a hospital bills for Part B payment following denial of a reasonable and necessary Part A hospital inpatient claim, hospitals must follow particular coding instructions indicating the claim is a rebilling, and not an appeal *(see* Medicare Claims Processing Manual*, 100-04, chapter 4, Section 240.1)*.

In addition, effective Oct. 1, 2013, payment may be made under Part B for a broader range of items and services where a Medicare Part A claim for inpatient hospital services is denied because the inpatient admission was not reasonable and necessary or if a hospital determines after the beneficiary is discharged that the admission was not reasonable and necessary in accordance with 42 C.F.R. Sections 482.30(d)Dr 485.641. In these cases, the hospital may file a timely claim for Part B services provided to the beneficiary, with the exception of those services that should be furnished only to hospital outpatients (i.e., observation services, outpatient diabetes self-management training, and hospital outpatient visits). Any Part B services furnished during the three-day payment window preceding a hospital inpatient admission that is later denied *(see discussion below)* may be billed on a Part B outpatient claim if the Part B coverage and payment rules are met. [42 C.F.R. Section 414.5; 78 Fed. Reg. 50496, 50912-50913 (Aug. 19, 2013)]

Where the beneficiary was admitted prior to Oct. 1, 2013, the hospital may be able to bill services under Part B where a Medicare Part A claim for inpatient hospital services was denied as not reasonable and necessary under Ruling 1455-R. [CMS, Clarification of Billing under Medicare Parts A and B, Ruling No. CMS-1455-R (Mar. 13, 2013), found at www.cms.gov/Regulations-and-Guidance/Guidance/Rulings/Downloads/CMS1455R.pdf] The Ruling applies only to those Part A hospital inpatient claims that:

1. Were denied by a Medicare review contractor between March 13, 2013 and Oct. 1, 2013 (the effective dates of the Ruling);
2. Were denied prior to March 13, 2013, as long as the time frame to file an appeal has not expired or an appeal is pending; or
3. Have a date of admission before Oct. 1, 2013 and were denied after Sept. 30, 2013.

[Ruling 1455-R; 78 Fed. Reg. 50496, 50927 (Aug. 19. 2013)]

As of March 14, 2013, CMS Ruling 1455-R ended CMS' Part A to Part B Rebilling Demonstration, which had allowed participating hospitals to rebill for 90 percent of the Part B payment where a Medicare contractor denied a Part A inpatient short stay claim as not reasonable and necessary. [CMS Part A to Part B Rebilling Demonstration, found at https://www.hhs.gov/guidance/document/medicare-fee-service-compliance-programs-part-part-b-rebilling-demonstration-0]

Definitions

Inpatient

An **"inpatient"** is a person who has been admitted to a hospital for bed occupancy for purposes of receiving inpatient hospital services. A person is considered an inpatient if he/she was formally admitted as an inpatient with the expectation that he/she would require a stay that crosses at least two midnights. *(See ""Two-Midnight" Rule," page 4.15.)*

Inpatient Day

The number of days of care charged to a beneficiary for inpatient hospital service is always in units of full days. A day begins at midnight and ends 24 hours later. The midnight-to-midnight method must be used in reporting days of care for beneficiaries.

A part day, including the day of admission, counts as a full day. However, the day of discharge or death is not counted as a day. If both admission and discharge or death occur on the same day, the day is considered a day of admission and counts as one inpatient day.

Leaves of Absence

The day on which the patient begins a leave of absence is treated as a day of discharge and is not counted as an inpatient day unless the individual returns to the hospital by midnight the same day. The day the patient returns to the hospital from a leave of absence is treated as a day of admission and is counted as an inpatient day.

Late Discharge

When a patient chooses to continue to occupy the hospital accommodations beyond the check-out time for personal reasons, the hospital may charge the beneficiary for a continued stay. Such a stay beyond the check-out time is not covered under the Medicare program and the hospital's agreement to participate in the program does not preclude it from charging the patient. However, the hospital must provide beneficiaries with the Important Message from Medicare (IM), informing them of their discharge appeal rights. [71 Fed. Reg. 68708, 68717-18 (Nov. 27, 2006)] The imposition of a late charge does not affect the counting of days for:

1. Ending a spell of illness;
2. The three-day prior hospitalization requirement for coverage of extended care services and Part A home health services; and
3. The number of days of inpatient care available to the individual.

If the patient's medical condition is the cause of the stay past the check-out time, the stay beyond the discharge hour is covered under the program and the hospital may not charge the patient.

Three-Day Payment Rule

The "Three-Day Payment Rule" prohibits hospitals from separately billing outpatient diagnostic and most nonphysician services furnished to a beneficiary on the date of the beneficiary's admission to the hospital and during the three calendar days immediately preceding the date of the beneficiary's admission to the hospital as these services are deemed to be included in Medicare's fixed fee for inpatient services. The rule extends to services furnished by the hospital or an entity wholly owned or operated by the hospital, including physician practices and clinics. However, the three-day rule does not apply to:

1. Ambulance services;
2. Maintenance renal dialysis;
3. Part A services furnished by skilled nursing facilities, home health agencies, and hospices;
4. Outpatient diagnostic services rendered to a patient by a CAH or an entity wholly owned or operated by a CAH; and
5. Hospitals and units excluded from IPPS (although, a similar "one-day" payment rule applies to such IPPS excluded hospitals and units).

[42 C.F.R. Section 412.2(c)(5); *Medicare Claims Processing Manual*, Pub. 100-04, chapter 3, Section 40.3]

Accordingly, all diagnostic services provided to a Medicare beneficiary by a hospital on the date of the beneficiary's admission or during the three calendar days immediately preceding the date of admission must be included on the bill for the inpatient stay. Similarly, all outpatient nondiagnostic services provided by the hospital on the day immediately preceding the date of admission are deemed clinically related to the admission, and must be billed with the inpatient stay. Finally, outpatient nondiagnostic services provided by the hospital during the three-day payment window are also deemed clinically related to the admission, and must be billed with the inpatient stay, unless the hospital attests that a specific nondiagnostic service is unrelated to the hospital claim by using condition code 51 (Attestation of Unrelated Outpatient Nondiagnostic Services) when billing for the service. [*Medicare Claims Processing Manual*, Pub. 100-04, chapter 3, Section 40.3]

Claims Submission

IPPS hospitals must submit claims when the beneficiary is discharged or otherwise ceases to need a hospital level of care, or when the beneficiary's benefits are exhausted. In the case of long-term treatment, IPPS hospitals may interim bill in at least 60-day intervals. Services provided at non-IPPS hospitals are billed at the following times:

1. Upon discharge of the beneficiary;
2. When the beneficiary's benefits are exhausted;
3. When the beneficiary's need for care changes; or
4. On a monthly basis.

(See Medicare Claims Processing Manual*, Pub. 100-04, chapter 1, Section 50.2.1, for further details.)*

ACA reduced the maximum time period for submission of Medicare fee-for-service claims to one calendar year after the date of service. These amendments apply to services furnished on or after Jan. 1, 2010.

Claims must be submitted to the Medicare Administrative Contractor (MAC) on the Form CMS-1450, also known as the UB-04, or the electronic equivalent, for all provider billing except for the professional component of physician services. Instructions for completion of the UB-04 can be found in chapter 25 of the *Medicare Claims Processing Manual*. [*Medicare Claims Processing Manual*, Pub. 100-04, chapter 25]

Elimination of the Inpatient Only (IPO) List Halted

When CMS first developed the Outpatient Prospective Payment System (OPPS) in the CY 2000 OPPS final rule, it designated certain procedures as "inpatient only" and barred OPPS payment for procedures on this IPO list. [65 Fed. Reg. 18434, 18455-18457 (April 7, 2000); 42 C.F.R. Section 419.22(n)] The IPO list identified services that require inpatient care because of the invasive nature of the procedure, the need for at least 24 hours of postoperative recovery time, or the underlying physical condition of the patient who would require the surgery. In the CY 2021 OPPS final rule, CMS eliminated the IPO list over a three-year transition period, beginning Jan. 1, 2021. For 2021, CMS removed 298 services from the IPO list, including 266 musculoskeletal related services and 16 related anesthesia codes. However, CMS halted this policy in its CY 2022 OPPS final rule [86 Fed. Reg. 63672-63673, 63676 (Nov. 16, 2021)]. In the CY 2022 OPPS final rule, CMS added back to the IPO list all but five of the services removed in the CY 2021 final rule [86 Fed. Reg. 63711 (Nov. 16, 2021)].

In the CY 2021 OPPS final rule, CMS also adopted a policy that indefinitely exempted procedures removed from the IPO list on or after Jan. 1, 2021, from site-of-service claim denials under Medicare Part A, eligibility for Beneficiary and Family-Centered Care Quality Improvement Organization (BFCC-QIO) referrals to Recovery Audit Contractors (RACs) for noncompliance with the "two midnight" rule (discussed below) and RAC reviews for "patient status." However, now that CMS is returning to a policy where it removes procedures from the IPO list based on identified criteria, CMS believes that an indefinite exemption is no longer appropriate [86 Fed. Reg.63711, 63738 (Nov. 16, 2021)]. CMS therefore rescinded the indefinite exemption and reinstated a 2-year exemption to all services removed on or after Jan. 1, 2020 [86 Fed. Reg. 63740 (Nov. 6, 2021)].

"Two-Midnight" Rule

Concerned over increases in the length of time that Medicare beneficiaries spend as hospital outpatients receiving observation services, CMS adopted several clarifications and changes in Medicare's policies regarding the inpatient admission guidelines and medical review criteria for inpatient stays. In addition, CMS changed its policies regarding the payment of hospital inpatient services under Medicare Part B *(see "Extent of Inpatient Coverage," page 4.10)*.

The centerpiece of these policy clarifications and changes is the "two midnight" rule, which was finalized in the 2014 IPPS final rule [78 Fed. Reg. 50496, 50938-52 (Aug. 19, 2013)]. This rule uses a time-based benchmark and presumption for inpatient admissions. The two-midnight benchmark provides guidance to admitting practitioners and reviewers to identify when an inpatient admission is generally appropriate for Medicare coverage and payment. Under this benchmark, inpatient admission is generally appropriate when the physician

expects the patient to require a stay that crosses at least two midnights. In addition, inpatient admission is appropriate where a patient enters a hospital for an inpatient-only procedure. [42 C.F.R. Section 412.3(d)(2); *see 42 C.F.R. Section 419.22(n) (listing inpatient-only procedures)*] Whether a patient's stay is expected to cross two midnights will be based on the physician's assessment of complex medical factors such as "patient history and co-morbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event." [42 C.F.R. Section 412.3(d)(1)(i)] These factors must be documented in the medical record to be considered.

Where a patient initially receives services as an outpatient (including observation services, treatment in the emergency department, and procedures provided in the operating room or other treatment area), that time may be considered for purposes of determining whether the two-midnight benchmark is expected to be met. [78 Fed. Reg. 50496, 50950 (Aug. 19, 2013)] Thus, if the physician is uncertain as to whether the patient will need an inpatient stay, the physician may provide observation services on an outpatient basis and consider the duration of these outpatient services when assessing the two-midnight benchmark. As a beneficiary approaches a second midnight as an outpatient, the physician will have greater certainty as to whether inpatient admission is appropriate. Thus, "beneficiaries in medically necessary hospitalizations should not pass a second midnight prior to the admission order being written." [78 Fed. Reg. 50496, 50946 (Aug. 19, 2013)] In CMS' opinion, the benchmark should virtually eliminate the use of extended observation stays. While the time a beneficiary spends receiving outpatient services counts toward the two-midnight benchmark, it will not be considered inpatient time for payment purposes and is subject to the three-day payment rule described under "Three-Day Payment Rule," page 4.14.

In addition, stays that do not cross two midnights may nonetheless satisfy the benchmark and be appropriate for payment under Medicare Part A. These shorter stays will satisfy the benchmark if the physician reasonably expected a stay spanning at least two midnights but unforeseen circumstances resulted in a shorter stay. For example, if the beneficiary dies, is transferred, improves more rapidly than reasonably expected, or leaves against medical advice before the second midnight, the benchmark may nonetheless be met based on documentation in the medical record supporting a reasonable expectation of a longer stay. [42 C.F.R. Section 412.3(d)(1)(ii); 78 Fed. Reg. 50496, 50946 (Aug. 19, 2013)]

CMS may also identify "rare and unusual circumstances" in which an inpatient admission would be reasonable in the absence of an expectation of a two-midnight stay. In 2013, CMS identified a potential exception for mechanical ventilation initiated during a stay. If a physician expects that a beneficiary with newly initiated mechanical ventilation will require only one midnight of hospital care, inpatient admission and Part A payment will nonetheless be appropriate. The exception does not apply to anticipated intubations related to minor surgical procedures or other treatment. In identifying this exception, CMS noted that newly initiated mechanical ventilation is rarely provided in hospital stays less than two midnights in duration and that this procedure embodies the same characteristics as those included in Medicare's inpatient-only list. [CMS, Reviewing Hospital Claims for Patient Status: Admissions on or After October 1, 2013 (Updated Nov. 27, 2013), found at www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medical-Review/Downloads/ReviewingHospitalClaimsforAdmissionFINAL.pdf]

In the 2016 OPPS final rule, CMS modified its "rare and unusual" exceptions policy to also allow for Medicare Part A payment on a case-by-case basis for inpatient admissions that do not satisfy the two-midnight benchmark, if the documentation in the medical record supports the admitting physician's determination that the patient requires inpatient hospital care despite an expected length of stay that is less than two midnights. The physician's determination in such cases should be based on complex medical factors including patient history and co-morbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event. Factors supporting the medical necessity of the inpatient admission in such cases must be supported by the medical record. [42 C.F.R. Section 412.3(d)(3); 80 Fed. Reg. 70298, 70540-45 (Nov. 13, 2015)]

Under the two-midnight *presumption*, inpatient hospital claims with lengths of stay greater than two midnights after the formal admission will be presumed generally appropriate for Part A payment and will not be the focus of medical review. Unlike the benchmark, the presumption does not account for any time the beneficiary spends as an outpatient prior to inpatient admission. The two-midnight presumption is met only where the stay spans at least two midnights after the beneficiary is formally admitted. [78 Fed. Reg. 50496, 50950 (Aug. 19, 2013)] In addition, inpatient stays crossing two midnights will not be entitled to the presumption where there is evidence of systematic gaming, abuse or delays in the provision of care in an attempt to qualify for the two-midnight presumption. Thus, if medically necessary treatment was not provided on a continuous basis throughout the hospital stay and the services could have been provided over a shorter time frame, the two-midnight presumption will not apply. [78 Fed. Reg. 50496, 50949 (Aug. 19, 2013)] Medical reviewers will select claims for review under a presumption that the occurrence of two midnights after admission appropriately signifies an inpatient status for a medically necessary claim. [78 Fed. Reg. 50496, 50952 (Aug. 19, 2013)]

In promulgating the two-midnight rule, CMS also clarified rules surrounding physician certification and inpatient admission. As a condition of Part A payment for inpatient services, a physician or other qualified practitioner knowledgeable about the patient's hospital course, medical plan of care, and current condition must order the inpatient admission. The order must "specify the admitting practitioner's recommendation to admit 'to inpatient,' as an inpatient, 'for inpatient services,' or similar language specifying his or her recommendation for inpatient care." [78 Fed. Reg. 50496, 50942 (Aug. 19, 2013)] The admitting practitioner must be qualified and licensed and have admitting privileges at the hospital as permitted by state law. The decision may not be delegated and must be furnished at or before the time of inpatient admission. [42 C.F.R. Section 412.3] The admission order cannot be effective retroactively, but a verbal inpatient admission order initially documented by staff in the medical record may be used if the practitioner properly authenticates (signs, dates and times) documentation of the verbal order prior to discharge and in accordance with applicable hospital rules or state law. [78 Fed. Reg. 50496, 50941 (Aug. 19, 2013)] Finally, the physician must complete, sign and document his or her certification of each hospital inpatient admission in the medical record prior to discharge. This certification includes the timely admission order along with the physician's certification of the following:

1. That the services were provided in accordance with 42 C.F.R. Section 412.3;
2. The reasons for hospitalization of the patient or special or unusual services for cost outlier cases;

3. The estimated length of stay; and
4. Plans for post-hospital care, if appropriate.

Under the 2019 IPPS Final Rule, CMS acknowledged that the strict documentation requirements for admission orders were leading to payment denials of medically necessary inpatient admissions. As a result, 42 C.F.R. Section 412.3(a) was revised to remove the requirement that the admission order be present in the medical record as a specific condition of Part A payment. This does not change the requirement that a beneficiary becomes an inpatient when formally admitted as an inpatient under an order for inpatient admission, and hospitals and physicians are still required to document relevant orders in the medical record to substantiate medical necessity requirements. [83 Fed. Reg. 41144, 41510 (Aug. 17, 2018)]

The certification must be signed by the physician responsible for the case or by another physician who has knowledge of the case and is authorized to do so by the responsible physician or by the hospital's medical staff. [42 C.F.R. Section 424.13]

Value-Based Purchasing

Section 3001 of the Patient Protection and Affordable Care Act established the Value-Based Purchasing (VBP) program, which applies to discharges made on and after Oct. 1, 2012. Under the program, CMS applies a value-based modifier to acute care hospital payments. The modifier reflects each hospital's performance on certain quality measures during a set performance period as compared to its performance or the performance of other hospitals on these measures during an earlier baseline period. The measures are focused on the clinical process of care, the patient experience of care, outcomes, and efficiency. Performance is measured based on hospital-reported data for each measure (e.g., the frequency with which heart failure patients receive certain discharge instructions, patient responses on the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey, and the 30-day mortality rate for heart failure patients).

Under the 2018 IPPS Final Rule, CMS replaced the pain management questions in the HCAHPS Survey with a composite measure termed Communication About Pain, which focuses on the hospital's communications with patients during the hospital stay about the occurrence, frequency and duration of the patients' pain. This change took effect with surveys administered in January 2018. [82 Fed. Reg. 38331 (Aug. 24, 2017)]

Under the 2019 IPPS Final Rule, CMS indicated that it will periodically review and revise the included quality measures in an effort to reduce costs and complexity of the program while continuing to incentivize improvement in the quality and value of care. CMS identified four measures to be removed from the VBP program, which were already covered by either the Hospital Readmissions Reduction Program or the Hospital-Acquired Condition (HAC) Reduction Program. These four measures were removed:

1. Elective Delivery;
2. Hospital-Level, Risk-Standardized Payment Associated With a 30-Day Episode-of-Care for Acute Myocardial Infarction;
3. Hospital-Level, Risk-Standardized Payment Associated With a 30-Day Episode-of-Care for Heart Failure; and

4. Hospital-Level, Risk-Standardized Payment Associated With a 30-Day Episode-of-Care for Pneumonia.

B. Medi-Cal Inpatient Billing

Claims Submission

Hospitals bill the Medi-Cal program for inpatient services using the UB-04 claim form. Most claims for inpatient services can also be submitted through Computer Media Claims (CMC) system. The CMC *Billing and Technical Manual* that provides submission instructions is available online at https://files.medi-cal.ca.gov/pubsdoco/CTM_manual.aspx. For providers submitting paper claims, there are specific requirements regarding the format and completion of such claims. These requirements are available at: http://files.medi-cal.ca.gov/pubsdoco/billing_tips/billing_tips_paper.aspx.

Providers should refer to the "UB-04 Special Billing Instructions for Inpatient Services," the "UB-04 Submission and Timeliness Instructions" and the "UB-04 Tips for Billing: Inpatient Services" in the *Medi-Cal Provider Manual*. These resources are available at www.medi-cal.ca.gov.

In general, bills for services provided pursuant to the Medi-Cal program must be "received" by the fiscal intermediary within six months following the month of service [Welfare and Institutions Code, Section 14115(a); Title 22, California Code of Regulations, Section 51008(a)]. **"Month of service"** is defined as the month in which a service is provided, or supplies are furnished [Title 22, California Code of Regulations, Section 51008(b)(1)(A)]. If a provider submits a bill for service between 6 and 12 months after the month of service without good case, reimbursement will be reduced by 25 percent for claims submitted seven to nine months after service, and 50 percent for claims submitted 10 to 12 months after service [Welfare and Institutions Code Section 14115(c)].

Upon a showing of good cause, the Department of Health Care Services (DHCS) may receive and authorize processing of late claims without the associated reduction in payment [Welfare and Institutions Code, Section 14115(b); Title 22, California Code of Regulations, Section 51008.5]. For example, a provider may submit a claim for up to one year after the month in which the service was provided if the patient failed to present identification as a Medi-Cal beneficiary due to incapacity or deliberate concealment [Title 22, California Code of Regulations, Section 51008.5(a)(1)]. Other types of "good cause" include, but are not limited to:

1. Delay related to billing other coverage;
2. Initiation of legal proceedings to obtain payment of a liable third party;
3. Delay or error in the certification or determination of Medi-Cal eligibility by the state or county;
4. Damage to, or destruction of, the provider's business office or records by a natural disaster;
5. Delay of required authorization by the Medi-Cal Field Services, Professional Standards Review Organization or California Children's Services;
6. Delay by DHS in enrolling a provider;
7. Theft, sabotage or other deliberate, willful acts by an employee; and

8. Other circumstances that are clearly beyond the control of a provider that have been reported to the appropriate law enforcement or fire agency.

[Title 22, California Code of Regulations, Section 51008.5(a)(2)-(4)] The following circumstances are not considered "good cause":

1. Negligence by employees;
2. Misunderstanding of, or unfamiliarity with, Medi-Cal regulations;
3. Illness or absence by any employee trained to prepare bills; and
4. Delays caused by the U.S. Postal Service or any private delivery service.

[Title 22, California Code of Regulations, Section 51008.5(b)]

Medicare/Medi-Cal Crossover Claims

Claims for Medicare/Medi-Cal recipients must first be billed to the appropriate Medicare intermediary. Typically, patients are eligible for Medicare if they are 65 or older, blind or disabled. If Medicare approves the claim, it must be submitted to the Medi-Cal program as a crossover claim. Crossover claims do not require a Treatment Authorization Request (TAR).

California law limits Medi-Cal's reimbursement for a crossover claim to an amount that, when combined with the Medicare payment, does not exceed Medi-Cal's maximum allowed for similar services. [Welfare and Institutions Code Section 14109.5]

Providers must submit Medicare payment or denial documentation with their claims for all Medi-Cal recipients for whom the Medi-Cal eligibility verification system indicates Medicare coverage. Claims lacking sufficient documentation will be denied. Providers should refer to the Medi-Cal Provider Manual for examples of acceptable documentation and for specific instructions on claim submission [*Medi-Cal Provider Manual, Inpatient Manual*, Part 2: Billing and Policy, Inpatient Services, Medicare/Medi-Cal Crossover Claims, available at: https://files.medi-cal.ca.gov/pubsdoco/Publications/masters-MTP/Part2/medicrip.pdf]

Providers must bill as a straight Medi-Cal claim if:

1. The services are not covered by Medicare;
2. Medicare benefits have been exhausted;
3. Medicare has denied the claim; or
4. The recipient is not eligible for Medicare.

Providers are required to submit formal documentation indicating a recipient is not eligible for Medicare when billing Medi-Cal for the following recipients:

1. Recipients age 65 or older (for example, those with alien status).
2. Recipients for whom the Medi-Cal eligibility verification system indicates Medicare coverage.

Crossover claims for Medicare Part A acute care inpatient services are paid based on a "comparative pricing" methodology. There must be a "service by service" comparison of the rate payable by a state Medicaid agency to the amount paid by the Medicare program for the same service. For Medi-Cal purposes, these claims are priced at an amount equal to what Medi-Cal would pay for a Medi-Cal only claim, but the Medi-Cal reimbursement will

not exceed the co-insurance and/or deductible amount(s) billed on the claim. Thus, if the Medi-Cal only payment for a claim would be less than what Medicare pays (excluding any co-insurance or deductible), then no Medi-Cal payment will be made for the claim. If the Medi-Cal only payment would be greater than Medicare's share of the claim, then Medi-Cal will pay the provider, but never more than the patient's co-insurance or deductible.

Moreover, providers who accept persons eligible for both Medicare and Medi-Cal cannot bill those patients for the Medicare deductible and co-insurance amounts. These amounts are to be billed to the Medi-Cal program. [Welfare and Institutions Code Section 14019.4(a)] However, some recipients who are entitled to Medicare also have Medi-Cal with a share of cost (SOC). In these cases, the patient's liability is limited to the amount of the Medicare deductible and co-insurance. Providers should bill recipients for any Medi-Cal SOC. [Welfare and Institutions Code Section 14019.4(g)] Any payments received from a Medi-Cal recipient, except for SOC payments, must be refunded upon receipt of Medi-Cal's Remittance Advice Details for that service. *(See Welfare and Institutions Code Section 14019.3.)*

Administrative Days

An acute administrative day rate is used to reimburse a hospital for services rendered to a patient awaiting placement in a Nursing Facility Level A or Nursing Facility Level B. Prior authorization is required from the local Medi-Cal field office and the patient's medical and nursing needs must meet the requirements for placement in a Level A or Level B facility.

When an acute administrative day is approved, revenue code 169 must be used when the provider bills for accommodation charges. Claims will be denied if they contain a mixture of acute administrative days and any other revenue code.

Additionally, there are limits on the reimbursement of ancillary services provided during acute administrative days. Only codes with a dagger (†) in the Ancillary Code section of the Medi-Cal Provider Manual are reimbursable.[4]

Treatment Authorization Requests (TARs)

Providers should note that, effective Oct. 1, 2019, CMS has authorized the Superior Systems Waiver (SSW) program for a five year period through Sept. 30, 2024. The SSW program allows acute inpatient hospitals to conduct a utilization review process using nationally recognized, evidence-based medical criteria in lieu of TAR authorization. As a result, the TAR requirements described in this part of the manual do not apply to reimbursement for acute inpatient hospital services for providers operating under the SSW. Information regarding the SSW application and procedures may be found at https://www.dhcs.ca.gov/services/medi-cal/Pages/SuperiorSystemsWaiver.aspx.

Certain medical procedures and services require authorization from Medi-Cal field offices before reimbursement is approved. For example, all inpatient hospital stays require authorization. Other services that require authorization are identified in the policy sections throughout Part 2 of the Medi-Cal provider manual. Providers should take note that a TAR must be submitted for the inpatient stay days whether or not any procedure performed during the stay requires a TAR. Authorization may be requested by either the physician performing the procedure or the hospital providing the inpatient stay.[5]

4 For a complete list of codes that may be billed during an acute administrative day, refer to the *Medi-Cal Inpatient Provider Manual*, Part 2: Billing and Policy, Inpatient Services, Ancillary Codes, available at www.medi-cal.gov

5 For a complete list of codes that may be billed during an acute administrative day, refer to the *Medi-Cal Inpatient Provider Manual*, Part 2: Billing and Policy, Inpatient Services, Ancillary Codes, available at www.medi-cal.gov.

The Medi-Cal Provider Training Workbooks include a useful TAR module, available online at http://files.medi-cal.ca.gov/pubsdoco/outreach_education/workbooks/modules/bb/tar_bb.pdf.

Providers generally should request authorization before rendering a service. If a Medi-Cal field office consultant denies authorization for a given hospital inpatient day, none of the services rendered to the recipient in the hospital for that date of service are reimbursable. This includes physician or ancillary services and emergency room, diagnostic, therapeutic, surgical and recovery services.

TAR forms may be found at http://files.medi-cal.ca.gov/pubsdoco/forms.aspx.

TAR Submission and Information Requirements

The majority of providers request authorization using a Treatment Authorization Request (Form 50-1). TARs are usually submitted by mail or electronically. Providers submit electronic treatment authorization transactions via the current electronic TAR (eTAR) system. Using eTAR is recommended as it eliminates mail and paper processing time. However, Medi-Cal has requested that providers do not update paper TARs using the eTAR application and submission process. If the paper TAR submission process was started, providers should complete the process in the same manner. Providers should no longer submit paper TARs to Medi-Cal field offices. Paper TARS should now be submitted to the TAR Processing Center to one of the following addresses, accompanied by documentation supporting the medical necessity of the service(s):

Attn: TAR Processing Center
California MMIS Fiscal Intermediary
820 Stillwater Road
West Sacramento, CA 95605-1630

Attn: TAR Processing Center
California MMIS Fiscal Intermediary
P.O. Box 13029
Sacramento, CA 95813-4029

The authorization request must include:

1. Principal and significant associated diagnoses;
2. Physician or licensed medical practitioner's signed prescription or inpatient doctor's order;
3. Medical condition necessitating the services; and
4. Type, number and frequency of services to be rendered by each provider.

If it is necessary for a Medi-Cal recipient to remain in a hospital for more days than authorized on the original TAR, the hospital is responsible for completing and submitting a "Request for Extension of Stay in Hospital" (Form 18-1). Information about the "TAR Request for Extension of Stay in Hospital" (Form 18-1) is located in the "TAR Request for Extension of Stay in Hospital" (Form 18-1) (tar req ext) section and the Diagnosis-Related Groups (DRG): Inpatient Services (diagnosis ip) section in the Part 2 *Inpatient Services Provider Manual*.

If, during the performance of an approved procedure, a provider determines that an additional and/or different procedure is medically necessary, the provider should submit a

new TAR to the TAR Processing Center or via eTAR with all appropriate justification. The submission should include a reference to the TAR number and procedure previously approved.

To request authorization for more than six items for a single recipient, the provider must submit more than one TAR. Six items are entered on the first TAR and the remaining items on subsequent TARs. Providers must cross-reference the TAR Control Numbers (TCNs) in the Medical Justification areas on each TAR (for example, TAR 00631304076 relates to TAR 00631304077).

Review of Adjudication Responses(AR)

Providers no longer receive TAR adjudication results on a paper TAR. Instead, providers receive an AR via the internet with the following information, as appropriate:

1. The status of the requested services
2. Information required to submit a claim for TAR-approved services
3. The reason(s) for the decision(s)
4. TAR decisions resulting from an approved or modified appeal
5. The TAR consultant's request for additional information, if necessary
6. The Pricing Indicator (PI) needs to be added to the TAR Control Number (TCN) when submitting a claim

Providers should keep a copy of the AR for resubmitting a deferred paper TAR, or when requesting an update or correction to a previously approved or modified paper TAR.

TAR Appeals

Providers may appeal TAR denials (for services other than vision) by submitting a written appeal within 180 calendar days from the date of the TAR, which is the date a decision on the TAR is made by the Medi-Cal consultant. Appeals must be sent to the TAR Processing Center Appeals at one of the following addresses:

TAR Processing Center Appeals
820 Stillwater Road
West Sacramento, CA 95605-1630

TAR Processing Center Appeals
P.O. Box 13029
Sacramento, CA 95813-4029

The Medi-Cal Clinical Assurance & Administrative Support Division (CAASD) in Sacramento handles the appeals process. The written appeal must include:

1. A copy of the Adjudication Response (AR) indicating the TAR was denied or modified and the service type requested. The AR lists the status of all service line submitted on the TAR. For additional information about ARs, providers may refer to "TAR Status on Adjudication Response" in the TAR Overview section of the Part 1 manual.
2. Date(s) or service(s) in dispute

3. Reason the appeal should be granted
4. Medical records and any additional documentation that a provider submits to support the conclusion that services are medically necessary
5. A new, completed paper TAR for the services appealed

[*Medi-Cal Provider Manual*, Part 2, "TAR: Submitting Appeals," (tar submit), page 1]

Provider-Preventable Conditions

As of July 1, 2012, all providers are required to report "provider-preventable conditions" (PPCs) that occur during treatment of Medi-Cal patients. Providers must report all PPCs that are associated with claims for Medi-Cal payment or with courses of treatment furnished to Medi-Cal patients for which Medi-Cal payment would otherwise be available. Providers do not need to report PPCs that existed prior to the provider initiating treatment for the beneficiary. Therefore, it is important for providers to properly document any PPCs present on admission.

For fee-for-service and Managed Care Plan Medi-Cal beneficiaries, providers must report PPCs through online reporting to DHCS within five working days of discovery of the PPC and confirmation that the patient is a Medi-Cal beneficiary. For beneficiaries enrolled in a Managed Care Plan, providers must also report to the beneficiary's plan. More information regarding reporting requirements is available at https://www.dhcs.ca.gov/individuals/Pages/PPC_Reporting.aspx.

Additionally, Medi-Cal will not pay providers for treatment of PPCs, unless such PPCs existed prior to the initiation of treatment of the patient by the provider. Reduction in payments will occur for PPCs that result in an increase in payment and to the extent that Medi-Cal can reasonably isolate the portion of payment directly related to the PPC. DHCS will investigate all reports of PPCs, including those it discovers through means other than self-reporting, to determine if payment adjustment is necessary. Specific information on payment reduction methods can be found in the State Plan Amendment for PPCs, available at www.dhcs.ca.gov/formsandpubs/laws/Documents/Recent%20Amendment%2012-004.pdf.

PPCs consist of "health care-acquired conditions" (HCACs) and "other provider-preventable conditions" (OPPCs). Medi-Cal HCACs consist of all Medicare HACs. (For the list of current HACs, "Hospital-Acquired Conditions," page 4.9). Only HACs occurring in acute inpatient hospital settings must be reported. OPPCs must be reported if they occur in any health care setting. Currently, the three OPPCs are as follows:

1. Wrong surgical or other invasive procedure performed on a patient;
2. Surgical or other invasive procedure performed on the wrong body part; and
3. Surgical or other invasive procedure performed on the wrong patient.

It should be noted that reporting PPCs for a Medi-Cal beneficiary does not preclude or satisfy the reporting of other reportable adverse events and health care-associated infections that are required by law.

Additional information and updates regarding PPCs can be found online at www.dhcs.ca.gov/individuals/Pages/PPC_Medical_Clarification.aspx. There is a FAQ section posted online at www.dhcs.ca.gov/individuals/Pages/PPC_FAQ_Landing_Page.aspx. In addition, hospitals may email questions about PPCs to PPCHCAO@dhcs.ca.gov.

V. OUTPATIENT BILLING

A. Medicare Outpatient Billing

Introduction

Hospitals are reimbursed for outpatient services rendered to Medicare beneficiaries based on the CMS OPPS. The Healthcare Common Procedure Coding System (HCPCS) forms the basis for reimbursement. Each reported procedure code is assigned to a corresponding Ambulatory Payment Classification (APC) which determines the hospital's reimbursement regardless of the specific level of resources actually required to provide the individual service. Errors and mistakes in procedure coding may subject a hospital to civil or criminal liability for submission of false claims. *(See chapter 3, "Federal and State False Claims Acts," for more information.)*

Procedure code modifiers are also used for outpatient coding. Modifiers are two-digit codes (listed after the procedure code and separated from the CPT and HCPCS code by a hyphen) that are used to communicate that the service or procedure performed was changed by a specific circumstance that did not affect the use of the CPT or HCPCS code. The list of current modifiers is contained in the CPT coding manual. Hospitals should monitor CMS transmittals and program memoranda that may introduce new modifiers or alter the application of modifiers for claims submission and reimbursement purposes.

Hospitals should ensure that their outpatient documentation practices result in claims based on complete medical records that support the levels of service claimed. The OIG requires that upon request, a hospital must provide documentation, such as patients' medical records and physicians' orders, to support the medical necessity of a service the hospital has provided. Claims not supported by the medical record may also be considered false claims.

LCDs issued by MACs should be incorporated into the hospital's regular coding and billing operations. The LCDs identify certain procedures that are reimbursable only when specific conditions are present. LCDs are published at www.cms.gov/Medicare/Coverage/DeterminationProcess/LCDs.

Availability of OPPS Reimbursement for Services in an Off-Campus Hospital Outpatient Department

Section 603 of the Bipartisan Budget Act of 2015 contained a site-neutral payment provision, under which the outpatient services of certain off-campus hospital outpatient departments are no longer eligible for OPPS payment after Dec. 31, 2016. This rule applies only to off-campus hospital outpatient departments, which are defined as those departments of a provider (as defined in 42 C.F.R. Section 413.65(a)(2)) that are not located on the main hospital campus or within 250 yards of a remote location of a hospital facility. [42 U.S.C. Section 1395l(t)(21)(B)(i)] The statute exempts items and services rendered by dedicated emergency departments, which continue to be reimbursable under OPPS [Id. at 1395l(t)(21)(A)]. The statute includes a grandfathering provision, under which off-campus hospital outpatient departments that were billing under OPPS for services furnished prior to Nov. 2, 2015 (the date of enactment of the Bipartisan Budget Act) are excepted from the prohibition on OPPS reimbursement [Id. at 1395l(t)(21)(B)(ii)]. On Dec. 13, 2016, Congress amended section 603 to provide an additional exception for outpatient departments that were mid-build as of Nov. 2, 2015. For CY 2017, mid-build departments for which a provider-based attestation had been submitted prior to Dec. 2, 2015, were excepted [Id. at 1395l(t)(21)(B)(iii)]. For CY 2018 and after, mid-build departments are excepted provided that:

1. A provider-based attestation was submitted prior to Feb. 13, 2017,
2. The department was added to the hospital's enrollment, and
3. By Feb. 13, 2017, the chief executive officer or chief operating officer submitted a written certification that the department meets mid-build requirements (i.e., a binding written agreement with an outside unrelated party for the actual construction of the department was in place before Nov. 2, 2015).

[Id. at 1395l(t)(21)(B)(iv)]

In 2019, CMS even reduced payment for off-campus outpatient services that were specifically covered by the grandfathering provision, causing a court battle that resulted in a December 2019 federal court decision blocking the reduction and ordering CMS to pay back grandfathered hospitals. However, CMS has indicated that it will appeal the decision and press ahead with payment reductions in 2020, which were not blocked by the court's decision. Hospitals should consult their legal counsel for updates on this ongoing litigation.

Claims for items and services furnished by non-excepted, off-campus hospital outpatient departments may still be payable, but at a lower rate based on the Medicare Physician Fee Schedule (PFS) [42 C.F.R. 419.48]. CMS calculates this lower rate by multiplying the OPPS reimbursement rate by a "PFS Relativity Adjuster," which was 50 percent in CY 2017 and 40 percent in CYs 2018 and beyond. Hospitals must use the "PN" modifier when billing Medicare for non-excepted, off-campus outpatient items and services. Alternatively, such locations can be separately enrolled as non-hospital locations and reimbursed under an applicable payment systems, such as the physician fee schedule or the Ambulatory Surgical Center payment system [Id. at 1395l(t)(21)(C)]. Hospitals must use the "PO" modifier when billing Medicare for excepted, off-campus outpatient items and services, and starting in CY 2019, must use the "ER" modifier when billing Medicare for items and services furnished in an off-campus emergency department.

Partial Hospitalization

A **"partial hospitalization program"** (PHP) is a distinct and organized intensive ambulatory psychiatric treatment service offering less than 24-hour daily care other than in an individual's home or in an inpatient or residential setting. Patients admitted to a PHP generally have an acute onset or decompensation of a covered Axis I mental disorder that severely interferes with multiple areas of daily life. As such, a PHP treatment program should closely resemble that of a highly structured, short-term hospital inpatient program. Treatment goals should be measurable, functional, time oriented, medically necessary and directly related to the reason for admission. [*Medicare Benefit Policy Manual*, Pub. 100-02, chapter 6, Section 70.3 and 70.3.A]

Patients admitted to a PHP must be under the care of a physician who certifies the need for at least 20 hours of treatment per week. Two types of patients meet PHP coverage criteria: those who have been discharged from an inpatient treatment program and the PHP is provided in lieu of continued hospitalization, and those who, in the absence of the PHP, would be at risk of requiring inpatient care. Patients must have a need for intensive and active treatment of their condition to maintain a functional level and prevent relapse or hospitalization in order to qualify for the PHP benefit. Each patient medical record must contain a physician certification that the individual would otherwise require inpatient care

in the absence of PHP services. Further, each patient's physician must recertify that the beneficiary would require impatient psychiatric care in the absence of a continued stay in the PHP on the 18th calendar day following admission to the PHP and at least every 30 days thereafter. [*Medicare Benefit Policy Manual*, Pub. 100-02, chapter 6, Section 70.3.B]

Examples of programs that would not constitute a PHP include one comprised primarily of diversionary activity, social or recreational therapy, or one that only monitors or manages medications for stable psychiatric patients. [*Medicare Benefit Policy Manual*, Pub. 100-02, chapter 6, Section 70.3.A] Non-appealable "benefit category denials" are issued for billing PHP services for day care programs, programs attempting to maintain psychiatric wellness, and for psychiatrically stable patients or those needing medication management only. Similarly, non-appealable coverage denials are issued based on excluded services such as inpatient care, meals, transportation, self-administered medications and vocational training. [*Medicare Benefit Policy Manual*, Pub. 100-02, chapter 6, Section 70.3.B.4]

Hospitals must component bill for PHP services. Component billing requires that a HCPCS code (if appropriate), a revenue code, and a charge identify each covered service provided. These services must be prescribed, supervised and reviewed by a physician to determine which treatment goals are realized. [*Medicare Claims Processing Manual*, Pub. 100-04, chapter 4, Section 260.1]

Complete progress notes are essential to obtaining reimbursement for PHP services. Specific areas of concern for reimbursement include lack of adequate content in the psychiatric assessment and inadequate documentation of therapeutic contact. Physician progress notes must demonstrate evidence of supervision and oversight showing a patient's progress or lack thereof. Signatures alone are not sufficient. Daily progress notes by appropriate staff must be entered for each patient and include a summary of the therapeutic activity or intervention, observation of the patient's status and responses to therapy, therapy plans, group participation, and patient behavior outside the group/program. The content of the notes must match the description used for billing within the revenue codes.

Weekly notes completed at treatment plan meetings should maximize treatment effectiveness by coordinating observations and treatment interventions. Physicians should document on a weekly basis current concrete observations of patient status and progress with reference to specific observations by the physician and staff, as well as affirming that the reasons for placement in the PHP have been reviewed and the empirical basis for continued treatment. The physician should also update references to discharge planning and indicate that all problems have been reviewed with clear documentation of the progress achieved, if any.

The MAC is likely to request the following documentation in its review of PHP services:

1. Current individualized multi-disciplinary treatment plan,
2. Psychiatric history/assessment,
3. History/physical assessment or health screen,
4. Progress notes,
5. Evidence of physician supervision,
6. Evaluation and certification,
7. Evidence of program components, and
8. Discharge summary.

The treatment plan should include the following information regarding services/interventions to be rendered:

1. Type/amount,
2. Frequency/duration,
3. Diagnosis,
4. Measurable goals,
5. Discipline providing service, and
6. Team signatures with dates.

All billable therapeutic events must contain corresponding physician orders.

Observation Days

Observation days involve a defined set of specific, clinically-appropriate services that are reasonable and medically necessary to treat the patient and evaluate whether the patient's condition necessitates an admission to the hospital as an inpatient for further treatment. The patient, who typically presents to the emergency department, requires ongoing short-term treatment, assessment and reassessment, to monitor and determine whether he or she requires further treatment as a hospital inpatient. Observation services are covered when ordered by a physician (or other individual authorized by state licensure and hospital bylaws to admit patients to the hospital or order outpatient testing). For an observation patient, typically the decision to discharge (after resolution of the symptoms/condition) or the decision to admit the patient as an inpatient can be made in less than 48 hours. In rare cases do reasonable and medically-necessary observation services last more than 48 hours. [*Medicare Benefit Policy Manual*, Pub. 100-02, chapter 6, Section 20.6] CMS expects that the two midnight rule (discussed at ""Two-Midnight" Rule," page 4.15) will "virtually eliminate the use of extended observation" because, as the second midnight of the patient's stay approaches, the physician will have greater certainty that the patient's stay will satisfy the two midnight benchmark for inpatient status. [78 Fed. Reg. 50496, 50946 (Aug. 19, 2013)]

Observation time begins at the clock time documented in the patient's medical record that coincides with the time observation care is initiated pursuant to a physician's order. This does not include services that are part of another Part B service, such as postoperative monitoring for 4-6 hours following a standard recovery period. Nor would observation services be billed concurrently with diagnostic or therapeutic services for which active monitoring is part of the procedure (such as chemotherapy). Observation time ends when the medically necessary services provided to the patient are completed, or when the patient is discharged from the hospital or admitted as an inpatient. [*Medicare Claims Processing Manual*, Pub. 100-04, chapter 4, Section 290.1]

The rules related to billing for observation services have undergone several significant changes since the introduction of the OPPS in 2000. [*Medicare Claims Processing Manual*, Pub. 100-04, chapter 4, Sections 290 *et seq.*; *see also 72 Fed. Reg. 66580, 66646 (Nov. 27, 2007)*] When OPPS was first introduced, all observation services were packaged services, and thus no separate payment was made for observation services, as the payment for observation was included in the APC payment for the procedure or visit with which it was furnished. This changed on April 1, 2002, when CMS created a separate APC payment for observation services that was available under certain limited circumstances. Thus, in

2002 separate payment for observation services was made if the beneficiary had chest pain, asthma or congestive heart failure (with specific diagnosis code requirements), and met additional criteria for diagnostic testing, minimum and maximum limits to observation care time (minimum eight hours), requirements for physician care and documentation in the medical record. [72 Fed. Reg. 66580, 66646 (Nov. 27, 2007)] CMS also made clear that observation services were never separately payable when associated with a procedure that has a "T status indicator" on the day of, or day before, observation care.

Beginning on Jan. 1, 2006, hospitals were required to report all observation services, whether separately payable or packaged, under one of the following HCPCS codes:

1. G0378 (Hospital observation service, per hour), or
2. G0379 (Direct admission of patient for hospital observation care).

However, separate payment for observation remained limited to the specific circumstances described above, e.g., where the patient met the diagnosis requirements (congestive heart failure, chest pain or asthma), time requirements (eight hours), received certain additional hospital services (emergency department visit, clinic visit, critical care, direct referral), and received a physician evaluation. [*Medicare Claims Processing Manual*, 100-04, chapter 4, Section 290.4.3]

Beginning on Jan. 1, 2008, HCPCS code G0378 for hourly observation services was assigned "status indicator N," signifying that its payment is always packaged, and thus "[n]o separate payment is made for observation services reported with HCPCS code G0378." [*Medicare Claims Processing Manual*, 100-04, chapter 4, Section 290.5.1] Accordingly, "[p]ayment for all reasonable and necessary observation services is packaged into the payments for other separately payable services provided to the patient in the same encounter." [*Medicare Benefits Policy Manual*, Pub. 100-02, chapter 6, Section 20.6(B)] Therefore, payment for these services is included in the APC payment for other separately payable services on the claim.

For observation services furnished beginning Jan. 1, 2016, there may be one comprehensive APC available under certain circumstances. When observation services are billed in conjunction with a clinic visit, Type A emergency department visit (Level 1 through 5), Type B emergency department visit (Level 1 through 5), critical care services, or a direct referral as an integral part of a patient's extended encounter of care, APC 8011 can be used to obtain comprehensive payment for all services on the claim including, the entire extended care encounter. [*Medicare Benefits Policy Manual*, Pub. 100-02, chapter 6, Section 290.5.3]

However, if the hospital provides observation services in association with a surgical procedure (T status procedure) or the hours of observation care reported are less than eight, it is not eligible for APC 8011.

Hospitals may not bill beneficiaries directly for reasonable and necessary observation services for which the hospital receives packaged payment [*Medicare Claims Processing Manual*, Pub. 100-04, chapter 4, Section 290.6]. In its 2011, 2012 and 2013 Work Plans, the OIG states that it will review Medicare payments for observation services provided during outpatient visits in hospitals to assess whether and to what extent hospitals' use of observation services affects the care Medicare beneficiaries receive and their ability to pay out-of-pocket expenses for health care services.

Physician Supervision of Therapeutic Services

Therapeutic services are those services that are incident to the services of physicians in the treatment of patients. Medicare Part B pays for hospital or critical access hospital (CAH) services and supplies furnished incident to a physician or nonphysician practitioner service to outpatients, if they are furnished by or under arrangements made by the participating hospital or CAH, as an integral though incidental part of a physician's or nonphysician practitioner's services, in the hospital or CAH or in a department of the hospital or CAH, and under the "direct supervision" of a physician or a nonphysician practitioner. [42 C.F.R. Section 410.27(a)(1)(iv)] **"Direct supervision"** means the physician or nonphysician practitioner is "immediately available" to furnish assistance and direction throughout the performance of the procedure.

CMS' view of what constitutes "immediate availability" of direct physician supervision of outpatient therapeutic services has been subject to considerable flux in recent years. CMS stated in 2009 that hospital outpatient therapeutic services must be provided under the direct supervision of physicians in the hospital and in all provider-based departments of the hospital, both on campus and off campus. Although CMS initially stated that "direct supervision" required that the physician must be present and on the premises of the location and immediately available to furnish assistance and direction throughout the performance of the procedures, it has since taken the position that direct supervision requires only the "immediate availability" of a physician. [75 Fed. Reg. 71800, 72008 (Nov. 24, 2010)]

CMS also instructed Medicare contractors to suspend evaluation and enforcement of the "direct supervision" requirements for therapeutic services for outpatients in CAHs from 2010 through 2019, expanding the scope of its non-enforcement to small rural hospitals having 100 or fewer beds in 2011. A **"small rural hospital"** is one that is either geographically located in a rural area or paid through the OPPS with a wage index for a rural area.

CMS acknowledged that outpatient therapeutic services may be supervised by nonphysician practitioners, including clinical psychologists, licensed clinical social workers, nurse practitioners, physician assistants, certified nurse midwives, or clinical nurse specialists so long as the services they are supervising are within their state scope-of-practice and hospital-granted privileges. However, mid-level practitioners were not permitted to supervise the provision of certain services, including pulmonary rehabilitation, cardiac rehabilitation, or intensive cardiac rehabilitation. Only physicians were permitted to supervise those services. [42 C.F.R. Section 410.27(a)(1)(iv)(D)]

Concerning clinically-appropriate supervision, CMS stated that **"direct supervision"** is "more than the capacity to respond to an emergency, and includes the ability to take over performance of a procedure or provide additional orders." According to CMS, this meant that the supervising physician necessarily must be of the same specialty as the procedure or service being performed, or that the hospital medical staff member who supervises the services must be in the same department as the ordering physician.

Nonetheless, CMS has made it clear that, to furnish appropriate assistance and direction, "the supervisory physician or nonphysician practitioner must have, within his or her state scope of practice and hospital-granted privileges, the knowledge, skills, ability and privileges to perform the service or procedure." To ensure compliance, hospitals will likely need to take action, such as amending medical staff bylaws and rules and regulations, and credentialing numerous practitioners, so that they have the necessary privileges to perform specific

outpatient therapeutic services and procedures, and to assure that supervision rules are consistent with the new requirements. [*Medicare Benefit Policy Manual*, Pub. 100-02, chapter 6, Section 20.5.2]

CMS also clarified that compliance with the supervision requirements is a condition of coverage and in its view, a condition of payment. In particular, CMS placed particular emphasis on ensuring the quality and safety of services provided in off-campus settings and will look to identify hospital noncompliance in those locations.

However, in the CY 2020 OPPS final rule, CMS acknowledged that it had created a two-tiered system of physician supervision requirements of direct supervision for most hospital outpatient therapeutic services and only general supervision requirements for the same services in CAHs and small rural hospitals with fewer than 100 beds. CMS determined that data had not indicated that this system had impacted the quality of such services in CAHs or small rural hospitals, and revised its position for CY 2020. As of Jan. 1, 2020, CMS uniformly requires general supervision for all outpatient therapeutic services provided by hospitals and CAHs. **"General supervision"** means that the procedure is furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the procedure. [42 C.F.R. Section 410.27(a)(1)(iv)(B)]

Similarly, as of Jan. 1, 2021, CMS requires general supervision for all non-surgical extended duration therapeutic services (NSEDTS), including the initiation portion, for which CMS previously required direct supervision [85 Fed. Reg. 85866 (Dec. 29, 2020)]. CMS will also permit direct supervision of pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services through virtual presence using audio/video real-time communications technology (excluding audio-only), subject to the clinical judgement of the supervising practitioner, until the end of the calendar year in which the COVID-19 public health emergency ends or Dec. 31, 2021, whichever comes later. CMS recently stated that, In future rulemaking, it will consider comments supporting direct supervision of cardiac rehabilitation, pulmonary rehabilitation, and intensive cardiac rehabilitation services through two-way, audio/video communication technology after the COVID-19 public health emergency ends [86 Fed. Reg. 63750 (Nov. 16, 2021)].

Same-Day Rule

CMS has taken the position that same-day discharges and readmissions may indicate premature discharges, medically-unnecessary readmissions or incorrect discharge coding. CMS has advised hospitals to review discharges and readmissions carefully for prudent clinical decision making and proper coding.

Generally, hospitals must include on a single OPPS claim all services provided to the same patient on the same day. This general rule applies to separately payable, non-repetitive hospital OPPS charges. There are some exceptions to this rule. If an individual OPPS service is provided on the same day as an OPPS repetitive service,[6] the individual service must be billed on the monthly repetitive claim. If the patient receives a non-OPPS service on the same day as an OPPS service, such as an emergency room visit, the services do not need to be

6 A repetitive service is a service repeated over a span of time, such as DME, respiratory therapy, occupational therapy, physical therapy, speech language pathology, skilled nursing, kidney dialysis and cardiac rehabilitation. [*Medicare Claims Processing Manual*, Pub. 100-04, chapter 1, Section 50.2.2]

billed on the same claim because one service is not subject to the OPPS. Charges subject to the three-day payment window[7] are also excepted from the same day rule.

Additionally, CMS has recognized that non-repetitive OPPS services furnished on the same date of service may be billed on different claims as long as all charges that pertain to each service are reported on the same claim as the HCPCS code that describes that service. CMS requires that all charges that pertain to a separately paid service be included on the same claim with the service being billed, so that the claim will accurately reflect the full cost of the service. For example, if charges for a packaged drug, recovery room time, and sterile supplies that were used in providing a surgical service are not included on the claim with the HCPCS code and line item charge for the use of the operating room, those charges would not be packaged with the charge for OR time and the claim would incorrectly lower the median cost for that surgical procedure.

Repetitive services that must be billed monthly or at the conclusion of treatment are DME rental, respiratory therapy, physical therapy, occupational therapy, speech pathology, skilled nursing, kidney dialysis, cardiac rehabilitation services and pulmonary rehabilitation services.

Coding from incomplete medical records may create problems in complying with the claim submission requirements. Hospitals should establish documentation practices that ensure medical records used for coding are complete and accurate.

Billing For Outpatient Procedures When Only Inpatient Service Provided

Reimbursement will be denied for nonphysician outpatient services that were already included in the hospital's inpatient payment under IPPS. Hospitals could face liability for submission of such claims, as CMS may consider this practice improper duplicate billing. Also, there are some procedures for which CMS has determined billing is allowed only when the service is performed in the inpatient setting. The list of inpatient-only procedures is published in the annual update to the OPPS rule. The OIG is likely to review claims that were denied for "inpatient only" reasons, particularly because Medicare beneficiaries may inappropriately be held liable for denied claims for these services.

The OIG recommends adopting the following pre-submission measures to ensure that erroneous duplicate billing of this nature does not occur:

1. Installing and maintaining computer software that identifies those outpatient services that may not be billed separately from an inpatient stay, or
2. Implementing a periodic manual review to determine the appropriateness of billing each outpatient service claim or scrutinizing the propriety of any potential bills for outpatient services rendered to inpatients, prior to submitting claims.

Post-submission, it is advisable for hospitals to test the billing process as follows:

1. Implement and maintain a periodic post-submission random testing process that examines or re-examines previously submitted claims for accuracy;
2. Inform the fiscal intermediary and any other appropriate government fiscal agents of the hospital's testing process; and

7 The inpatient PPS provides a payment amount for diagnostic preadmission services otherwise payable under Medicare Part B furnished during the three calendar days immediately preceding the date of the beneficiary's admission to the hospital. [42 C.F.R. Section 412.2(c)(5)]

3. Advise the fiscal intermediary and any other appropriate governmental fiscal agents in accordance with current regulations or program instructions with respect to return of overpayments of any incorrectly submitted or paid claims and, if the claim has already been paid, promptly reimburse the fiscal intermediary and the beneficiary for the amount of the claim paid by the government payer and any applicable deductibles or copayments, as appropriate.

[63 Fed. Reg. 8987-02, 8991 (Feb. 23, 1998)]

Payment for Interpretation of Diagnostic X-Rays in Emergency Department

The OIG has focused on payment for interpretation of diagnostic X-rays in a hospital emergency department, as the costs of diagnostic services provided to Medicare beneficiaries has significantly increased. According to the OIG's 2011 Work Plan, in 2008 the Medicare program reimbursed approximately $227 million to physicians for interpreting imaging services performed in emergency departments.

Radiology services furnished by a physician are paid on a fee schedule basis only if:

1. The services are personally furnished for an individual beneficiary by a physician;
2. The services contribute directly to the diagnosis or treatment of an individual beneficiary;
3. The services ordinarily require performance by a physician; and
4. They are identifiable, direct, and discrete diagnostic or therapeutic services furnished to an individual beneficiary, such as interpretation of X-ray plates, angiograms, myelograms, pyelograms or ultrasound procedures.

[42 C.F.R. Sections 415.102 and 415.120(a)]

Federal regulations provide that the Medicare program will reimburse for interpretations of diagnostic X-rays only when the hospital maintains a written report of the interpretation in the patient's medical record [42 C.F.R. Section 415.120(a)]. As detailed in the *Medicare Claims Processing Manual*, Pub. 100-04, chapter 13, Section 100.1, MACs generally distinguish between an "interpretation and report" and a "review" of the diagnostic procedure. The professional component of the diagnostic procedure includes the interpretation and report for the medical record (including the findings, relevant clinical issues, and comparative data if available), while merely a review of the procedure without a report would not satisfy the conditions for payment because a review is included in the emergency department evaluation and management payment. Generally, MACs will pay for only one "interpretation and report" of the X-ray furnished to an emergency room patient. MACs will reimburse a second interpretation only under unusual circumstances, such as a questionable finding on the first study that required a second opinion or if the diagnosis changed following a second interpretation of the same study. The Medicare Program does not reimburse for quality control interpretations. [*Medicare Claims Processing Manual*, Pub. 100-04, chapter 13, Section 100.1]

National Correct Coding Initiative Edits

In addition to developing a national correct coding methodology, CMS developed the National Correct Coding Initiative (NCCI) as a means of controlling improper coding that would lead to improper payment of Medicare Part B claims. The NCCI edits identify certain

codes that should not be used together because the codes are either mutually exclusive or one code is a component of the other code. If a hospital uses code pairs that are listed in the NCCI and those codes are not detected by the editing routines in the hospital's billing system, the hospital may submit duplicate or unbundled claims that may result in overpayments or in liability for a pattern of inappropriate billing. Therefore, to minimize the risk, hospitals should utilize coding software that includes current NCCI edit files. Hospitals may obtain the *National Correct Coding Initiative Policy Manual* for Medicare Services on the CMS website at www.cms.gov/Medicare/Coding/NationalCorrectCodInitEd/index. Frequently asked questions related to NCCI edits are also posted on the CMS website.

Laboratory Issues

Hospitals should develop policies and take all reasonable steps to ensure that claims for clinical and diagnostic laboratory testing services are accurate, and correctly identify the services ordered by the physician and performed by the laboratory. The hospital's written policies and procedures should require at a minimum that:

1. The hospital bills for laboratory services only after the services are performed;
2. The hospital bills only for medically-necessary services and tests actually ordered by a physician and provided by the hospital laboratory;
3. The CPT and HCPCS codes used by the billing staff accurately describe the service that was ordered and performed;
4. The coding staff:
    a. Only submit diagnostic information obtained from qualified personnel; and
    b. Contact the appropriate personnel to obtain diagnostic information if the individual who ordered the test failed to provide such information; and
5. Where diagnostic information is obtained from a physician or the physician's staff after receipt of the specimen and request for services, the receipt of such information is documented and maintained.

[63 Fed. Reg. 8987-02, 8992 (Feb. 23, 1998)]

For hospitals paid under the OPPS, beginning Jan. 1, 2014, outpatient laboratory tests generally are packaged as ancillary services and do not receive separate payment. There are some exceptions where the hospital may be eligible for separate payment under the Clinical Diagnostic Laboratory Fee Schedule (CLFS). This includes:

1. When the hospital only provides the patient with outpatient laboratory services and no other hospital outpatient services on that day; and
2. When the hospital provides an outpatient laboratory service on the same day as other outpatient services, but the lab test is clinically unrelated to the other service (the laboratory test and other outpatient services are ordered by different practitioners).

The hospital has the option of seeking separate payment under the CLFS. [*Medicare Claims Processing Manual*, 100-04, chapter 16, Section 30.3]

Billing for Tests Ordered, Performed, and Medically Necessary

CMS will pay for laboratory tests only if they meet the Medicare coverage criteria and are reasonable and necessary to treat or diagnose the patient. To be reasonable and medically necessary, all testing must be ordered by the physician or nonphysician practitioner who is treating the beneficiary (i.e., the physician who furnishes the consultation or treats the beneficiary for a specific medical problem and who uses the results in the management of the patient's specific medical condition). [42 C.F.R. Section 410.32(a)]

Use of Disease-Oriented Panels

An organ or disease-oriented panel is a panel composed of clinically-relevant groupings of automated multi-channel tests for which there is a general presumption of medical necessity (e.g., a basic metabolic panel includes calcium, carbon dioxide, chloride, creatinine, glucose, potassium, sodium, and urea nitrogen). The panels were developed for coding purposes only and should not be interpreted as clinical parameters. Organ or disease-oriented panels must be paid at the lower of the billed charge, the fee amount for the panel, or the fee amounts combined for all components. [*Medicare Claims Processing Manual*, Pub. 100-04, chapter 16, Section 90.2]

Standing Orders

Standing orders are used to order a series of laboratory tests to be done for the beneficiary at a specified frequency for a certain length of time. For blood glucose tests, the ordering physician must certify that the test is medically necessary. It is not sufficient to utilize a physician's standing order to order a series of blood glucose tests payable under the clinical laboratory fee schedule. [42 C.F.R. Section 424.24(f)]

Use of Modifiers

Modifiers are two-digit codes (listed after the procedure code and separated from the CPT and HCPCS code by a hyphen) that are used to communicate that the service or procedure performed was changed by a specific circumstance that did not affect the use of the CPT or HCPCS code. For example, to indicate a repeat clinical diagnostic laboratory test, the claim should indicate the modifier "91." To ensure correct use of modifiers, providers should become familiar with the NCDs for the most common clinical lab tests (available at www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx).

Reflex Testing

Reflex testing occurs when initial test results are positive or outside normal parameters and indicate that a second related test is medically appropriate. The reflex test will automatically occur in the case of certain findings from the initial test without further orders from the physician. This will result in additional testing charges. Reflex tests that will be performed by the hospital lab should be approved by the medical staff on an annual basis. Physicians should be informed of which tests are reflexed and given the option to order the test without the reflex test. [63 Fed. Reg. 45076-03, 45081 (Aug. 24, 1998)]

Documentation Issues

All diagnostic laboratory tests must be ordered by the physician or nonphysician practitioner who is treating the beneficiary (i.e., the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem). Tests not ordered by the physician treating the

beneficiary are not considered reasonable and necessary. The physician or nonphysician practitioner who orders a laboratory test must maintain documentation in the beneficiary's medical record supporting medical necessity for the test. [42 C.F.R. Section 410.32(d)(2)] To avoid payment denials, hospitals should have a system in place to ensure that ordering physicians or nonphysician practitioners adequately document medical necessity.

Orders Versus Requisitions

An **"order"** is a communication from the treating physician/practitioner requesting that a diagnostic test be performed. An order may be delivered in the following three ways:

1. Written document signed by the treating physician/practitioner, which is hand delivered, mailed or faxed. Note that no signature is required on orders for clinical diagnostic tests paid on the basis of the clinical laboratory fee schedule (CLFS), the physician fee schedule, or for physician pathology services;
2. Telephone call by the treating physician/practitioner or his or her office; or
3. Electronically, by the treating physician/practitioner or his or her office.

If the order is made by telephone, both the treating physician/practitioner and the testing facility must document the call in the medical records. *(See* Medicare Benefit Policy Manual*, Pub. 100-02, chapter 15, Section 80.6.1.)*

A **"requisition"** is the actual paperwork, such as a form, that is provided to a clinical diagnostic laboratory that identifies the test to be performed. It is ministerial in nature, and serves as an administrative convenience to providers and patients. A written order (which may be part of the medical record) and the requisition, are two different documents, although a requisition that is signed may also act as an order. [76 Fed. Reg. 73026, 73302 (Nov. 28, 2011)]

In 2010, CMS finalized its proposed policy to require the physician's signature on requisitions paid under the CLFS. CMS noted that the rule would not affect physicians who chose not to use requisitions. Due to concerns regarding the practical effect of the new rule, CMS decided not to enforce the policy in 2011. On Nov. 28, 2011, CMS announced a final rule reinstating the prior policy, so that a signature is not required on a requisition for Medicare purposes for a clinical diagnostic laboratory test paid under the CLFS. [76 Fed. Reg. 73026, 73304 (Nov. 28, 2011)]

State Anti-Markup Payment Limitation

In California, a health facility may not charge, bill, or otherwise solicit payment for a clinical laboratory service if the service was not actually rendered by the facility, unless disclosure is first made to the patient or third party payer. The first charge, bill, or other solicitation for payment must state the name, address, and charges of the clinical laboratory and state whether that charge is included in the total amount. This disclosure requirement does not apply if the clinical laboratory is owned or operated by the facility, or if the facility's standardized billing form requires a summary entry for all clinical laboratory charges. Further, a health facility may not charge additional charges for clinical laboratory services that it does not actually render. A number of exceptions exist, including a situation where the health facility contracts directly with a health plan so that services are provided on a prepaid basis. [Business and Professions Code Section 655.5(e)]

Medicare Referrals by Physicians Not Enrolled in Medicare

Section 6405 of the Affordable Care Act requires physicians or other eligible non-physician practitioners to enroll in Medicare to order or refer services for Medicare beneficiaries. Beginning on Jan. 6, 2014, CMS instructed contractors to deny claims for services ordered or referred by providers not enrolled in Medicare. Contractors will deny claims without a valid individual National Provider Identifier (NPI), including claims from clinical laboratories for ordered tests, claims from imaging centers for ordered imaging procedures, and claims from suppliers of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) for ordered DMEPOS. *(See MLN Matters Article #SE1305, "Full Implementation of Edits on the Ordering/Referring Providers in Medicare Part B, DME, and Part A Home Health Agency (HHA) Claims (Change Requests 6417, 6421, 6696, and 6856" (Rev. October 2015)); see also www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/MedicareOrderingandReferring.html.)* Such claims must also include the ordering and referring provider's legal name and address *(see* Medicare Claims Processing Manual*, 100-04, chapter 1, Section 80.3.2)*. To avoid claim denials, hospitals should review their policies of accepting orders or referrals from doctors not on their medical staffs. Before accepting non-medical staff orders or referrals, hospitals should check for the physician's Medicare enrollment, as well as check to ensure the physician is not on the excluded provider list.

B. Medi-Cal Outpatient Billing

Introduction

Hospital providers bill Medi-Cal for outpatient services using the UB-04 claim form. The Medi-Cal Provider Training Workbooks include a useful UB-04 module, revised September 2020, available online at https://files.medi-cal.ca.gov/pubsdoco/outreach_education/workbooks/Workbook_bb.pdf. For general billing information, providers should reference the following *Medi-Cal Provider Manual* sections:

1. UB-04 Completion: Outpatient Services, updated September 2020, available online at https://files.medi-cal.ca.gov/pubsdoco/publications/masters-mtp/part2/ubcompop.pdf;
2. UB-04 Special Billing Instructions for Outpatient Services, updated August 2020, available online at https://files.medi-cal.ca.gov/pubsdoco/publications/masters-mtp/part2/ubspecop.pdf;
3. UB-04 Submission and Timeliness Instructions, updated September 2020, available online at https://files.medi-cal.ca.gov/pubsdoco/publications/masters-mtp/part2/ubsub.pdf;
4. Share of Cost (SOC): UB-04 for Outpatient Services, updated August 2020, available online at https://filesacceptttest.medi-cal.ca.gov/pubsdoco/publications/masters-mtp/part2/shareop.pdf; and
5. UB-04 Tips for Billing: Outpatient Services, updated August 2020, available online at https://files.medi-cal.ca.gov/pubsdoco/publications/masters-mtp/part2/ubtipsop.pdf.

The Medi-Cal Provider Manuals are available at http://files.medi-cal.ca.gov/pubsdoco/Manuals_menu.aspx.

The following discussion highlights some areas where provider billing errors lead to payment delays, denials, and overpayments.[8] Denied claims may include claims that are incomplete, services billed that are not payable or information given by the provider that is inappropriate. Many Remittance Advice Details (RAD) codes and messages include billing advice to help providers correct denied claims. It is important to verify information on the original claim against the RAD.

Medicare/Medi-Cal Crossover Claims

Medi-Cal recipients are generally eligible for Medicare coverage if they are 65 years or older, blind or disabled. *Rules for billing for crossover claims are highly technical, and hospitals should consult the M*edi-Cal Provider Manual*, Medicare/Medi-Cal Crossover Claims: Outpatient Services, updated August 2020, available online at https://files.medi-cal.ca.gov/pubsdoco/publications/masters-mtp/part2/medicrop.pdf.*

Generally, claims for services provided to patients with both Medicare and Medi-Cal coverage must first be billed to the appropriate Medicare intermediary. If Medicare approves the claim, it must then be billed to Medi-Cal as a crossover claim. Providers must submit Medicare payment or denial documentation with claims for Medi-Cal recipients. Additionally, situations under which providers must bill as a straight Medi-Cal claim, include:

1. The services are not covered by Medicare;
2. Medicare benefits are exhausted;
3. Medicare denied the claim; or
4. The recipient is not eligible for Medicare.

A Treatment Authorization Request (TAR), discussed below, is necessary for services billed as straight Medi-Cal claims if the service normally requires prior authorization.

When billing Medicare noncovered, exhausted or denied services for a recipient who has other health coverage through any private insurance, the provider must bill the private insurer before billing Medi-Cal. Providers must submit formal documentation indicating the patient is not eligible for Medicare when billing Medi-Cal for patients who are age 65 years or older or for whom the Medi-Cal eligibility verification system indicates Medicare coverage. Official documentation from the Social Security Administration is acceptable to demonstrate that the patient is not eligible for Medicare.

Treatment Authorization Requests and Appeals

Outpatient clinics use TARs to request approval for certain procedures and services.[9] Providers may bill Medi-Cal for TAR authorized services only after an approved TAR is received from the Medi-Cal TAR Processing Center. Notably, providers no longer receive TAR adjudication results on a paper TAR. Instead, providers receive an Adjudication Response (AR) via the internet.

TARs are discussed in more detail in “Treatment Authorization Requests (TARs),” page 4.21.

8 More information about common outpatient denials is available in DHCS's module, "Outpatient Common Denials," at https://files.medi-cal.ca.gov/pubsdoco/outreach_education/workbooks/modules/io/Workbook_opcomdenial_io.pdf. .

9 For a list of CPT-4 procedures requiring a TAR, providers should refer to the Medi-Cal Provider Manual, TAR and Non-Benefit List, revised January 2021, available online at https://files.medi-cal.ca.gov/pubsdoco/publications/masters-mtp/part2/tarandnoncd9.pdf.

Supplies and Drugs for Outpatient Services

HCPCS code Z7610 should be used by outpatient providers to bill for miscellaneous supplies, but only when the item does not have a unique billing code and the supply is not related to a surgical procedure. If the provider uses HCPCS code Z7610 for supplies used in a surgical procedure or items that have their own unique billing codes, it can result in an underpayment or denial. The following items have unique billing codes and thus should not be billed with HCPCS code Z7610:

1. IV solutions/medications
2. Injections
3. Casts
4. Crutches
5. Blood products
6. Laboratory procedures
7. Radiology procedures
8. Glasses/lenses
9. Orthotics/prosthetics
10. Surgical trays/supplies (require a UA or UB modifier)
11. Take-home medications (billed by pharmacy providers)

CPT-4 code 99070 should be used only to bill for supplies and materials provided by the physician over and above those routinely used during an office visit.

For more information, see *Medi-Cal Provider Manual*, Supplies and Drugs for Outpatient Services, (supp drug op), revised August 2020, and available online at https://files.medi-cal.ca.gov/pubsdoco/publications/masters-mtp/part2/suppdrugop.pdf.

Medi-Cal Observation Days

Unlike the Medicare program, the Medi-Cal program does not recognize outpatient observation level of care. When Medi-Cal providers order this designation, the Medi-Cal program considers the patient to be an "inpatient" for reimbursement purposes. As a result, Medi-Cal denies claims billed for outpatient observation services under Evaluation and Management Codes 99217-99220 and 99234-99236. *(See Medi-Cal Update, March 2011/Bulletin 438.)* Since the Medi-Cal program views an order for an admission to observation status the same as an order to admit to inpatient status, the inpatient Evaluation and Management codes should be used (9922199223, 99231-99233, 99238, and 99239).

VI. ADVANCE BENEFICIARY NOTICE OF NONCOVERAGE (ABN)

A. Purpose

An **"Advance Beneficiary Notice of Noncoverage"** (ABN) is a notice that the hospital provides to a Medicare beneficiary or his/her representative when the hospital offers services or items that Medicare will not pay for, or there is the probability that Medicare will not pay for them on this particular occasion. A beneficiary must receive a properly-executed ABN so

that he or she is "on notice" of liability. By signing the ABN, the beneficiary acknowledges that he or she understands the potential for liability and agrees to pay for the item or service described. This allows the beneficiary to decide whether to proceed with the services or items, knowing that the beneficiary will be responsible for payment.

ABNs are required whenever:

1. A provider believes that an otherwise covered item or service will likely be denied either as not reasonable and necessary, or
2. The item or service constitutes custodial care.[10]

ABNs are required under such circumstances because, under the Limitation on Liability (LOL) protections of the Social Security Act Section 1879, Medicare beneficiaries may not otherwise be held financially responsible for denied claims under these circumstances. [42 U.S.C. Section 1395pp(a); *Medicare Claims Processing Manual*, 100-04, chapter 30, Section 50.2.1]

If an ABN is not provided, providers may not shift financial liability for such items or services to beneficiaries if Medicare denies the claim. Furthermore, a health care provider who fails to comply with the ABN instructions risks potential financial liability and sanctions. A provider who can demonstrate that he or she did not know, and could not reasonably have been expected to know, that Medicare would not make payment will not be held financially liable for failure to give notice. However, a provider who gave defective notice may not claim that he or she did not know, or could not reasonably have been expected to know, that Medicare would not make payment, because the defective notice is clear evidence of the provider's knowledge.

Common examples of care that require delivery of an ABN include custodial care, hospice care for a patient who is not terminally ill, medical equipment and/or supplies denied in advance, and care not considered reasonable or necessary. [*Medicare Claims Processing Manual*, Pub. 100-04, chapter 30, Section 50.3.1]. These situations usually arise at the initiation, reduction or termination of care (known as "triggering events"). At these times, the beneficiary may elect to continue receiving the services that Medicare will not cover.

The provider may, but is not required to, provide an ABN for care that is statutorily excluded from the Medicare program or fails to meet a technical benefit requirement, such as a required certification. For care that is never covered by the Medicare program, such as routine eye care, dental care, routine foot care, and personal comfort items, providers may issue an ABN in place of the Notice of Exclusion from Medicare Benefits (NEMB). [*Medicare Claims Processing Manual*, Pub. 100-04, chapter 30, Section 50.3.2]

The provider must provide an ABN in a timely and effective manner to the beneficiary or the beneficiary's authorized representative. All methods to provide notice to the beneficiary (or representative) must be exhausted and these efforts must be clearly documented in the beneficiary's medical record.

Effective March 1, 2009, CMS revised the ABN process, implementing the Advance Beneficiary Notice of Noncoverage, Form CMS-R-131, for use by providers, physicians,

10 A hospital may not issue an ABN to a beneficiary who has a medical emergency or is under similar duress [*Medicare Claims Processing Manual*, Pub. 100-04, chapter 30, Sections 40.3.7 and 50.15.2].

practitioners and suppliers in all situations where a Medicare denial of payment is expected, including laboratory tests.[11] The CMS-R-131 replaces the ABN-G, ABN-L and NEMB [*Medicare Claims Processing Manual*, Pub. 100-04, chapter 30, Sections 50.1 and 50.3]. Failure of the hospital to comply with ABN instructions results in the risk of financial liability and/or sanctions and may affect compliance with Medicare Conditions of Participation.

B. ABN Standards

Proper Notice Documents

The Form CMS-R-131 is the CMS approved standard notice. Failure to use this form could render the ABN defective and the hospital liable for payment of the services or items. CMS provides the Form CMS-R-131 in both English and Spanish; the hospital should utilize the appropriate form depending on the beneficiary's language and level of understanding.[12] The hospital should document whether other translation assistance was provided in the "Additional Information" section of the form [*Medicare Claims Processing Manual*, Pub. 10004, chapter 30, Section 50.6.1].

General Notice Preparation Requirements

There are specific instructions that hospitals must follow when the use of the ABN is mandatory. There must be a minimum of two copies (including the original) so that the hospital and the beneficiary each have a copy of the notice. Any reproductions must conform to the form and manual instructions in chapter 30 of the *Medicare Claims Processing Manual*. The ABN form must not exceed one page in length, though the hospital may use additional pages to list additional services or items in accordance with CMS manual provisions. If an attachment is necessary, it must allow for clear matching of the items or services in question with the reason and cost estimate information. [*Medicare Claims Processing Manual*, Pub. 100-04, chapter 30, Section 50.6.2]

The hospital must also use a visually high-contrast combination of dark ink on a pale background and, to the extent practicable, use the fonts as they appear on the downloaded ABN from the CMS website. If the hospital is not able to do this, it should use alternative fonts that are easily readable, such as Arial or Times New Roman. There should not be any other changes to the font (e.g., italics, bold, etc.) The font size should generally be 12-point.

The hospital may either type or legibly handwrite the information in the blank spaces on the ABN. The hospital may not modify the ABN notice except as specifically allowed by the instructions provided in the Medicare Claims Processing Manual, Pub. 100-04, chapter 30, Section 50.6.2(G).

Delivery Requirements

ABNs must be provided to the beneficiary or representative far enough in advance of delivering the potentially noncovered items or services to allow sufficient time for the beneficiary to consider all available options. Additionally, to be effective, an ABN must be delivered to a capable recipient and comprehended by that recipient. All of the beneficiary's

11 The revised ABN may not be used for services or items provided by the Medicare Advantage Program or for prescription drugs under the Medicare Prescription Drug Program (Part D) [*Medicare Claims Processing Manual*, Pub. 100-04, chapter 30, Section 50.3].

12 The CMS-R-131 form and instructions are available on the CMS website at www.cms.gov/Medicare/Medicare-General-Information/BNI/ABN.html.

related questions must be answered timely, accurately, and completely to the best of the notifier's ability. The notice must be signed by the beneficiary or representative. [*Medicare Claims Processing Manual*, Pub. 100-04, chapter 30, Section 50.7.1(A)]

ABNs should be delivered in person and prior to the delivery of medical care which is potentially noncovered. If in-person delivery is not possible, notifiers may deliver an ABN in one of the following ways:

1. Telephone contact;
2. Mail;
3. Secure fax machine; or
4. Internet email.

All methods of delivery must comply with all statutory privacy requirements under HIPAA. In order to validate delivery, the notifier must receive a response from the beneficiary or his or her representative. [*Medicare Claims Processing Manual*, Pub. 100-04, chapter 30, Section 50.7.2]

Retention Requirements

The hospital must prepare the ABN with an original and at least one copy. The beneficiary (or representative) is provided with a copy of the signed and dated ABN immediately, and the hospital should retain the original copy in the beneficiary's record unless circumstances prevent retention of the original, in which case a copy of the signed document should be retained (e.g., receipt of the executed ABN delivery by fax). The hospital must retain the notice in all cases, including those where the beneficiary refuses care, refuses to choose an option on the ABN, or refuses to sign the notice. Generally, unless other applicable requirements exist under state law, the hospital must retain the notice for five years from discharge/completion of the delivery of care. Electronic retention of the signed document is permitted. [*Medicare Claims Processing Manual*, Pub. 100-04, chapter 30, Section 50.6.4].

Under California law regulating retention of medical records, if an ABN is put in the medical record it must be kept for a minimum of seven years, except for minors whose records must be kept at least one year after the minor has reached the age of 18 years, but in no case less than seven years. [Title 22, California Code of Regulations, Section 70751(c)]

Period of Effectiveness

An ABN remains effective for up to one year unless a new triggering event occurs within that period. If so, a new ABN must be provided. The hospital may give a beneficiary a single ABN describing an extended or repetitive course of noncovered treatment if the ABN lists all items and services that the hospital believes to be noncovered and the ABN specifies the duration of the treatment period. The use of a single ABN for an extended or repetitive course of treatment is limited to one year. A new ABN is required within the year if there is a change in care or additional noncovered items or services are needed. [*Medicare Claims Processing Manual*, Pub. 100-04, chapter 30, Section 50.7.1.D]

Other Considerations During ABN Completion

Beneficiary Refusal to Sign

If the beneficiary refuses to sign the ABN, the hospital should indicate the refusal to sign on the notice. The hospital may also list witnesses to this effect, though this is not required.

If the beneficiary refuses to sign the ABN, the hospital should consider not providing the services unless the health and safety of the patient, or other considerations such as civil liability, dictate otherwise. [*Medicare Claims Processing Manual*, Pub. 100-04, chapter 30, Section 50.6.5.B]

Beneficiary Changes His or Her Mind

If the beneficiary changes his or her mind after completing and signing the ABN, the hospital should have the beneficiary annotate the original ABN to include the new option and have the beneficiary sign and date the annotation. When the hospital is unable to provide the beneficiary with the ABN in person, the hospital may annotate the ABN to indicate the new choice, but must immediately forward a copy of the annotated notice to the beneficiary to sign, date, and return. In both situations, a copy of the annotated ABN must be provided to the beneficiary. If a claim has been filed, it should be revised or canceled if necessary. [*Medicare Claims Processing Manual*, Pub. 100-04, chapter 30, Section 50.6.5.A]

Routine ABN Prohibition

Hospitals are prohibited from issuing ABNs on a routine basis. **"Routine"** use of an ABN means providing an ABN to a beneficiary "where there is no specific, identifiable reason to believe that Medicare will not pay." [*Medicare Claims Processing Manual*, Pub. 100-04, chapter 30, Section 40.3.6]

However, a provider may give a single ABN to a beneficiary describing an extended or repetitive course of noncovered treatment, provided that the ABN lists all items and services that the provider believes Medicare will not cover. The ABN must also specify the duration of the period of treatment, if applicable. If during the course of treatment additional noncovered items or services are needed, the provider must give the beneficiary another ABN. A single ABN for an extended course of treatment may be used for only one year. When the specified treatment extends beyond one year, a new ABN is required. [*Medicare Claims Processing Manual*, Pub. 100-04, chapter 30, Section 50.7.1.B]

VII. MEDICARE SECONDARY PAYER

A. Purpose

Initially, the Medicare program served as the primary payer for services furnished to Medicare beneficiaries, with the exception of those covered by workers' compensation. Subsequently, Congress enacted provisions, known as the Medicare Secondary Payer (MSP) provisions, found at 42 U.S.C. Section 1395y(b), that established other insurers as initial payers of a claim for services furnished to Medicare beneficiaries. As part of their Medicare participation agreements, hospitals are required to determine whether Medicare is the primary payer for a claim or the secondary payer. As detailed in the *Medicare Secondary Payer Manual*, Pub. 100-05, chapter 3, Section 10.2, Medicare is the secondary payer when the beneficiary is:

1. Treated for a work-related injury or illness (though Medicare will consider payment if workers' compensation denies the claim);
2. Treated for an illness or injury caused by an accident and liability and/or no-fault insurance will cover the medical expenses as the primary payer;
3. Covered under their employer's (or spouse's employer's) group health plan;

4. Disabled with coverage under a large group health plan; or
5. Suffering from permanent kidney failure (end stage renal disease), within the 30-month coordination period.

If the primary payer does not pay for the services in full, then Medicare secondary benefits may be paid for the services.

B. Determining Who is the Primary or Secondary Payer

Federal law requires that the hospital bill any other primary payers prior to submitting a claim to Medicare [42 C.F.R. Section 489.20(g)]. The hospital is required to determine whether Medicare is the primary or secondary payer for each inpatient admission and outpatient encounter prior to submitting a claim to the Medicare program.[13] All known payers must be identified on the claim submission to Medicare.

To determine whether Medicare is the primary or secondary payer, the hospital must obtain necessary information from the beneficiary or his or her representative regarding any other health insurance coverage. To assist providers, CMS created the form "Admission Questions to Ask Medicare Beneficiaries," which may be used to determine which is the primary payer for the hospital services. This form can be found on the CMS website in the *Medicare Secondary Payer Manual*, chapter 3, Section 20.2.1. The beneficiary need not sign the questionnaire. However, the hospital must document the responses and maintain the information for at least 10 years after the date of service. Specific billing requirements for particular insurers and instructions on how to submit claims when there are multiple payers can be found in the *Medicare Secondary Payer Manual*, Pub. 100-05, chapter 3, Sections 30 and 40.

VIII. CREDIT BALANCES

A. Purpose

A credit balance is an improper or excess payment made to a provider as a result of a patient billing or claims processing error. Examples of credit balances include:

1. A provider is paid twice for the same service either by Medicare or by Medicare and another insurer;
2. A provider is paid for services planned but not performed, or for noncovered services;
3. A provider is overpaid because of errors made in calculating beneficiary deductible and/or co-insurance amounts; and
4. A provider bills and is paid for outpatient services included in a beneficiary's inpatient claim.

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13 Some exceptions apply. A hospital is not required to collect Medicare Secondary Payer (MSP) information to bill for reference laboratory services furnished without a face-to-face encounter between the Medicare beneficiary and the hospital. However, Medicare may still recover funds when a mistaken payment is later identified. In addition, if a hospital outpatient receives recurring services, the MSP information should be verified once every 90 days. Lastly, a hospital is not required to ask for MSP information if the beneficiary is a member of a Medicare Advantage Plan. [*Medicare Secondary Payer Manual*, chapter 3, Sections 20.1(1)-(3)]

Providers are responsible for reporting and repaying all improper or excess payments they have received from the time they began participating in the Medicare program. *(See chapter 15, "Repayment and Self-Disclosure," for detailed information on repayments.)*

Credit balances do not include proper payments made by Medicare in excess of a provider's charges, such as DRG payments made to hospitals under the Medicare prospective payment system. [*Medicare Financial Management Manual*, Pub. 100-06, chapter 12, Section 20]

B. The Medicare Credit Balance Report — Form CMS-838

Hospitals are required to use the quarterly CMS Form 838[14] to disclose Medicare credit balances. This form identifies the number of credit balances and the amounts for refund. The hospital is responsible for identifying and repaying all Medicare credit balances, regardless of how the hospital classifies the money in its accounting records — that is, liability for repayment is not relieved merely because the hospital transfers the money to another account or writes off the funds. [*Medicare Financial Management Manual*, Pub. 100-06, chapter 12, Sections 10.1 and 20]

Completing and Submitting Form CMS-838

Hospitals are required to submit the CMS-838 to the MAC within 30 days after the close of each calendar quarter [*Medicare Financial Management Manual*, Pub. 100-06, chapter 12, Section 20.1] CMS-838 should include all Medicare credit balances shown on the hospital's accounting records as of the last day of the reporting quarter. While the hospital is required to report and repay all excess payments, they need to be identified only once on the CMS-838 report. The hospital is not to report the same credit balance on subsequent reports.

CMS-838 consists of a certification page and a detail page. The detail page requires specific information about each credit balance on a claim-by-claim basis, including:

1. The beneficiary name;
2. Medicare Health Insurance Claim Number;
3. Internal control number;
4. Type of bill;
5. Admission and discharge date;
6. Date claim was paid;
7. Whether the claim is open or closed;
8. The amount of Medicare credit balance;
9. The amount of Medicare credit balance repaid;
10. The method of payment;
11. The amount of Medicare credit balance outstanding;
12. The reason for the Medicare credit balance;
13. The Value Code; and
14. The name and billing address of the primary insurer.

14 CMS Form 838 may be downloaded from the CMS website at www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS838.pdf.

An officer or administrator of the hospital must sign and date the certification page. This is required even if the hospital has no Medicare credit balances for the reporting quarter. If the MAC permits, the detail page(s) may be submitted by a secure electronic transmission [*Medicare Financial Management Manual*, Pub. 100-06, chapter 12, Section 20.2].

Exceptions

Federal regulations [42 C.F.R. Section 489.20(h)] provide a limited exception to the repayment rules when Medicare is a secondary payer. A hospital is required to repay Medicare within 60 days from the date it receives payment from a primary payer to Medicare for the same service. The *Medicare Financial Payment Manual*, Pub. 100-06, chapter 12, Section 20.7, details the specific requirements for addressing Medicare Secondary Payer (MSP) credit balances. In these cases, the hospital must report credit balances from MSP payments only if they have not been paid by the last day of the reporting period. Therefore, if the hospital has identified and repaid an MSP credit balance during the reporting quarter (because of the 60-day requirement), then the credit balance would no longer be in the accounting records and thus it would not be included on the CMS-838. If, on the other hand, the CMS-838 is due prior to expiration of the 60-day MSP repayment requirement, the credit balance will need to be included in the CMS-838 report; however, payment would not have to be made at the time the report is submitted. The hospital would need to repay the money within the 60-day time frame for repayment of MSP balances.

Another exception to submitting CMS Form-838 exists for hospitals with extremely low Medicare utilization. A **"low utilization provider"** is defined as a facility that files a low utilization Medicare cost report or files less than 25 Medicare claims per year. [*Medicare Financial Management Manual*, Pub. 100-06, chapter 12, Section 20.6] A low utilization provider must submit information to its contractor who may then authorize less than a full cost report. Under this situation, the contractor will require that the provider furnish all of the following information using program forms:

1. The first page of the applicable cost report form;
2. The officer certification sheet;
3. The balance sheet;
4. The statement of income and expense; and
5. Other financial and statistical data the contractor may deem appropriate.

[*CMS Provider Reimbursement Manual* — Part 1, Pub. 15-1, chapter 24, Section 2414.4(B)]

However, the contractor may require full cost reporting and auditing if that is necessary to serve the best interest of the program, regardless of low Medicare utilization or the amount of aggregate interim reimbursement. Under this alternate procedure, providers must submit the forms and data within the same time period required for full cost reports. [*CMS Provider Reimbursement Manual* — Part 2, Pub. 15-2, chapter 1, Section 110)B)]

When to Repay Credit Balances Owed to Medicare

The hospital is required to repay the credit balance owed to Medicare at the time the CMS-838 is submitted. This may be accomplished by check or an adjustment bill. The hospital may request an extended repayment schedule if the credit balance repayment creates a financial hardship. [*Medicare Financial Management Manual*, Pub. 100-06, chapter 12, Section 20.3][15]

Records Necessary to Support CMS-838 Data

Hospitals must develop and maintain documentation of their review of each patient record that has a credit balance, to establish whether any credit balances were owed to the Medicare program and to support preparation of the CMS-838 form. According to Section 20.4 of the *Medicare Financial Management Manual*, Pub. 100-06, chapter 12, the hospital should do the following:

1. Identify whether the patient is an eligible Medicare beneficiary;
2. Identify other liable insurers and the primary payer;
3. Adhere to applicable Medicare payment rules; and
4. Ensure that any credit balance is due and refundable to Medicare.

Failure to submit the CMS-838, or to maintain sufficient documentation to support the credit balance data, may result in the suspension of Medicare payments and the inability to participate in the Medicare program.

15 *See also* Medicare Financial Management Manual*, Pub. 100-06, chapter 12, Section 10.8 (permitting providers to request "an extended repayment schedule in accordance with Pub. 100-06, Chapter 4, Section 50").*

5 Proper Cost Reporting Practices

I. Introduction 5.1

II. An Overview of Cost Reporting 5.1

A. Current Uses for Cost Reports 5.2

B. The Importance of Accurate Cost Reporting 5.2

C. Sources of Authority Governing Cost Reporting 5.3

III. Cost Reporting Under the Medicare Program 5.3

A. Items and Services Directly Impacted by Cost Reports 5.3

B. Legacy Issues with Cost Reporting 5.4

IV. General Medicare Cost Reporting Principles 5.4

A. Cost Report Certification 5.4

B. Maintenance of Adequate Data and Documentation 5.6

C. Reasonable Cost Reimbursement 5.6

D. Appropriate Cost Apportionment and Allocation 5.7

Cost Allocation Methodologies 5.7

The Step-Down Method 5.8

The Double Apportionment Method 5.8

Statistical Proxies 5.8

Direct Assignment 5.8

V. Application of Medicare Cost Reporting Principles to Medi-Cal 5.10

VI. Significant Cost Reporting Issues for Compliance Purposes 5.11

A. Including "Appropriate" Claims on the Cost Report as a Condition of Reimbursement 5.11

B. Establishing Reserves 5.12

C. Protested Items 5.13

VII. PRRB Deadlines Suspended Due To Pandemic 5.15

VIII. Special Rules Governing Particular Types of Medicare Program Payments 5.15

A. Medicare IME/DGME Payments 5.16

Nonhospital Rotations for Cost Reporting Periods Beginning on or After July 1, 2010 (for DGME) and for Discharges on or After July 1, 2010 (for IME) 5.19

Nonhospital Rotations for Cost Reporting Periods Beginning on or After Oct. 1, 2007 and Prior to July 1, 2010 (for DGME) and Discharges on or After Oct. 1, 2007 and Prior to July 1, 2010 (for IME) 5.19
Shared Rotational/Affiliation Agreements 5.20
Consolidated Appropriations Act of 2021 ..... 5.21
Available Bed Count 5.22

B. Traditional Medicare DSH Payments 5.22
C. Uncompensated Care DSH Payments 5.25
D. Medicare Bad Debt Payments 5.28
Definitions: Non-Indigent and Indigent Beneficiaries 5.28
Reasonable Collection Efforts 5.29
Collection Agency Issues 5.29
Indigent Patients 5.31
Dual Eligible Beneficiaries 5.31
Other Medicare Bad Debt Issues 5.32
E. Medicare Outlier Payments 5.33
F. Allied Health Programs 5.34
G. Organ Acquisition Costs 5.35
H. Wage Index Data 5.37
Overstated Pension and Other Post-Retirement Benefit Costs 5.38
Misstated Wages, Fringe Benefit Costs, Home Office Costs and Nonsalary Costs 5.38
Misstated and Unsupported Costs for Contract Labor 5.38
Costs for Nonallowable Part B Services 5.38
I. FQHCs and RHCs 5.39
J. Market-Based MS-DRG Relative Weight Estimation — Repealed 5.39
K. Other Common Cost Reporting Compliance Issues 5.40

IX. Accounting for Cost Report Issues as Part of a Compliance Program 5.40
A. Training and Education 5.41
B. Auditing and Monitoring 5.41
C. Response and Prevention 5.41

FORMS & APPENDICES

HC 5-A Hospital and Hospital Health Care Complex Cost Report Certification and Settlement Summary

5 Proper Cost Reporting Practices

I. INTRODUCTION

This chapter outlines potential risks arising from cost reporting practices and offers guidance on how to avoid adjustments and reduced reimbursement. Both the Medicare and Medicaid programs require most hospital providers to submit cost reports at least annually. Even though most services for most hospitals are paid on a predetermined, prospective basis, cost reports remain significant. Accurate cost reporting serves to maximize reimbursement for cost-based services, as well as certain incentive or supplemental payments that are determined, in part, through cost report data. Every provider's goal should be to maximize reimbursement lawfully and avoid any adjustments during a desk review or audit.

Inaccurate cost report submissions can also trigger liability under federal and state statutes and can result in civil money penalties or exclusion from the Medicare or Medicaid programs altogether. Because cost reports include a statement that must be signed by the provider certifying the accuracy of the information, the government relies on the certification as a basis for alleging liability under the Federal False Claims Act (FCA) — even where providers may have unknowingly submitted inaccurate information.

This chapter gives an overview of hospital cost reporting principles and requirements, including:

1. Significant risk areas associated with improper cost reporting
2. Similarities and differences of cost reporting under Medicare and Medi-Cal
3. Special rules that govern particular Medicare payments
4. Medicare bad debts and collections
5. Accurate reporting of wage index data
6. Disproportionate share hospital (DSH)/Uncompensated care payments
7. Direct and Indirect graduate medical education reimbursement (DGME and IME)
8. Accounting needs for compliance programs

II. AN OVERVIEW OF COST REPORTING

This section provides an overview of the current uses for cost reports; the importance of, and authority governing, cost reporting; differences in cost reporting under Medicare and Medi-Cal; issues regarding cost reporting for compliance purposes; and special rules governing certain types of payments available under Medicare.

In the health care field, cost reports are reports that health facilities compile that set forth expenses incurred in a particular time period to provide health care services to beneficiaries.

A typical cost reporting period for a health care provider is the entity's fiscal year. Historically, cost reports were used by government-sponsored health care programs, principally Medicare and Medicaid, to determine reimbursement for services on a retrospective basis.

A. Current Uses for Cost Reports

The Medicare and Medicaid programs use provider cost reports to determine reimbursement. How cost reports influence reimbursement varies between (and within) the two programs for different classes of hospitals and types of services. Some items and services continue to be reimbursed based directly on information contained in provider cost reports. For most services and most hospitals, however, cost report information is relevant to reimbursement only to the extent it is used in determining prospective payment rates or certain additional, special payments. Internally, many hospitals use the cost report for planning purposes.

B. The Importance of Accurate Cost Reporting

There are several reasons why hospital providers should strive to submit cost reports that are as accurate as possible. First and foremost, accurate cost reporting will minimize exposure to various potential sources of liability. For example, the submission of inaccurate information on a cost report potentially implicates the FCA *(see chapter 3)*. Because the cost reports submitted to government payment programs include a statement that must be signed by the provider certifying the accuracy of the information contained therein, the government frequently uses the certification as a hook for alleging liability under the FCA, even where providers arguably have not knowingly submitted any objectively false information on a cost report.

Inaccurate cost report submissions also potentially trigger liability under various federal and state statutes that allow regulatory authorities to impose civil money penalties or exclusion from the Medicare or Medicaid programs altogether. The standards for liability under these statutes are discussed in more detail in other chapters of this manual *(see chapters 11 and 15)*.

Finally, inaccurate or inappropriate cost reporting practices can subject providers to an obligation to repay "overpayments." Providers that participate in Medicare and/or Medicaid are obligated to voluntarily refund any amounts they receive that were inappropriately paid. Failure to disclose and repay known overpayments can subject a provider to liability such as civil money penalties and prosecution under the FCA.

Second, just as cost reporting errors can lead to overpayments, mistakes also can lead to program underpayments. Thus, aside from potential liability, it is important for providers to work toward fully compliant cost reporting practices that properly result in complete allowable reimbursement for items and services that are cost based or determined to some extent by data included in the cost report.

Finally, accurate and strategic cost reports serve to maximize reimbursement lawfully.

Compliance Tip: Accurate cost reporting not only minimizes potential liability, but can assure complete and proper program payments.

C. Sources of Authority Governing Cost Reporting

The requirements for filing program cost reports are set forth in the statutes, regulations, instructions and bulletins that govern the Medicare and Medicaid programs. For Medicare, the relevant cost reporting requirements are mainly set out in federal statutes and regulations, particularly in Title 42 of both the United States Code and the Code of Federal Regulations. Other important Medicare rules governing cost reporting are established by program manuals promulgated by the Centers for Medicare & Medicaid Services (CMS). For hospitals, the most important CMS manual for cost reporting purposes is the Provider Reimbursement Manual, Part 1 (PRM-I) and Part 2 (PRM-II). The Provider Reimbursement Manual can be found on CMS' website at www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals.html.

Federal laws and regulations also are relevant to cost reports submitted for the purpose of Medicaid reimbursement. However, because Medicaid is administered at the state level by state agencies, the most important authorities governing Medicaid cost reporting practices are state statutes and regulations.

In California, the key statutory requirements for Medi-Cal, California's version of Medicaid, are found in the Welfare and Institutions Code, while the pertinent regulations are mainly found in Title 22 of the California Code of Regulations. As with Medicare, there are manual provisions governing Medi-Cal, promulgated by the California Department of Health Care Services (DHCS), the agency responsible for administering the Medi-Cal program. Those manuals, some of which contain rules and instructions relevant to provider cost reporting practices, can be found on DHCS' website at http://files.medi-cal.ca.gov/pubsdoco/manuals_menu.aspx.

III. COST REPORTING UNDER THE MEDICARE PROGRAM

Cost reimbursement was the original Medicare payment method for hospitals and other institutional providers. Prospective payment systems have now supplanted cost reimbursement for most purposes, including most inpatient and outpatient hospital reimbursement. However, cost reports remain important because:

1. The Medicare appeals process is slow and certain cost-based appeals are still unresolved *(see B. "Legacy Issues with Cost Reporting," page 5.4)*;
2. A few remaining services and providers are still paid either fully, or in part, based on cost report data; and
3. CMS uses cost reports to revise prospective payment rates, as well as for other purposes that can impact payments to providers.

A. Items and Services Directly Impacted by Cost Reports

Currently, cost report data have a relatively small overall direct impact on hospital payments from Medicare. The following items are paid based, at least in part, on cost report data:[1]

1. Direct Graduate Medical Education (DGME)
2. Indirect Graduate Medical Education (IME)

1 Federally Qualified Health Centers (FQHC) were paid based on cost prior to Oct. 1, 2014, when the FQHC Prospective Payment System was established.

3. DSH payments, including Uncompensated Care DSH ("UC DSH") payments
4. Medicare bad debt payments
5. Medicare outlier payments
6. Organ acquisition costs
7. Wage index data
8. Sole Community/Critical Access Hospital services
9. Cancer hospital services
10. Rural Health Clinic (RHC) services
11. Children's hospital services

Although these items and services constitute only a small percentage of total Medicare reimbursable services, they still carry a material financial impact for many Medicare participating hospitals and are addressed in more detail below.

B. Legacy Issues with Cost Reporting

Within the last 15 to 20 years, certain items were cost-based or partially cost-related, but have transitioned to prospective payment systems. These items include:

1. Capital costs
2. Hospitals and units exempt from prospective payment systems (e.g., psychiatric hospitals and units)
3. Hospital outpatient services
4. Hospital-based skilled nursing facility services

Due to the slow Medicare audit and appeals process, some hospital providers have not yet been reimbursed for these items for certain years in which payment was based, in whole or in part, on cost report data and/or have appeals pending regarding those items for the same years. Accordingly, even now, providers should be familiar with the rules and principles relevant to seeking reimbursement related to these items on a cost basis.

IV. GENERAL MEDICARE COST REPORTING PRINCIPLES

There are a number of requirements and principles providers generally must observe for all cost reports submitted to the Medicare program. As discussed below, these same principles may also apply to certain categories of reimbursement under Medi-Cal. These requirements are separate from rules governing specific types of items and services. A brief discussion of several key general cost reporting concepts follows.

A. Cost Report Certification

The cost report certification statement and the way federal courts have applied it create a strong incentive for hospital providers to strive for regulatory compliance. The certification statement is part of the Medicare cost report form and is a broad attestation as to the accuracy of the information in the cost report and the provider's compliance with applicable regulatory requirements. The certification must be made by the hospital's administrator or

chief financial officer. Currently, the certification on the cost report form, which immediately precedes the dated signature of the provider's administrator or chief financial officer, reads as follows:

> Misrepresentation or falsification of any information contained in this cost report may be punishable by criminal, civil and administrative action, fine and/or imprisonment under federal law. Furthermore, if services identified in this report were provided or procured through the payment directly or indirectly of a kickback or were otherwise illegal, criminal, civil and administrative action, fines and/or imprisonment may result.
>
> **Certification by Chief Financial Officer or Administrator of Provider(s)**
> I hereby certify that I have read the above certification statement and that I have examined the accompanying electronically filed or manually submitted cost report and the Balance Sheet and Statement of Revenue and Expenses prepared by _____ _____ (Provider Name(s) and Number(s)) for the cost reporting period beginning _____ and ending _____ and to the best of my knowledge and belief, this report and statement are true, correct, complete and prepared from the books and records of the provider in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding the provision of health care services, and that the services identified in this cost report were provided in compliance with such laws and regulations.

An example of this certification form, CHA Appendix HC 5-A, "Hospital and Hospital Health Care Complex Cost Report Certification and Settlement Summary," can be found at the end of this chapter. In light of the broad language contained in the certification, many people regard the cost report certification statement as a promise by the submitting provider of global regulatory compliance.

The cost report certification statement has become increasingly important in recent years. This is because some courts have allowed plaintiffs pursuing claims under the FCA to establish liability based on the certification. The theory is that a hospital is submitting a false claim for reimbursement if an officer of the hospital executes a certification statement attesting to regulatory compliance, but the hospital is actually in violation of some rule or requirement that applies to the items or services claimed in the cost report. Some FCA plaintiffs have used this theory of liability to advance claims against hospitals based on very technical, arguably minor regulatory requirements. Chapter 3, "Federal and State False Claims Acts," contains more information about this potential liability.

> **Compliance Tip:** The cost report certification statement has become increasingly important in recent years because some courts have allowed plaintiffs pursuing claims under the FCA to establish liability for hospitals on the theory that inaccurate cost reports are false claims.

B. Maintenance of Adequate Data and Documentation

The rules requiring adequate record keeping often cause providers difficulty. Medicare regulations require that any claims for reimbursement predicated on the cost report must be supported by adequate data based on a facility's statistical and financial records, which can be verified through an audit. The cost data must be based on an approved method of cost finding, discussed further in this chapter, and on the accrual basis of accounting. [42 C.F.R. Section 413.24]. In addition to these general documentation principles, CMS also has developed more specific rules about the type of documentation a provider must maintain to support a claim for reimbursement for particular items and services, such as Medicare bad debts. These more specific documentation requirements are covered below.

Failure to maintain adequate data and documentation, by itself, is a sufficient basis for the Medicare program to deny reimbursement for particular items and/or services. Essentially, the Medicare program, whether operating through Medicare Administrative Contractors (MACs)[2] or CMS, takes the position that unless a provider can appropriately document that an item or service was furnished to a Medicare beneficiary, the item or service was not furnished and is therefore not payable. Thus, providers should strive to make adequate documentation a high priority.

Compliance Tip: Medicare takes the position that if a service is not properly documented, it was not furnished and thus not payable to the facility.

C. Reasonable Cost Reimbursement

For items and services reimbursed on a cost basis, the Medicare program will not necessarily pay any costs claimed by a provider on a cost report, even if adequately documented. In order for Medicare to pay, the claimed costs must be reasonable and necessary "in the efficient delivery of needed health services" [42 U.S.C. Section 1395x(v)(1)(A)]. Items and services that are not deemed reasonable and necessary "for the diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body member" are excluded from Medicare coverage [42 U.S.C. Section 1395y(a)(1)(A)]. There are some types of services, such as certain experimental or investigational treatments, that are categorically deemed to be not reasonable and necessary [42 U.S.C. Section 1395y(a)(1)(D)&(E)]. For services not categorically excluded from Medicare coverage, providers must maintain documentation demonstrating the beneficiary's medical need for the service.

A corollary of the Medicare "reasonable and necessary" principle is the concept that the cost of treating Medicare beneficiaries should not be borne by non-Medicare patients and vice versa [42 U.S.C. Section 1395x(v)(1)(A)]. Commonly referred to as the "prohibition on cross-subsidization," this statutorily-established rule means that the Medicare program will pay providers only for items and services provided to Medicare beneficiaries. Consequently, hospitals participating in the Medicare program must be able to apportion costs properly between Medicare and non-Medicare patients on their cost reports.

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2 The contractors charged with processing Medicare provider cost reports were formerly known as "fiscal intermediaries" and, until recently, many Medicare regulations continued to refer to intermediaries, rather than MACs. However, in 2015, CMS made technical amendments to those regulations to ensure that those authorities now only use the term "contractor" [80 Fed. Reg. 70298, 70551 (Nov. 15, 2015)]. Since the use of the term "fiscal intermediary" has been eliminated from controlling authorities, this chapter will also use only the terms "MAC" or "contractor."

D. Appropriate Cost Apportionment and Allocation

Apportionment of allowable costs is the process of determining how to divide the total allowable costs of a provider's services between Medicare beneficiaries and non-Medicare patients. The Medicare regulations provide for a cost allocation and apportionment system designed to separate the apportionment of routine costs (often referred to as room-and-board costs) from the apportionment of other costs, called "ancillary" costs. CMS defines **"routine services"** as those generally included in a daily service charge, including the regular room, food, nursing services, minor medical and surgical supplies, social services and the use of certain equipment for which a charge usually is not made. [PRM-I (CMS Pub. 15-1), ch. 22, Section 2202.6]. **"Ancillary services"** include laboratory, radiology, drugs, delivery room, operating room and therapy services, and may include other items for which a separate charge is usually made. [PRM-I (CMS Pub. 15-1), ch. 22, Section 2202.8]. This system is based on the assumption that routine costs are equivalent for Medicare beneficiaries and non-Medicare patients on a per-day basis for a given inpatient hospital stay, but that ancillary costs vary greatly between Medicare beneficiaries and non-Medicare patients on a per-day basis. [42 C.F.R. Section 413.50(e)].

The separation of routine from ancillary costs is accomplished using what is referred to in Medicare parlance as the "departmental" method of cost apportionment [42 C.F.R. Section 413.53(a)(1)]. This method attempts to reflect actual usage of resources and services by each class of patients. Under the departmental method the ratio of Medicare beneficiary charges to total patient charges for the services of each ancillary department, such as housekeeping and administration, is applied to the cost of the department; to this is added the cost of routine services for program beneficiaries, determined on the basis of a separate average cost per diem for general routine patient care areas, taking into account, in hospitals, a separate average cost per diem for each intensive care unit, coronary care unit, and other intensive care type inpatient hospital units. This methodology assumes that a hospital's charges to each group of patients are a good proxy for the respective costs attributable to each group.

Application of the departmental method of cost apportionment requires that a provider make determinations to designate each cost as a routine service cost or assign the cost to a specific ancillary department. The Medicare program calls this allocation process "cost finding."

The cost finding process begins with the establishment of accounting categories called "cost centers" (e.g., routine service costs; ancillary service costs; general service costs, such as capital-related costs and administrative and general costs; other reimbursable cost centers; and nonreimbursable cost centers, such as the gift shop). The Medicare cost reporting forms list recommended cost centers, which can be used without prior approval. The establishment of nonallowable cost centers is required to ensure that overhead and administrative costs attributable in part to running nonreimbursable functions, such as the hospital gift shop, are allocated to those functions.

Cost Allocation Methodologies

Costs are allocated to the appropriate cost center using various methodologies. With respect to some kinds of costs, allocation is fairly easy. For example, the salaries of employees working in the hospital laboratory are attributed to the laboratory. These salary costs are known as "direct" costs and are allocated "directly" to the department utilizing the cost.

Allocation of overhead and other "indirect" costs is more difficult. Generally, the actual costs of indirect services are determined by using the "step-down" method, or the "double apportionment" method of cost finding.

The Step-Down Method

Under the step-down method, costs in each of the general service cost centers, which are indirect costs, are redistributed to the other revenue-producing cost centers. The process starts with the general service cost center serving the greatest number of other centers and then proceeds in descending order. The costs in each general service cost center are redistributed until all such costs have been distributed into the routine and ancillary cost centers that the department uses for apportionment. [PRM-1 (CMS Pub. 15-1), ch. 23, Section 2306.1; 42 C.F.R. Section 413.24(d)(1)]

The Double Apportionment Method

The double apportionment method may be used by a provider upon approval of its MAC. This method also recognizes that services rendered by certain nonrevenue-producing departments or centers are utilized by certain other nonrevenue-producing centers, as well as by the revenue producing centers. As the name implies, the double apportionment method entails two rounds of cost allocation. The first allocation of the costs of the revenue-producing centers is made to all cost centers serviced by these centers. These centers are not "closed" after the first allocation. They remain "open," accumulating their portion of the costs of all other nonrevenue-producing centers from which service is received. The first allocation is followed by a second allocation of costs involving the allocation of all costs remaining in the nonrevenue-producing centers. The second allocation effectively uses the step-down method of cost allocation, as described above. [PRM-I (CMS Pub. 15-1), ch. 23, Section 2306.2; 42 C.F.R. Section 413.24(d)(2)(i)]

Statistical Proxies

CMS directs providers to base the allocation of costs in each general service cost center on statistics. These statistics serve as proxies for actual usage of costs by particular departments. Again, CMS provides recommended statistics for allocation purposes on the Medicare cost reporting forms. For example, the capital-related costs of building and fixtures are allocated on the basis of square footage occupied by each department, and general and administrative costs are allocated on the basis of total costs otherwise accumulated in each cost center.

Direct Assignment

The alternative to statistically-based cost finding is the direct assignment of costs based on actual usage. CMS allows direct assignment only if four requirements are satisfied:

1. All costs within the general service cost center that can be directly allocated must be assigned to the benefitting cost centers as part of the provider's routine accounting process.
2. Any indirect supervision and residual costs remaining in the cost center, together with any previously allocated overhead, must be allocated through cost finding to all remaining benefitting cost centers.

3. The basis for assigning directly allocable costs of a general service cost center to the benefitting cost centers must be on a factual and auditable basis. This precludes the use of averages, estimates or statistical surrogates such as square feet. For example, the assignment of actual housekeeping salaries by each employee based on actual hours worked in the benefitting cost centers is acceptable, whereas the use of the surrogate, square feet, is inappropriate for direct assignment.

4. The basis of allocation for cost finding any indirect supervisory costs, residual costs and allocated overhead must be an appropriate measure of the benefits provided to the remaining cost centers. Any deviation from the allocation basis prescribed for cost finding must be reviewed and approved by the intermediary in advance as part of the provider's request for direct assignment of costs [PRM-1 (CMS Pub. 15-1), ch. 23, Section 2307(A)].

However, as with the double apportionment method, providers must obtain prior approval from their MAC to use the direct assignment method [PRM-1 (CMS Pub. 15-1), Ch. 23, Section 2307].

As much as possible, hospitals should make at least reasonable efforts to follow the Medicare guidelines on cost allocation and apportionment when preparing cost reports for Medicare. Given the broad nature of the certification form, failure to follow the CMS *Provider Reimbursement Manual* rules with respect to cost allocation and apportionment could fuel allegations of an FCA violation. If hospitals deviate in any way from the methods and principles of cost allocation and apportionment in the *Provider Reimbursement Manual*, they must be able to demonstrate through documentation that the methods they used resulted in a more accurate distribution of costs on the cost report than would have been achieved through use of the standard methods.

CMS has paid increased attention to cost apportionment and cost allocation issues in connection with the shift in methodology for determining payment rates under the inpatient prospective payment system, which started to take effect in the 2006 Medicare fiscal year. For a variety of reasons, inaccurate cost reporting practices, including the way hospital charges are reported, have an increased potential to skew inpatient payment rates because of the way costs are weighted under the current methodology. Along those lines, CMS has focused on trying to ensure that, as part of the cost apportionment and allocation process, hospitals match costs and charges for a given service and place them in the same cost center. Although this principle was already in existence, CMS directed its contractors to remind providers of their obligation in this regard. In addition, consistent with its directives on cost reporting accuracy, CMS changed the Medicare cost reporting form in early 2010 to address what had been identified as a particularly problematic cost reporting practice. Specifically, the cost reporting form directs hospitals to separate less costly medical supplies and higher cost implantable devices between two different cost centers on the cost report. Around the same time, for similar reasons, CMS created a new cost center for MRIs and CT scans to distinguish them from other types of radiology services and an additional new cost center for cardiac catheterization, to separate it from other types of cardiology services [78 Fed. Reg. 50496, 50504 (Aug. 19, 2013)].

CMS' attention to cost reporting issues provides an incentive to hospitals to strive for full compliance in this area. Along those lines, hospitals should make an effort to stay aware of additional announcements from the agency regarding cost reporting guidance.

Compliance Tip: Failure to follow the CMS *Provider Reimbursement Manual* rules regarding Medicare guidelines on cost allocation and apportionment could result in allegations of a False Claims Act violation.

V. APPLICATION OF MEDICARE COST REPORTING PRINCIPLES TO MEDI-CAL

As with Medicare, there are relatively few services still reimbursed on a direct cost basis under Medi-Cal. However, hospital cost reports are still important for Medi-Cal reimbursement and are required by law to be submitted to Medi-Cal authorities. Effective for dates of services rendered on or after July 1, 2013, California started reimbursing all categories of hospitals for inpatient services under a fully prospective methodology based on "diagnosis related groups" or "DRGs" [Welfare and Institutions Code Section 14105.28]. The California Department of Health Care Services (DHCS) has made clear through public notices that the conversion to the DRG-based payment system does not alter the obligation of Medi-Cal participating hospitals to submit cost reports annually. Information contained in the cost reports will be used by DHCS to set DRG-based payment amounts. *See Department of Health Care Services, "Diagnosis Related Groups-Part 1: APR-DRG Reimbursement Implementation," available at http://files.medi-cal.ca.gov/pubsdoco/bulletins/docs/20746.3Rev1-Part1.pdf.* Along those same lines, even under the DRG system, hospital cost reports remain subject to audit by DHCS.

A much higher portion of the payments to hospitals under the APR-DRG system are outlier payments than the portion of payments that are outlier payments under the Medicare DRG system. As under Medicare, outlier payments under the APR-DRG system are based to a large extent on a hospital's allowable costs determined using Medicare reimbursement principles. Outlier payments are made under fee-for-service Medi-Cal, and may also be made under managed Medi-Cal where the hospital does not have a contract with the health plan or the contact provides that payment will be based on the Medi-Cal APR-DRG system. Accordingly, costs reported on a Medi-Cal cost report can have a material impact on hospital payments. Because of this, DHCS has increased its audit scrutiny of outlier payments.

Additionally, under the Medi-Cal Hospital/Uninsured Care Demonstration Project Act, "designated public hospitals" (county and University of California hospitals) are reimbursed based in part on certified public expenditures and uncompensated costs which are determined on a cost basis, with specific adjustments [Welfare and Institutions Code Section 14166 *et seq]*. Even some of the prospective payments made under Medi-Cal for certain categories of services, such as care furnished in nursing facilities that are distinct-part units of hospitals or in hospital "subacute" units, are determined based on facility cost report information [Title 22, California Code of Regulations, Section 51511 and 51511.5]. Reimbursement for such services is generally the lower of the hospital's projected costs

based on the hospital's costs in a prior period or a statewide limit. Finally, many hospitals or hospital systems own and/or operate entities that are reimbursed in whole or in part based on methodologies dependent on an evaluation of provider costs under applicable Medi-Cal rules. These entities include rural health clinics (RHCs), federally qualified health centers (FQHCs) and certain kinds of behavioral health providers. For example, Medi-Cal pays FQHCs and RHCs using prospective rates determined based on "Medicare reasonable cost principles." [Welfare and Institutions Code Section 14132.100]

To the extent the Medi-Cal program bases certain classes of reimbursement on provider costs, or, going forward, will use provider costs to inform the setting of prospective payment rates, DHCS has established that cost reports should be compiled and maintained in accordance with Medicare cost reimbursement principles. *(See, e.g., Welfare and Institutions Code Section 14166.4 (governing reimbursement to designated public hospitals); see also Title 22, California Code of Regulations, Section 51536(a)(2) (stating that, for purposes of inpatient hospital reimbursement, allowable costs are "determined in accordance with applicable Medicare standards and principles of reimbursement."); and 51545(81)).* Accordingly, hospitals participating in the Medi-Cal program that submit cost reports should follow Medicare practices for their Medi-Cal cost reports.

VI. SIGNIFICANT COST REPORTING ISSUES FOR COMPLIANCE PURPOSES

There are a number of rules related to cost reporting that providers must be familiar with in addition to the Medicare coverage and payment rules governing particular items and services. As such, there are a number of ways that providers might inadvertently claim inappropriate costs, or claim costs in an inappropriate manner. Unfortunately for providers, it is sometimes not clear whether a particular cost was claimed appropriately due to ambiguities in government regulations. There are various ways that providers can deal with potentially problematic costs when submitting a Medicare cost report.

A. Including "Appropriate" Claims on the Cost Report as a Condition of Reimbursement

For cost reporting periods beginning on or after Jan. 1, 2016, CMS's Medicare regulations governing cost reporting expressly condition a hospital's eligibility for any type of payment determined through the cost report on the hospital having included an "appropriate claim" for the item on its cost report [42 C.F.R. Section 413.24(j)(1)]. The "appropriate claim" requirement extends to special payments, like DSH adjustments or bad debt (discussed later in this chapter). For items that the hospital believes comport with Medicare policy, the hospital must simply claim the item on the cost report in accordance with the policy. Further, if the hospital believes the claimed reimbursement item might not comport with Medicare policy (e.g., where a hospital believes CMS's current payment policy is invalid), then the hospital must expressly "self-disallow" the item on the cost report. [42 C.F.R. Section 413.24(j)(1)].

To self-disallow an item, the provider must (1) include an estimated reimbursement amount in the protested line Item of the cost report; and (2) attach a separate worksheet to the cost report explaining why the Item is being self-disallowed and describing how the estimated reimbursement amount was calculated [42 C.F.R. Section 413.24(j)(2)].

If a hospital's cost report omits a proper claim for a particular item (whether it is allowable or self-disallowed), the regulations state that payment for the item will not be included in the Notice of Program Reimbursement (NPR) issued by the MAC for the fiscal period at issue or, later, as part of any administrative review of that NPR determination.

CMS previously sought to require self-disallowance to establish jurisdiction before the Provider Reimbursement Review Board (PRRB). However, CMS effectively rescinded that jurisdictional policy for cost reporting periods starting before Jan. 1, 2016 *(see discussion of CMS Ruling 1727-R under C. "Protested Items," page 5.13)*. Instead, CMS established the above-described "appropriate claim" requirement as a condition of reimbursement for particular items [80 Fed. Reg. 70298, 70563-70564 (Nov. 13, 2015)]

CMS has made one exception to the requirement for making an "appropriate claim" in the original cost report. In finalizing the policy in the Medicare cost-reporting regulations, CMS acknowledged, in response to comments from the industry, that hospitals may not always have complete information when they are required to initially submit their cost reports. Specifically, CMS acknowledged that complete data concerning Medicaid-eligible patient days, which is needed to compute eligibility for supplemental DSH payments (discussed below), may be unavailable when the cost report is due. Problems can arise because state Medicaid agencies often have not generated Medicaid eligibility reports for particular hospitals and fiscal periods before those hospitals have to submit their Medicare cost reports for the relevant fiscal period. In such circumstances, it is impossible for a hospital to submit an "appropriate claim" for DSH reimbursement when initially filing its cost report. Thus, CMS created a limited exception to the "appropriate claim" requirement solely for this Medicaid eligible days data issue. Under that exception, a MAC "must accept one amended cost report submitted within a 12-month period after the hospital's cost report due date, solely for the specific purpose of revising a claim for DSH by using updated Medicaid-eligible patient days, after a hospital receives updated Medicaid eligibility information from the State." [80 Fed. Reg. at 70560]. In all other situations where a hospital believes it obtains or discovers information that impacts reimbursement for items claimed on an already-submitted cost report, the hospital still has the option of submitting an amended cost report, but the MAC has discretion whether or not to accept an amended cost report.

CMS' "appropriate claim" requirement makes it imperative that hospitals attempt to gather all information necessary to support reimbursement for particular items before a cost report for a particular period is due. Hospitals should decide the items they will be claiming for payment in association with a particular cost report, including any self-disallowed items, well ahead of filing their cost reports. Such advance planning will minimize any risk of failing to include all required costs and other data.

B. Establishing Reserves

Creating "reserve" cost reports is a practice that hospitals developed to account for the possibility that the Medicare program would disallow some of the costs the hospital claimed for Medicare reimbursement purposes. A **"reserve"** cost report is a second additional cost report that a hospital prepares concurrently with the cost report it will submit to the Medicare program. The provider generally takes a more conservative approach in creating the reserve cost report with respect to costs that potentially could be determined to be nonallowable by the Medicare program. The reserve cost report therefore gives the provider an idea of

the impact on Medicare reimbursement if the Medicare program, upon audit, disallows certain costs. Traditionally, providers did not disclose the existence of reserve cost reports to Medicare contractors or CMS.

For example, a hospital might establish a reserve with respect to Medicare bad debts. The hospital would claim $50,000 in inpatient bad debt and $30,000 in outpatient bad debt on the cost report it submits for Medicare reimbursement. However, the hospital also concurrently creates a reserve cost report that decreases the amount of both inpatient and outpatient bad debt by $10,000. The provider's motivation in creating the bad debt reserve may be that, in prior years, the provider's contractor disallowed a certain percentage of the provider's inpatient and outpatient bad debts. The reserve cost report would allow the provider to plan for the eventuality that the contractor will make similar disallowances for bad debt with respect to the current year cost report.

Reserve cost reporting by hospitals or hospital systems played a central role in several high profile FCA cases. The FCA plaintiffs in these cases asserted that the fact that the hospitals established reserve cost reports was evidence that the hospitals claimed reimbursement from the Medicare program that they knew was not allowable. As most of these cases were settled without a trial, no court ruled that the existence of reserve cost reports necessarily shows intent by providers to submit false claims. However, these cases make clear that a hospital's creation of reserve cost reports, at the least, gives potential relators fuel for false claims allegations *(see chapter 3, "Federal and State False Claims Acts")*.

Although reserve cost reporting is not prohibited, providers should be very cautious about undertaking or continuing the practice in the current regulatory climate. While providers may have very good arguments as to why the way they claimed certain costs on their Medicare cost reports was proper, the fact that they felt compelled to establish a reserve cost report at least suggests that there was some doubt as to whether the costs actually were allowable. Although this kind of doubt may not, by itself, be enough to create FCA liability, it is a factor that potential FCA plaintiffs could seek to use to their advantage. The potential risks of creating reserve cost reports are significant enough that providers should avoid the practice, particularly given there are more accepted ways to deal with situations when it is unclear whether or not certain costs are allowable. *(See the discussion under C. "Protested Items" below.)*

C. Protested Items

The Medicare cost reporting form gives providers a vehicle to address items and services with which they disagree with Medicare program policy, or are unclear about. Specifically, the cost report form includes lines on which to report "protested items." By claiming costs on the protested items line, the provider is indicating to the MAC that the provider disputes costs deemed nonallowable and preserves its right to appeal if the MAC disallows the costs. A provider uses the protested items line when claiming costs inconsistent with clearly expressed Medicare program policy (whether through statutes, regulations or CMS publications/issuances) or prior audit adjustments to the same kind of costs. A provider that claims costs in a manner inconsistent with either clear Medicare policy or prior audit adjustments without using the protested item mechanism may be exposed to significant civil, administrative, or criminal liability. *(See, for example, Welfare and Institutions Code Section 14171.5(b).)*

As discussed under A. "Including "Appropriate" Claims on the Cost Report as a Condition of Reimbursement," page 5.11, for cost reporting periods starting on or after Jan. 1, 2016, the Medicare cost reporting regulations require self-disallowance to potentially receive payment for an item. For each protested item, the regulations require the provider to (1) include an estimated reimbursement amount in the protested line Item of the cost report and (2) attach a separate worksheet to the cost report explaining why the Item is being self-disallowed and describing how the estimated reimbursement amount was calculated [42 C.F.R. Section 413.24(j)(2)].

Previously, for cost reporting periods starting before Jan. 1, 2016, CMS regulations required hospitals to protest any item that is arguably not allowable under Medicare policy as a prerequisite to obtaining administrative review before the PRRB, which hears Medicare cost report disputes. This regulation was first replaced by the "appropriate claim" cost reporting requirement, as discussed above, making protest a requirement for payment, rather than a prerequisite to administrative appeal jurisdiction over particular disputes. In addition, in 2018, CMS issued Ruling 1727-R (available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings/Downloads/CMS-1727-R.pdf), following the holding in *Banner Heart Hospital v. Burwell*, 201 F. Supp. 3d 131 (D.D.C. 2016). Pursuant to Ruling 1727-R, for appeals of cost reporting periods that ended on or after Dec. 31, 2008, and began before Jan. 1, 2016, that were pending or filed on or after April 23, 2018, certain types of appealed issues did not have to be claimed or protested on a cost report. If a provider did not include an item on its cost report due to a "good faith belief" that the item was subject to a payment regulation or other policy that gave the MAC no authority or discretion to make payment in the manner the provider sought, then the self-disallowance and protest requirements do not apply. A "good faith belief" that an item was not allowable exists if reimbursement for such item in the cost report would have been "futile" because the item was subject to a regulation or other payment policy that left the MAC with no authority or discretion to make payment in the manner sought by the provider. Naturally, the safest course of action is simply to protest items on the cost report.

Another potential advantage to utilizing the protested item process is that the question about whether an item claimed as protested is, in fact, payable, may now be resolved more quickly. CMS has instructed MACs to work with providers on self-disallowed items during the cost report audit process [80 Fed. Reg. 70298, 70557-59 (Nov. 13, 2015)]. If a MAC determines that an item claimed as protested is actually an allowable cost under controlling Medicare policy, the MAC is obligated to pay the provider accordingly through the relevant NPR.

Finally, using the protested items line eliminates risk from a compliance perspective as compared to taking undisclosed reserves, particularly now that CMS has established use of the protested items line as a necessary condition of reimbursement for items for which there is some uncertainty as to whether reimbursement is available under Medicare policy.

Compliance Tip: Use of the protested items line on the Medicare cost reporting form, though potentially leading to a slower reimbursement time, provides much lower risk from a compliance perspective than taking undisclosed reserves.

VII. PRRB DEADLINES SUSPENDED DUE TO PANDEMIC

On March 25, 2020, the Provider Reimbursement Review Board (PRRB or Board) issued Alert 19, suspending all "Board-Set Deadlines" starting March 13, 2020, until the Board resumes normal operations and provides "further guidance on the deadlines for these suspended filings." The suspension applies to deadlines "set to make certain filings in existing appeals including, but not limited to, deadlines for filing preliminary or final position papers, Schedules of Providers, witness lists, and case status reports ...." *See "ALERT 19: Temporary COVID-19 Adjustments to PRRB Processes (March 25, 2020)," available at:* https://www.cms.gov/Regulations-and-Guidance/Review-Boards/PRRBReview/PRRB-Alerts.

Importantly, the deadlines for filing an appeal of a Notice of Program Reimbursement (NPR) (within 180 days after notice of the NPR) or adding issues to a pending PRRB appeal (no later than 60 days following the expiration of the 180-day period) remain in effect unchanged — they cannot be suspended because they are set by statute and/or regulation and, thus, are not "Board-Set Deadlines."

Since issuing Alert 19, the PRRB has yet to issue guidance that it has resumed normal operations. Nevertheless, providers with PRRB appeals should strive to meet all case deadlines. Doing so will both avoid any risk of adverse action by the PRRB and avoid any delays that could result because of a future backlog caused by deferred filings. The PRRB is still accepting all filings and, as of Nov. 1, 2021, has made it mandatory for providers to use the Office of Hearings Case and Document Management System (OH CDMS) electronic filing system, unless an exemption applies. *(See "Revised PRRB Rules v 3.1 with Cover Order 2 (Nov. 1, 2021)," available at: https://www.cms.gov/files/document/revised-prrb-rules-v-31-cover-order-2-november-1-2021.pdf)*. This electronic filing requirement generally applies to Schedules of Providers for group appeals.

VIII. SPECIAL RULES GOVERNING PARTICULAR TYPES OF MEDICARE PROGRAM PAYMENTS

There are several categories of items and services the Medicare program still pays for based on information in the cost report. Providers must follow very particular rules to claim and receive reimbursement. As a result, these cost report-based items can present potential compliance pitfalls for hospitals. The sections below will help providers avoid problems with claiming reimbursement for the following:

1. Medicare IME/DGME payments
2. Traditional Medicare DSH payments
3. Uncompensated care DSH payments
4. Medicare bad debt payments
5. Medicare outlier payments
6. Allied Health Programs
7. Organ acquisition costs
8. Wage index data
9. FQHCs and RHCs
10. Market-based MS-DRG relative weight estimation — repealed

A. Medicare IME/DGME Payments

Compliance and documentation issues are similar for both Indirect Graduate Medical Education (IME) and Direct Graduate Medical Education (DGME) payments. DGME and IME are both formula-driven payments based in large part on the number of interns and residents trained by the hospital. For IME, as noted below, the count of available beds is also important.

A hospital's Medicare payment for DGME is calculated, in part, by multiplying the hospital's updated per-resident amount by the number of intern and resident full-time equivalents (FTEs), the product of which is then multiplied by the hospital's Medicare patient load [42 C.F.R. Section 413.76]. The per-resident amount is based on historical DGME costs per resident for the hospital's base period, which is typically 1984 or 1985 for hospitals that have been training residents since that time. For other hospitals, the per-resident amount is based on DGME costs per resident during the first year that the hospital trained residents in an approved residency training program, even if the hospital did not claim DGME costs in its Medicare cost report. Over the years, the per-resident amounts have been subject to various adjustments and caps [42 C.F.R. Section 413.77].

Payment for IME is calculated, in part, by multiplying a hospital's total diagnosis related group (DRG) revenue for inpatient operating costs by the applicable education adjustment factor [42 C.F.R. Section 412.105(e)(1)]. In calculating this educational adjustment factor, the regulations use, in large part, the ratio of intern and resident FTEs to available beds. [42 C.F.R. Section 412.105(a)(1), (d)(1)]

Both IME and DGME reimbursement is limited by intern and resident FTE caps that are generally based upon a hospital's FTEs in its cost reporting period ending on or before Dec. 31, 1996 (FTE cap) [42 C.F.R. Sections 412.105(f)(1)(iv)(A) and 413.79(c)]. There are some limited exceptions and adjustments to this 1996 FTE cap. For instance, a hospital can receive a temporary adjustment to its FTE cap if it trains residents who are displaced if a hospital or residency program closes. A hospital also can develop a new FTE cap if it trains residents in newly accredited programs as long as it did not have an existing cap and did not train residents during its 1996 cost reporting period. However, CMS has made it clear that merely securing new accreditation is not sufficient for a residency program to be considered "new." Instead, CMS has stated that a hospital may not rely solely on an accrediting body's characterization of whether a program is new. CMS requires a hospital to evaluate whether a particular program is a newly established one for Medicare DGME purposes by considering whether a program was initially accredited "for the first time," and is not a program that existed previously at another hospital. In evaluating whether a program is truly new, it is important to consider not only the characterization by the accrediting body, but also supporting factors such as (but not limited to) whether there are new program directors, new teaching staff, and whether there are only new residents training in the program(s) at the different site. It may also be necessary to consider factors such as the relationship between hospitals (for example, common ownership or a shared medical school or teaching relationship) and the degree to which the hospital with the original program continues to operate its own program in the same specialty. [74 Fed. Reg. 43754, 43908-917 (Aug. 27, 2009)] If a program qualifies as truly new, if the hospital had no allopathic or osteopathic residents in its cost reporting period ending on or before Dec. 31, 1996, and if the hospital

begins training residents in that new medical residency training program for the first time on or after Oct. 1, 2012, the hospital will be given a window of five years to develop before its resident cap is finalized. [42 C.F.R. Section 413.79(e)]

Compliance Tip: If any factor noted above does not clearly indicate that the program is brand new, consult an attorney or CMS in advance of starting the new program and claiming any FTEs on the cost report to obtain written confirmation that the program will qualify for a new program FTE cap adjustment.

Effective with hospitals closing on or after March 23, 2008, the Patient Protection and Affordable Care Act (ACA) of 2010 allows for the FTE cap of a closed hospital to be redistributed to certain hospitals that apply, with preference to hospitals in the same core-based statistical area, or that had a shared rotational agreement with the closed hospital [42 U.S.C. Section 1395ww(d)(5)(B)(v) and (h)(4)(H)(vi)].

For IME and DGME cost reporting purposes, it is important that hospitals maintain an accurate and documented count and location of intern and resident FTEs. Generally, contractors expect detailed rotation schedules that show the location and nature of a resident's assigned rotation on at least a monthly basis. Indeed, some contractors appear to expect accurate rotation schedules that show the weekly or even daily location of a hospital's claimed residents. The location and nature of a resident's rotation are important because different rules exist depending on where the residents are on rotation and what type of training is occurring for a given rotation. Further, ACA requires hospitals to maintain and provide records of its DGME FTE counts associated with nonprovider site rotations for purposes of comparing such rotations to the fiscal period that began on or after July 1, 2009. CMS has made clear that the documentation for this purpose can be detailed rotation schedules so long as they show the amount of nonprovider rotation time by program for each primary care program, and the overall nonprovider rotation time for nonprimary care programs. [42 U.S.C. Section 1395ww(h)(4)(E)]

Compliance Tip: For both IME and DGME purposes, it is critical for a hospital to accurately document when a resident is on rotation at another hospital, freestanding clinic or physician's office.

Specifically, for IME purposes, a hospital can claim only residents assigned and on rotation in that part of the hospital subject to IPPS and outpatient departments of the hospital. For DGME purposes, a hospital can claim residents on rotation in all areas of the hospital complex.

For both IME and DGME purposes, it is critical for a hospital to accurately document when a resident is on rotation to another hospital or at a nonhospital site such as a freestanding clinic or physician's office. Although a hospital may not claim the time that a resident rotates at another hospital (except in accordance with current COVID waivers in place during the Public Health Emergency), it can claim the time that a resident rotates at a nonhospital

site under certain conditions. Moreover, a rotation schedule must document if and when a resident is assigned to research or didactic activity.

Also, the ACA, and regulations issued in November 2010, make it clear that vacation, leave of absence, sick and orientation time that does not extend the time the resident trains in an approved program may be included in the FTE count for IME [42 U.S.C. Section 1395ww(d)(5)(B)(x)(I); 42 C.F.R. Section 412.105(f)(1)(iii)(D)] and DGME [42 U.S.C. Section 1395ww(h)(4)(K); 42 C.F.R. Section 413.78(h)].

CMS revised the definition of **"resident,"** as of cost reporting periods beginning on or after Oct. 1, 2010, to mean an intern, resident or fellow who is formally accepted, enrolled, and participating in an approved medical residency program, including programs in osteopathy, dentistry and podiatry, as required in order to become certified by the appropriate specialty board. Specifically, CMS set forth a new rule that residents training beyond the accredited length of a program are not considered residents. Further, CMS set forth a new rule that residents who have already completed one residency and who are not training toward board certification in another subspecialty cannot count as residents for DGME or IME purposes. Finally, CMS also clarified that individuals acting as chief resident after they have completed the accredited program and have satisfied minimum requirements for board certification are not considered residents for DGME or IME purposes. [75 Fed. Reg. 50042, 50296-50298 (Aug. 16, 2010)]

Compliance Tip: Make sure that any resident claimed on the cost report for DGME or IME purposes is squarely within an approved residency program and that the training is required to achieve board certification.

Significantly, ACA, and regulations issued in November 2010, clarify that a hospital may not count nonpatient care-related research time unless such activities occur in the hospital complex, and then only for DGME purposes. However, effective with cost reporting periods beginning on or after July 1, 2009 (for DGME) and as of Jan. 1, 1983 (for IME), ACA and regulations issued in November 2010 allow providers to claim didactic or classroom time so long as that time is spent in the hospital setting for IME purposes, or in a nonprovider site that is primarily engaged in patient care for DGME purposes. For DGME purposes, providers have been, and continue to be, able to count didactic time in the hospital setting. Note, though, that in a Nov. 24, 2010 Federal Register, CMS indicated that it does not view dental or medical schools as primarily engaged in patient care [75 Fed. Reg. 71800, 72143 (Nov. 24, 2010)]. However, CMS did clarify that medical school clinics and dental school clinics qualify as "primarily engaged in patient care" and the didactic time in such clinics can be included in the DGME FTE counts. [75 Fed. Reg. 71800, 72144 (Nov. 24, 2010)] Providers may not claim didactic time in nonprovider sites for IME purposes. [42 U.S.C. Section 1395ww(d)(5)(B)(x)(II)]

Effective for cost reporting periods beginning on or after Oct. 1, 2019, CMS changed its policy and now permits an IPPS teaching hospital to count, for DGME and IME purposes, resident time spent at a facility designated as a "Critical Access Hospital" or "CAH," where the teaching hospital incurs the costs of training the residents at that site. [84 Fed. Reg. 42044, 42411-42416 (Aug. 16, 2019)]

Compliance Tip: Effective with portions of cost reporting periods on and after Jan. 1, 2011, CMS is no longer allowing providers the benefit of the one workday rule for the exclusion of didactic time. Thus, didactic time must be carefully and thoroughly documented for all nonprovider rotations since didactic time for IME purposes is still not allowable in nonprovider settings. Apparently, CMS expects any and all such time to be removed from the FTE count whether or not the resident spent a full day in didactic activities. [75 Fed. Reg. 71800, 72144 (Nov. 24, 2010)]

Nonhospital Rotations for Cost Reporting Periods Beginning on or After July 1, 2010 (for DGME) and for Discharges on or After July 1, 2010 (for IME)

ACA Section 5504 and November 2010 regulations require only that a hospital incur all the costs of the residents' salaries and fringe benefits (including travel and lodging, where applicable) in order to claim nonhospital rotation time in the DGME or IME FTE count. A hospital no longer needs to incur any costs associated with the teaching or supervising physicians' time during a nonhospital rotation. In addition, ACA and November 2010 regulations allow more than one hospital to share in the costs of sending residents in the same program to the same nonhospital site. In such situations, each hospital claims its proportion of the FTEs, but each hospital must enter into a written agreement that sets forth a reasonable basis for establishing each hospital's proportion of the FTEs. [42 C.F.R. Sections 413.78(g) and 412.105(f)(1)(ii)(E)]

Further, the rule on whether a written agreement between the hospital and the nonhospital site is required remains the same. No such written agreement is required if the hospital incurs the resident salary and fringe benefit costs within three months after the month of the rotation. If the hospital does not incur the costs within three months of the rotation, then the hospital must enter into a written agreement with the nonhospital site setting forth the amount of resident salary and fringe benefit costs (including travel and lodging where applicable) that will be incurred by the hospital for the nonhospital rotation. If the hospital enters into a written agreement with the nonhospital site, it must be dated and signed prior to the start of the claimed rotations. [42 U.S.C. Section 1395ww(d)(5) and (h)(4)]

Nonhospital Rotations for Cost Reporting Periods Beginning on or After Oct. 1, 2007 and Prior to July 1, 2010 (for DGME) and Discharges on or After Oct. 1, 2007 and Prior to July 1, 2010 (for IME)

A hospital must incur all, or substantially all, resident training costs at a nonhospital site in a given residency training program. Two or more hospitals may not share the costs of sending residents in the same residency program to the same nonhospital site. Only one hospital can claim the nonhospital FTEs for the residents in a given program and only if that one hospital incurs all the necessary costs as discussed next. CMS allows a hospital to meet this requirement by incurring 90 percent of the total of:

1. A resident's salary and fringe benefits; and
2. The cost of a teaching physician's time related to nonbillable teaching and supervision activities.

The 90 percent cost requirement can either be based on actual documented teaching time and cost information or by using some or all of the CMS-approved proxies for teaching time and teaching physician salaries.

For instance, CMS allows a hospital to assume that teaching time is three hours per week (divided by the number of hours per week that the nonhospital site is open to the public). CMS allows the use of certain published average teaching physician compensation figures in lieu of actual compensation information. If a hospital prefers to document actual teaching time, it must require the teaching physicians to fill out periodic time studies to support and document the actual nonbillable teaching time at a particular nonhospital site. Likewise, if a hospital prefers to use actual teaching physician compensation amounts, it must document the amounts paid and may also need to demonstrate to the MAC that such amounts are reasonable and appropriate.

In order to count residents rotating in a nonhospital setting, the hospital must either document that it paid the above-mentioned training costs within three months after the month of the rotation to the nonhospital site or enter into a written agreement with the nonhospital site. If the hospital chooses to enter into a written agreement, it must be dated and signed prior to the start of the claimed rotations. The written agreement also must indicate that the hospital is incurring the costs of resident salaries and fringe benefits, and expressly state the amount the hospital is paying for supervisory teaching costs. [42 C.F.R. Section 413.78(f)(3)]

If a hospital is claiming residents in a nonhospital site who were taught or supervised by volunteer teaching physicians, the hospital must demonstrate to the contractor that the teaching physicians were volunteering. If there is no written agreement, then the hospital should secure a signed statement from the teaching physicians, clearly stating their volunteer status. If there is a written agreement, it must clearly state that no payment is being made for teaching or supervision because the teaching physicians are volunteers. It is likely that CMS and contractors will agree that teaching physicians are volunteering only if they are solo practitioners or members of a medical group in which physicians essentially function as solo practitioners and their income is based entirely on patient care revenue.

Shared Rotational/Affiliation Agreements

For some hospitals, a key piece of documentation is a shared rotational agreement used to document that two or more hospitals jointly train residents and share their DGME and/or IME FTE caps. [42 C.F.R. Section 413.79(f)] To enter into a shared rotational agreement, at least two hospitals must share the training of at least one resident in one training program. The hospitals in a shared rotational agreement must be:

1. Located in the same urban or rural area or in a contiguous area and meet specified rotation requirements;
2. Listed jointly as sponsors or participating institutions in a given program; or
3. Commonly owned.

The shared rotational agreement must be in writing. The agreement must be for a term of at least one year effective as of July 1, and indicate the specific number of FTEs that each hospital will gain or lose with the net sum equaling zero (i.e., in the aggregate, the FTE caps remain the same). The shared rotational agreement must be received by CMS and the

contractor on or before July 1 of the academic year for which the agreement will be in effect. [42 C.F.R. Sections 413.75(b) and 413.79(f)]

Until recently, new urban teaching hospitals (i.e., those urban teaching hospitals that developed their FTE caps after the 1996 cap-setting year) were not permitted to loan their slots to other hospitals through Medicare GME affiliation agreements. Effective July 1, 2019, new urban teaching hospitals can loan FTE slots to another new urban teaching hospital or to an existing urban teaching hospital, effective with the July 1 date (the residency training year) that is at least five years after the start of the hospital's cost reporting period that coincides with or follows the start of the sixth program year of the first new program. [42 C.F.R. Section 413.79(e)(1)(iv)(B)]

Hospitals that do not operate, and have not previously operated, a medical education teaching program should carefully consider whether to serve as a teaching site for another program before entering into an affiliation agreement. This is because Medicare policy states that any time a hospital hosts a resident, even if only as part of an affiliation agreement, it may trigger the calculation of that facility's average per resident amount (APRA) for DGME purposes (depending on the number of residents trained). In this regard, if the facility incurs little or no costs in association with hosting the resident under the affiliation agreement, it could mean that facility would be bound by an artificially low APRA for DGME purposes if it were to ever establish a new teaching program of its own in the future. Therefore, if a facility that is asked to serve as a teaching site for an established program under an affiliation agreement has reason to believe it may establish its own residency training program at some point in the future, it may want to either decline to move forward with the arrangement or structure the agreement so that it is incurring an appreciable amount of costs as part of the affiliation. Moreover, if asked to serve as a teaching site for a program where the host teaching hospital is in its FTE cap-building period, there is a risk that, in addition to the APRA being triggered, the rotation site hospital could also have its FTE cap triggered. It is recommended that hospitals contact experienced legal counsel to discuss the potential implications of a proposed IME/DGME affiliation agreement before participating in such an arrangement.

Compliance Tip: Hospitals that do not operate, and have not previously operated, a medical education teaching program should carefully consider whether to host residents from another hospital as part of an affiliation agreement. It could affect DGME and IME reimbursement for a hospital's own residency training program in the future.

Consolidated Appropriations Act of 2021

Effective Dec. 27, 2020, the Consolidated Appropriations Act of 2021 (CAA) contains three DGME/IME reimbursement laws which have the potential to importantly impact teaching hospital reimbursement:

1. Sec. 126, which allocates a thousand new residency slots over the next five years to teaching hospitals;
2. Sec. 127, which dictates changes to the rural training track (RTT) rules that will

increase flexibility for rural and urban hospitals to partner and will expand RTT programs in specialties other than family medicine; and

3. Sec. 131, which specifies circumstances in which hospitals may reset their very low APRA and/or FTE caps.
4. CMS is contemplating the implementation of these three laws through its federal fiscal year (FFY) 2022 IPPS rulemaking. However, citing the hundreds of public comments it received on this crucial subject, CMS did not finalize its CAA-related DGME/IME reimbursement proposals when it issued its FFY 2022 IPPS Final Rule on Aug. 2, 2021. CMS instead indicated that it would address the proposed changes to DGME/IME reimbursement in a separate document, which has not been published as of Nov. 29, 2021.

Compliance Tip: Once CMS issues its final rule implementing the CAA-related DGME/IME reimbursement provisions, consult an experienced graduate medical education reimbursement attorney or CMS in advance of taking any actions under the CAA-related DGME/IME reimbursement provisions.

Available Bed Count

For both IME and DSH purposes, the count and documentation of available beds is important. Sometimes, a hospital's licensed bed capacity is greater than its available beds for any number of reasons, including construction or conversion of inpatient areas to office space, call rooms, or outpatient units. For both DSH and IME purposes, a hospital's available bed count is determined using the same approach. Whether it is appropriate to include beds in the available bed days count largely depends on whether, and to what extent, a given unit or ward of a hospital is used to provide inpatient acute care of the type payable under IPPS. [42 C.F.R. Sections 412.105(b) and 412.106(a)(1)(i)] For instance, a hospital should deduct from the count of available beds those beds in a unit or ward documented to have not provided any acute care services of the type payable under IPPS for the three preceding consecutive months. [42 C.F.R. Section 412.105(b)(1)] In such a circumstance, the beds would not be counted starting in the fourth such month. (See 42 C.F.R. Section 412.105(b) for a list of the other circumstances in which a bed is not considered available for IME or DSH purposes.) However, especially for IME purposes, a MAC will expect the hospital to document that the bed or unit at issue meets the regulatory criteria for exclusion from the hospital's complement of available beds.

B. Traditional Medicare DSH Payments

Certain Medicare participating hospitals that treat a disproportionate share of low-income patients may be eligible for additional reimbursement [42 U.S.C. Section 1395ww(d)(5)(F)]. CMS and contractors use a relatively complex calculation established by statute to determine if a hospital is eligible for a Medicare disproportionate share hospital (DSH) payment adjustment and the amount of any such adjustment. A hospital's qualification for a Medicare DSH adjustment is determined, in part, by its "disproportionate patient percentage" (DSH patient percentage). The DSH patient percentage is essentially a proxy for the provider's utilization by low-income patients and consists of the sum of two fractions:

1. A provider's inpatient days associated with treating Medicare patients entitled to Supplemental Security Income (SSI) during the time of their inpatient care, divided by the provider's total Medicare patient days in the fiscal year; and
2. A provider's Medicaid-eligible (but not also entitled to benefits under Part A) patient days divided by total patient days in the fiscal year.

[42 U.S.C. Section 1395ww(d)(5)(F)(vi)][3]

A provider's eligibility for DSH payments also depends, in part, on whether the hospital is located in an urban or rural area and its number of available beds. As noted in the previous IME section, hospitals need to pay special attention to properly documenting the count of available beds.

Accurate reporting of patient days is the primary issue that arises with DSH payments. Hospitals must make sure that any patient day figures recorded on the cost report, whether Medicare patient days or Medicaid days, are supported by adequate and appropriate documentation. Hospitals should refrain from estimating or making approximations. If a provider questions whether CMS or its MAC will count particular days, or categories of days, for DSH purposes, the provider should use the protested items line on the cost report *(see A. "Including "Appropriate" Claims on the Cost Report as a Condition of Reimbursement," page 5.11 and C. "Protested Items," page 5.13)*. Again, providers are required to supply a workpaper explaining the reason for protesting items and how they were estimated.

There has been considerable litigation regarding whether certain types of patient days of low-income patients can be included in the DSH calculation – and, if so, in what fraction of the calculation. For example, the courts have uniformly declined to mandate the inclusion of general assistance (GA) or "charity" days, associated with state or county "welfare" programs for patients who do not qualify for Medicaid due to income levels that exceed eligibility requirements. *(See, e.g.,* Verdant Health Comm'n v. Hargan*, 708 Fed. Appx. 459 (9th Cir. 2018);* Owensboro Health Inc. v. Burwell*, 832 F. 3d. 615 (6th Cir. 2016);* Univ. of Washington Med. Ctr. v. Sebelius*, 634 F.3d 1029 (9th Cir. 2011);* Cooper Hospital University v. Burwell*, 179 F. Supp.3d 31 (D.D.C. 2016))*.

Compliance Tip: Hospitals should not count, for DSH purposes, days associated with patients who are not clearly eligible for benefits under a traditional state Medicaid program or a 1115 waiver program, but if there is any doubt the days should be treated as a protested item.

The placement of dual-eligible exhausted or non-covered days in the DSH calculation's Medicare fraction or in the Medicaid fraction remains at issue. Hospitals have challenged

3 Similar to DSH payments, hospitals that operate inpatient rehabilitation facilities or units that are paid under the Medicare inpatient rehabilitation prospective payment system are also subject to additional payments for treating low-income patients. *(See 42 C.F.R. Section 412.624(e); see also Medicare Claims Processing Manual (MCPM) (CMS Pub. 100-04), Ch. 3, Section 140.2.5.3.)* The formula for calculating a hospital's entitlement to a low-income patient (LIP) adjustment related to rehabilitation services involves multiplying a hospital's DSH percentage by a figure established by CMS. *(See MCPM, Ch. 3, Section 140.2.5.3.)* Thus, a hospital's entitlement to a LIP payment adjustment is dependent on calculations related to its DSH percentage.

CMS's 2005 regulation directing the placement of exhausted and non-covered days of dual-eligible patients in the Medicare fraction. In *Stringfellow Memorial Hospital v. Azar*, 317 F. Supp. 3d. 168 (D.D.C. 2018), the court upheld the agency's regulation. However, in *Empire Health Foundation v. Azar*, 958 F.3d 873 (2020), the Ninth Circuit Court of Appeals, which has jurisdiction over California, held that the CMS regulation was substantively invalid because the agency failed to apply the clear language of the Medicare statute that patients who have exhausted their Medicare benefits yet are "eligible for Medicaid," should be included in the Medicaid fraction. The Supreme Court granted review of the agency's appeal of the Ninth Circuit's decision and will likely make a final decision on this issue before June 2022. [*Becerra v. Empire Health Foundation*, Case No. 20-1312.]

Compliance Tip: Until the Supreme Court decides *Becerra v. Empire Health Foundation*, California hospitals should consider including as a protested item in the cost report dual eligible exhausted or non-covered days in the Medicaid fraction of the DSH calculation.

Providers have also successfully challenged the exclusion of Section 1115 Waiver Days from the DSH calculation because state programs were covered under the 1115 waiver program; patients were eligible for federal matching funds and received inpatient hospital services under the program. *(See,* Bethesda Health v. Azar*, 389 F. Supp.3d 32 (D.D.C. 2019) aff'd. 2020 WL 6684706 (Nov. 13, 2020); also see,* Health Alliance Hospitals v. Azar*, 346 F. Supp. 3d 43 (D.D.C. 2018).)*

Compliance Tip: California hospitals should consider including 1115 waiver days in the Medicaid fraction of the DSH calculation.

Providers have been challenging CMS' policy of including Part C days in the Medicare or SSI fraction and excluding Part C days for dually-eligible patients (i.e., patients eligible for both Medicare and Medicaid) from the Medicaid fraction. On Sept. 13, 2011, the United States Court of Appeals for the District of Columbia Circuit (D.C. Circuit) invalidated CMS' attempt to include Part C days in the SSI percentage for years prior to 2004 when CMS revised the DSH regulation to expressly direct the inclusion of Part C days in the SSI fraction. [*Northeast Hosp. Corp. v. Sebelius*, 657 F.3d 1 (D.C. Cir. 2011)]. In 2014, the D.C. Circuit ruled invalid and vacated the agency's 2004 regulatory change that requires inclusion of Part C days in the SSI fraction is valid. However, the Court ruled the regulation was procedurally invalid so it remanded the matter back to CMS for further consideration as to the appropriate way to factor Part C days into the DSH calculation. [*Allina Health Services v. Sebelius*, 746 F.3d 1102 (D.C. Cir. 2014)]

CMS maintains that, even though the 2004 rule was procedurally invalid, its policy of including Part C days in the SSI fraction and excluding dually-eligible Part C days from the Medicaid fraction is proper under the DSH statute. CMS re-promulgated, through notice and comment, its Part C policy in the Fiscal Year 2014 IPPS rule, which governs DSH payments

from Oct. 1, 2013 forward. Hospitals are currently challenging this regulation and, after losing the initial round before the district court, their case in on appeal before the D.C. Circuit. [*Florida Health Sciences Ctr. v. Becerra*]

For cost-reporting years covering periods before Oct. 1, 2013, the Part C issue continues to be litigated. In a second *Allina Health* case, the D.C. Circuit determined that CMS could not apply this policy through adjudication and was required to go through notice and comment rulemaking [*Allina Health Services v. Price*, 863 F.3d 937 (D.C. Cir. 2017)]. On review, the Supreme Court affirmed the D.C. Circuit's decision, holding that the Medicare Act requires notice-and-comment rulemaking for any establishment of, or change to, a substantive legal standard concerning Medicare benefits or payment, including those that may be viewed as interpretive under the Administrative Procedure Act (APA). [*Azar v. Allina Health Services*, 139 S. Ct. 1804 (2019)]. The matter was again remanded to CMS.

Thereafter, on Aug. 6, 2020, CMS issued a proposed rule to once again count Part C days In the SSI fraction of the DSH calculation, but this time to do so retroactively to periods before Oct. 1, 2013 [85 Fed. Reg. 47723 (Aug. 6, 2020)]. CMS has not issued a final rule on this subject. Therefore, hospitals should continue to protest the placement of Part C days in the SSI fraction and state that such days should be placed in the Medicaid fraction when filing their Medicare cost reports.

Compliance Tip: Until litigation over the Part C days issue is resolved, hospitals should continue to protest placement of Part C days in the SSI fraction and the exclusion of such days for dually eligible patients in the Medicaid fraction.

Regardless of the specific category, if a provider believes that certain types of days should factor into its DSH payment calculation, the provider must identify those days on its cost report in some capacity. The Medicare administrative tribunal responsible for processing appeals arising from cost reports (the Provider Reimbursement Review Board) issued a decision in 2014 setting a standard for adding additional days to the DSH calculation not identified on the cost report. A provider must show that there was a practical impediment that precluded the appeal of such days, e.g., the failure of the state to timely determine Medicaid eligibility. [*Danbury Hospital v. BCBSA*, PRRB Dec. No. 2014-D3 (Feb. 11, 2014)]. CMS has instructed MACs to accept one amended cost report submitted within a 12-month period after the hospital's cost report due date, solely for the specific purpose of revising Medicaid-eligible patient days in order to calculate DSH payments after a hospital receives updated Medicaid-eligible patient days from the State. [80 Fed. Reg. 70298, 70560 (Nov. 13, 2015)]. A provider may also seek to add additional days to the hospital's DSH calculation through the reopening process or within three years of the date of the NPR. Finally, some MACs are open to accepting additional Medicaid eligible days prior to commencing a desk review or audit — if available, take advantage of this opportunity.

C. Uncompensated Care DSH Payments

Beginning Oct. 1, 2013, CMS changed the methodology for calculating the Medicare DSH payment. Pursuant to the new methodology, an eligible provider will receive two payments — (1) 25 percent of the amount it previously would have received under section 1886(d)(5)(F) of the Act for DSH ("the empirically justified amount"), and (2) an additional payment for

the DSH hospital's proportion of uncompensated care, determined as the product of three factors. These three factors are:

1. 75 percent of the payments that would otherwise be made;
2. 1 minus the percent change in the percent of individuals who are uninsured; and
3. A hospital's uncompensated care amount relative to the uncompensated care amount of all DSH hospitals expressed as a percentage.

The uncompensated care pool is distributed to DSH hospitals based on the ratio of the amount of their uncompensated care to the total amount of uncompensated care furnished by all DSH hospitals. Each hospital's uncompensated care payment is the product of three factors:

1. The first factor is the remaining 75 percent DSH hospitals would have otherwise been paid.
2. The second factor is, for FYs 2014 through 2017, one minus the percent change in the percent of individuals under the age of 65 who are uninsured, determined by comparing the percent of such individuals who were uninsured in 2013, the last year before coverage expansion under the ACA, and the percent of individuals who were uninsured in the most recent period for which data are available, minus 0.1 percentage point for FY 2014, and minus 0.2 percentage point for FYs 2015 through 2017. For FY 2018 and subsequent fiscal years, the second factor is one minus the percent change in the percent of individuals who are uninsured, as determined by comparing the percent of individuals who were uninsured in 2013, and the percent of individuals who were uninsured in the most recent period for which data is available, minus 0.2 percentage point for FYs 2018 and 2019. For FY 2020, to calculate Factor 2, use the uninsured estimates produced by the CMS Office of the Actuary (OACT) as part of the development of the National Health Expenditure Accounts in conjunction with more recently available data that take into consideration the effects of COVID-19. CMS is using data from the OACT for FY 2021. [IPPS Final Rule, 85 Fed. Reg. 58432, 58436 (Sept. 18, 2020)]
3. The third factor is a percent that represents a hospital's uncompensated care amount for a given time period relative to the uncompensated care amount for that same time period for all hospitals that receive Medicare DSH payments in the applicable fiscal year. This is known as the UC DSH payment.

The determination of the amount of a hospital's uncompensated care will, by statute, be based on "appropriate data." Previously, CMS used each eligible hospital's proportion of low-income insured days (Medicaid and Medicare SSI patient days) as a "proxy" for determining a hospital's share of uncompensated care. CMS calculated this factor for all DSH hospitals, even those projected to be ineligible for DSH payments, so that if hospitals are later determined to be eligible, they can receive uncompensated care payments at the time of cost report settlement. [78 Fed. Reg. 50496, 50523 (Aug. 19, 2013)] However, beginning in federal fiscal year 2018, CMS moved away from determining a hospital's portion of uncompensated care based on the "proxy" method described above, and uses Worksheet S-10 of the cost report as a source of data for calculating uncompensated care. CMS is now using Worksheet S-10 data for factor 3 calculations.

More specifically, CMS will use one single year of data from Worksheet S-10 of the FY 2018 cost reports to calculate Factor 3 in the FY 2022 methodology to calculate the additional DSH payment for uncompensated care. CMS will continue to use the most recent single year of audited Worksheet S-10 data for all future years [86 Fed.Reg. 4744 at 45236 (Aug. 13, 2021)] Providers should ensure that all uncompensated care data are accurately captured on their cost reports. [42 U.S.C. Section 1395ww(r)]. Courts have found that the methodology employed by the agency in determining Factor 3 is not judicially reviewable. *(See* DCH Regional Medical Center v. Price*, 257 F. Supp.3d 91 (D.D.C. 2017);* Florida Health Sciences Center v. Price*, 89 F. Supp.3d 121 (D.D.C. 2015); accord, Ascension Borges Hospital v. Becerra, 2021 WL 3856621 (Aug. 30, 2021).)*

Worksheet S-10 audits by MACs are proceeding. The S-10 audits include a review of a provider's compliance with its own documented charity care and financial assistance policies (FAP), as well as the Medicare Cost Report instructions, the completeness and accuracy of provider's bad debts, reconciliation of the provider's financial accounting records with the bad debt amounts, and charity care/FAP amounts reported on Worksheet S-10. The audits of Worksheet S-10 may result in adjustments to both bad debt and charity care amounts. As a result, accuracy and the documentation for such amounts are critical to a successful audit.

Line 20 of Worksheet S-10 is of particular importance, as it is used to record total charity care charges (not costs) for patients eligible under a hospital's charity care policy. The instructions for Worksheet S-10 state that, for cost reporting periods beginning prior to Oct. 1, 2016, the amount on line 20 includes "the total initial payment obligation, measured at full charges, for patients, including uninsured patients, who are given a full or partial discount based on the hospital's charity care policy or FAP (financial assistance policy), including any uninsured discount policy within that FAP, for health care services during this cost reporting period for the entire facility." **"Full charges"** means the "full charges for uninsured patients and patients with coverage from an entity that does not have a contractual relationship with the provider." Furthermore, "charges for non-covered services provided to patients eligible for Medicaid or other indigent care programs if such inclusion is specified in the hospital's charity care policy or FAP and the patient meets the hospital's policy criteria." For cost reporting periods beginning after Oct. 1, 2016, Line 20 includes "the actual charge amounts for the entire facility (except physician and other professional services), of uninsured patients who were given full or partial discounts that were: (1) determined in accordance with the hospital's charity care criteria/policy or FAP, and (2) written off during this cost reporting period, regardless of when the services were provided." [PRM-II (CMS Pub. 15-2), ch. 40, Section 4012]

Charges include "the total charges, or the portion of the total charges, written off to charity care, for uninsured patients, and patients with coverage from an entity that does not have a contractual relationship with the provider who meet the hospital's charity care policy or FAP." Charges also include "charges for non-covered services provided to patients eligible for Medicaid or other indigent care programs, if such inclusion is specified in the hospital's charity care policy or FAP and the patient meets the hospital's policy criteria." Line 20 of Worksheet S-10 does not include government payment shortfalls for covered services to patients eligible for Medicaid, other government health programs, bad debts, discounts to patients who do not meet the hospital's charity care or uninsured discount policies, or charity care furnished by physicians and other professionals. [PRM-II (CMS Pub. 15-2), ch. 40, Section 4012]

Because each hospital's charity care and uninsured discount policies dictate which services are included on line 20 of Worksheet S-10, hospitals with more generous charity care and uninsured discount policies will likely have more charity care to report there. In this regard, hospital personnel involved in the cost reporting process must be familiar with the hospital's charity care and uninsured discount policies to ensure that costs and charges are appropriately reported in Worksheet S-10 of the cost report.

D. Medicare Bad Debt Payments

For Medicare purposes, the term **"bad debt"** refers to coinsurance and deductible amounts that Medicare beneficiaries are obligated to pay for services they receive, but that providers are unable to collect. The Medicare program reimburses hospitals a percentage of uncollected Medicare deductibles and coinsurance if certain requirements are met. [42 C.F.R. Sections 412.2(f)(4) and 413.89] The general rule is that bad debts are reimbursable under these circumstances:

1. The debt is related to covered services and derived from deductible and coinsurance amounts;
2. The provider establishes that "reasonable collection efforts" were made;
3. The debt was actually uncollectible when claimed as worthless; and
4. Based on sound business judgment there was no likelihood of recovery at any time in the future.

[42 C.F.R. Section 413.89(e); PRM-I (CMS Pub. 15-1) ch. 3, Section 308]

A provider must demonstrate that it meets the criteria above through adequate documentation. CMS has published very specific guidelines establishing what providers must document to meet the criteria for bad debt reimbursement. *(See, e.g., PRM-I (CMS Pub. 15-1) ch. 3, Sections 310-14.)*

In the 2021 IPPS Final Rule, 85 Fed. Reg. 58432 (Sept. 18, 2020), CMS issued specific regulatory guidance for claiming bad debts and made many of these requirements effective, "before, on, or after" the effective date of the rule, i.e., retroactively [85 Fed. Reg. at 58991]. The agency cited the repeal of the Bad Debt Moratorium as the basis to "clarify," update, and codify certain longstanding Medicare bad debt principles into the regulations. While many regulatory provisions are retroactive, a number of "new requirements" had an Oct. 1, 2020 effective date.

Definitions: Non-Indigent and Indigent Beneficiaries

The 2021 IPPS Final Rule defines both non-indigent and indigent Medicare beneficiaries for bad debt purposes.

A non-indigent Medicare beneficiary is defined as a beneficiary who has not been determined to be categorically or medically needy by a State Medicaid Agency to receive medical assistance from Medicaid and has not been determined to be indigent by the provider for Medicare bad debt purposes. The definition, containing no substantive change, is retroactive.

An indigent non-dual eligible beneficiary for Medicare bad debt purposes is defined as a Medicare beneficiary who is determined to be indigent by the provider and not eligible for Medicaid as categorically or medically needy.

Reasonable Collection Efforts

A provider's efforts to collect deductible and coinsurance amounts from beneficiaries receive close attention during the Medicare cost report audit process. One key issue involves a comparison of the provider's effort to collect coinsurance and deductibles from Medicare patients with the provider's efforts to collect similar obligations from non-Medicare patients. The Medicare rules require that, in order to be reimbursed for bad debts, collection efforts must be consistent between Medicare and non-Medicare accounts of similar size. [PRM-I (CMS Pub. 15-1) ch. 3, Section 310]. This requirement has been codified in a regulation [42 C.F.R. 413.89 (e)(2)(i)(A)].

The agency has set a standard for the issuance of a first bill. To constitute a reasonable collection effort, a bill must be issued on or before 120 days after the latest of the following:

1. The date of the Medicare remittance advice;
2. The date of the remittance advice from the beneficiary's secondary payer, if any; or
3. The date of the notification that the beneficiary's secondary payer does not cover the service furnished to the beneficiary.

A reasonable collection effort must also include other actions such as subsequent billings, collection letters and telephone calls or other personal contacts with the party so as to constitute a genuine rather than a token collection effort. Such efforts must be "similar," i.e, the same for both Medicare beneficiaries and non-Medicare patients. Documentation of collection efforts must be maintained that includes the provider's debt collection policy for Medicare and non-Medicare patients, the beneficiary's account history together with the file that documents all collection activities. The "120-day requirement for the issuance of a bill" was effective Oct. 1, 2020. [85 Fed. Reg. at 58993]. Providers should note that the PRRB continues to hold that in order to obtain the presumption of the 120-day rule, (i.e., bad debts worthless after 120 days of reasonable collection effort), a provider must implement its own debt collection policy developed based on its own business judgment. *(See, UHS 2006-2009 Bad Debts Still at Collection Agency CIRP Group v. Novitas, PRRB Case No. 2020-D20, 2020 WL 5551972 (Aug. 31, 2020).)* Providers should review their bad debt policy to ensure compliance with current regulatory requirements and take steps to ensure its consistent implementation.

The regulation specifies the requirement that a provider must conduct collection activities for 120 days before a debt can be deemed worthless [42 C.F.R 413.89(e)(2)((i)(A)(2) or (3)] This eliminates the writing off of a bad debt before 120 days from the date of the Medicare remittance advice, payment by a secondary payer or notice of "no coverage" from the secondary payer. The agency also promulgated a requirement that the 120-day collection period be "continuous" and that any partial payment "restarts the clock," i.e., restarts the 120-day period or sets the clock again at day one [85 Fed. Reg. at 58993]. These provisions are retroactive as a codification of "longstanding policy" [85 Fed. Reg at 58994].

Collection Agency Issues

The Medicare rules do not require hospitals to send delinquent accounts to collection agencies in order to be reimbursed for bad debt [PRM-I (CMS Pub. 15-1) ch. 3, Section 310]. However, there are certain principles a provider should keep in mind if it uses a collection agency to try to recover unpaid coinsurance and deductible amounts. First, as with any other type of collection efforts, a provider's use of collection agencies should be consistent

between Medicare and non-Medicare accounts of similar size. The provider must use the same criteria for both Medicare and non-Medicare patients to ascertain whether, and when, to send accounts to collections and how long the accounts stay at collections before being written off.

There has been extensive litigation regarding when it is appropriate for a provider to write off accounts pending with collection agencies. In light of this litigation, the agency has revised its regulation to state that Medicare bad debts cannot be written off while pending at a collection agency because the provider cannot establish that there is "no likelihood of recovery at any time in the future" and is not "worthless" when written of. [85 Fed Reg. at 58995]. Citing various court decisions, the agency observed that none of them precluded the issuance of the requirement by regulation. This regulation is retroactive.

The agency's policy has produced an abundance of litigation. Providers have challenged the "policy" now in regulation that denied reimbursement for Medicare bad debts pending at a collection agency.

The federal court of appeals for the Sixth Circuit effectively ratified the agency's view in a 2007 decision [*Battle Creek Health System v. Leavitt*, 498 F.3d. 401 (6th Cir. 2007)]. Although the Sixth Circuit's decision is not technically controlling in geographic areas falling outside the Sixth Circuit, including California, the decision likely still means that providers everywhere will not be reimbursed by Medicare for bad debts associated with accounts that still are pending at collection agencies. At least two United States district courts outside of the jurisdiction of the Sixth Circuit have followed the *Battle Creek* decision with respect to whether accounts pending at a collection agency can be written off as bad debt. [*Lakeland Regional Health System v. Sebelius*, 958 F. Supp. 2d 1 (D.D.C. 2013); *Community Health Systems, Inc. v. Burwell*, 113 F. Supp. 3d 197 (D.D.C. 2015); *Mesquite Community Health System v. Leavitt*, 2008 WL 4148970 (N.D. Tex. 2008)]

However, it also is notable that multiple federal district court decisions declined to follow the *Battle Creek* opinion, finding that CMS' position that accounts pending at outside collection agencies may not be deemed uncollectible is a change of bad debt policy that is prohibited under a statutory "moratorium" on such changes [*Foothill Memorial v. Leavitt*, 558 F.Supp.2d 1 (D.D.C. 2008); *District Hosp. Partners L.P. v. Sebelius*, 932 F.Supp.2d 194 (D.D.C. 2013)]. As district court decisions, the *Foothill* and *District Hosp. Partners* cases are not binding on any other federal courts. In light of the absence of a controlling decision on the issue by the Court of Appeals for the District of Columbia, the issue remains unresolved.

To pursue this issue or preserve it for further federal court developments, providers should use the protested items line on the cost report, as described under C. "Protested Items," page 5.13. However, the simplest and probably least risky way for hospitals to deal with this issue is to simply wait until patient accounts are returned by the outside collection agency before claiming any Medicare bad debt on the cost report associated with those accounts.

Compliance Tip: Hospitals can use the "protested items" line on the cost report to claim bad debts associated with accounts still pending at collection agencies. However, the simplest and least risky strategy is to wait until the collection agency returns the accounts and claim them on the cost report for the year in which the debt is written off.

Indigent Patients

Another important issue involving a provider's efforts to collect deductible and coinsurance amounts is whether a patient with a delinquent account can be deemed indigent. [PRM-I (CMS Pub. 15-1) ch. 3, Section 312, now 42 C.F.R. 413.89(e)(ii)]. A Medicare bad debt may be deemed uncollectible, irrespective of actual collection efforts, if the beneficiary is indigent. However, in order to take advantage of the indigency rule for bad debts, providers must make a timely, individualized indigency determination that takes into account the patient's income and resources. Providers must also maintain:

1. A specific policy for determining indigency; and
2. Adequate documentation of the indigency determination for a particular patient.

The agency has defined a non-dual indigent beneficiaries and stated in the regulation the steps a provider must take to determine that a beneficiary is a non-dual eligible beneficiary.

A provider must:

1. Not use the beneficiary's declaration of inability to pay as sole proof of indigency;
2. Take into account an assessment of the beneficiary's assets and income, and any extenuating circumstances (liabilities and expenses);
3. Determine no source other than the beneficiary would be legally liable for the beneficiary's medical expenses; and
4. Make available to the MAC, upon request, a copy of its indigency policy.

The agency represents that this policy "will reduce the burden to providers when determining a beneficiary's indigence" [85 Fed Reg. at 58999]. This policy took effect Oct. 1, 2020.

Compliance tip: Maintain detailed documentation of all steps to determine indigency; ensure your policy "mirrors" the regulation

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The Medicare bad debt policy concerning indigency determinations differs from California state law concerning when patients are eligible for "charity care" discounts from hospitals, as set forth in Health and Safety Code Section 127405 *(see chapter 8)*. Unlike the rules governing Medicare bad debt, California's charity care law permits consideration of patient income only, and not assets. Although some Medicare beneficiaries may be eligible for charity care discounts under Health and Safety Code Section 127405, those patients are not necessarily indigent for Medicare bad debt purposes, such that the patients' deductible and coinsurance obligations could automatically be deemed uncollectible without the provider engaging in reasonable collection efforts. *(For more information on California's charity care laws, see chapter 8, "Hospital Fair Pricing Policies.")*

Dual Eligible Beneficiaries

The regulation codifies the agency's "must bill" policy; namely that for a beneficiary who is eligible for both Medicare and Medicaid, the provider must determine whether the state's Medicaid program is responsible to pay all or a portion of the beneficiary's deductible and/or co-insurance by submitting a bill to the state Medicaid agency. This requirement is retroactive.

[85 Fed. Reg. at 5899]. The agency represents that this policy existed before the enactment of the Bad Debt Moratorium barring the agency from changing any of its debt collection policies after Aug. 1, 1987, and, as a result, the Moratorium does not serve as a bar to the application of this rule retroactively.

Recognizing that many providers have encountered issues in following the agency's policy — state Medicaid agencies have failed or refused to issue any remittance advice denying any payment of a dual eligible beneficiary's deductible or coinsurance, the agency has agreed to accept "alternative documentation" [85 Fed. Reg at 59004]. To constitute a reasonable collection effort, a provider must submit all of the following:

1. The state Medicaid notification evidencing that the state has no obligation to pay a beneficiary's Medicare cost sharing or notification evidencing the provider's inability to participate in the state's Medicaid program for the purpose of processing a claim and obtaining a remittance advice,
2. Documentation setting forth the state's liability, or lack thereof, for Medicare cost sharing. This provision is retroactive and the agency instructs MACs to work with providers to resolve pending PRRB cases "so that providers may experience relief and burden reduction through the application of this rule to their existing cases" [85 Fed. Reg. at 59004].

This policy took effect Oct. 1, 2020.

The agency's "must bill" policy has been the subject of substantial litigation – and upheld by many courts. *(See, e.g.,* New LifeCare Hospitals of N.C. v. Becerra*, 7 F.4th 1215 (D.C. Cir. 2021).)* However, other courts have held that the policy was invalid because it was not issued pursuant to the Medicare statute's mandate for notice and comment or the policy violated the Bad Debt Moratorium barring changes in the agency's bad debt policies after Aug. 1, 1987. *(See, e.g.,* Select Specialty Hospital-Denver, Inc. v. Azar*, 391 F. Supp. 3d 53 (D.D.C. 2019) (notice and comment required);* Kindred Healthcare, Inc. v. Azar*, No. 1:18-cv-650, 2020 WL 3574614, at *8 (D.D.C. July 1, 2020); Select, 391 F. Supp. 3d at 59, reconsideration denied, No. 1:10-cv-1356, 2019 WL 5697076 (D.D.C. Nov. 4, 2019), appeal dismissed, No. 20-5004, 2020 WL 768266 (D.C. Cir. Jan. 28, 2020);* Mercy Gen. Hosp. v. Azar*, 410 F. Supp. 3d 63, 77 (D.D.C. 2019) (cases citing the violation of the Moratorium).)*

The new regulation's provisions for the acceptance of documentation that the state Medicaid agency has no liability for the dual-eligible beneficiary's unpaid co-insurance and deductible and inability to participate in the Medicaid program, together with the willingness of MACs to work to resolve these cases are positive measures that may result in a provider's obtaining some bad debt reimbursement for the unpaid co-insurance and deductible of dual eligible beneficiaries in these circumstances.

Other Medicare Bad Debt Issues

Claim Bad Debts in the Year Written Off

Providers should pay attention to timing when seeking bad debt reimbursement. Medicare authority establishes that bad debt should be claimed in the period when it is written off and not when the coinsurance and deductible payment obligation accrued. Bad debt claimed too early will be disallowed. Reimbursable bad debt must be offset by bad debt recoveries

on accounts claimed as bad debt in a prior period. This means that if a provider successfully collects in 2021 on an account that was claimed as bad debt on the provider's 2020 cost report, the provider must deduct the amount collected on the account from the total amount of bad debt claimed on the provider's 2021 cost report. Accordingly, providers must carefully track recoveries to ensure that they properly reduce otherwise allowable bad debt.

Documentation

Consistent with the general rules of cost reimbursement discussed in this chapter, providers must adequately document all aspects of the bad debt collection and write-off process. The new regulations require the provider to furnish the following information when requested:

1. The provider's bad debt collection policy which describes the collection process for Medicare and non-Medicare patients,
2. The patient account history documents that show the dates of various collection actions such as the issuance of bills to the beneficiary, follow-up collection letters, reports of telephone calls and personal contact, etc.; and
3. The beneficiary's file with copies of the bill(s) and follow-up notices.

[42 C.F.R. 413.89 (e)(2)(i)(A)(6)]

Manual provisions reference the same requirements. [PRM-I (CMS Pub. 15-1), ch. 3, Section 310] Providers also should maintain copies of all documents necessary to meet these requirements — internal collection policies (both current and past), collection agency policies, copies of agreements with collection agencies, Medicare Remittance Advices (RAs), documentation of indigency determinations, if any, and support for write-off dates and recoveries. Providers are commonly denied a component of bad debt reimbursement because of inadequate documentation.

Bad Debt Associated with Services Paid Under a Fee Schedule

Finally, hospitals should be aware that CMS takes the position that unpaid patient coinsurance and deductible obligations associated with services paid under Medicare Part B pursuant to a fee schedule are not reimbursable as bad debt. This issue may be relevant for hospitals that provide certain therapeutic services, such as physical therapy, to Medicare beneficiaries in their outpatient departments. According to CMS, Medicare payments made under a fee schedule already necessarily provide some compensation for bad debt, so it is therefore inappropriate to furnish providers with additional compensation for unmet deductible and coinsurance amounts. CMS' position on this issue has been affirmed by at least two different federal courts when challenged by adversely impacted providers. Given CMS' stated policy with respect to bad debt associated with services paid under a fee schedule, as well as the court decisions on this issue, the only way that a hospital could claim such bad debt without facing any compliance risks would be to use the protested items line on the cost report. *(See A. "Including "Appropriate" Claims on the Cost Report as a Condition of Reimbursement," page 5.11 and C. "Protested Items," page 5.13.)*

E. Medicare Outlier Payments

The Medicare program recognizes that prospective payment rates paid under IPPS will not always adequately compensate hospitals for particularly costly cases. For that reason,

Medicare has made available special, additional payments for "outlier" cases in both the inpatient and outpatient hospital settings. [42 U.S.C. Section 1395ww(d)(5)(A); 42 U.S.C. Section 1395l(t)(5)] As with DSH payments, Medicare outlier payments are determined through a relatively complex calculation. Simplified, a particular case will qualify as an "outlier" if the costs a hospital incurred in caring for the patient exceeded the standard Medicare payment amount plus a fixed dollar amount known as a "threshold." [42 C.F.R. Section 412.80; 42 C.F.R. Section 419.43(d)] The outlier threshold is set by CMS for each Medicare fiscal year.

Outlier payments are required by statute to approximate the marginal cost of providing care beyond the threshold. CMS makes this approximation, in part, by assuming a fixed relationship between hospital charges and hospital average costs. To calculate costs for a particular patient discharge, the Medicare program uses "cost-to-charge" ratios developed for each hospital. The ratios generally are calculated using data from hospital cost reports.

For several years, outlier payments were at the forefront of regulatory enforcement activities by both CMS and the Office of Inspector General (OIG) for the United States Department of Health and Human Services (DHHS). Federal regulatory authorities became aware that, because of the way outlier payments were calculated, these payments were particularly susceptible to intentional manipulation. In particular, some hospitals were able to make themselves eligible for more outlier payments than they otherwise would have been by taking advantage of delays in updating cost-to-charge ratios. Typically, this kind of manipulation is accomplished by greatly increasing charges for services over a short period of time before cost-to-charge ratios are updated through the cost-report tentative settlement process. Although CMS has revised the Medicare outlier policies to eliminate some of the susceptibility to this kind of "gaming," outlier payments remain a sensitive compliance issue.

Hospitals will want to keep in mind the compliance issues with outlier payments both when compiling Medicare cost reports and designing or altering hospital cost or charge structures. As both costs and charges figure into the outlier payment calculation, hospitals will want to be able to ensure they have a reasonable basis for costs claimed on Medicare cost reports as well as the charges they use. If a hospital becomes aware that it received significantly more outlier payments during a particular year than it had historically, it would be advisable for the hospital to investigate the matter and try to determine the reason for the increase.

Providers have brought actions alleging that methodologies used by the Secretary of DHHS for setting fixed loss thresholds for outlier payments to their hospitals under the Medicare Act were arbitrary and capricious. The actions have, thus far, resulted in courts remanding several of CMS's outlier thresholds and upholding others. *(See, e.g.,* County of L.A. v. Shalala*, 192 F.3d 1005 (D.C. Cir. 1999) (remanding 1985 and 1986 thresholds);* Dist. Hosp. Partners, L.P. v. Burwell*, 786 F.3d 46 (D.C. Cir. 2015) (remanding 2004 threshold);* Banner Health v. Price*, 867 F.3d 1323 (D.C. Cir. 2017) (remanding 2004-2006 thresholds, upholding 1998-2003 and 2007 thresholds;* Billings Clinic v. Azar*, 901 F.3d 301 (D.C. Cir. 2018) (upholding 2007-2011 thresholds).)*

F. Allied Health Programs

MACs have been denying pass-through treatment or reasonable cost reimbursement of the costs of hospital operated allied health programs, e.g., pharmacy residency and clinical pastoral programs, based on alleged non-compliance by the hospital with 42 C.F.R. Section

413.85(f), finding, among other things, that the hospitals are not the "legal" operators of the programs. MACs have cited the administrative services provided by a home office, e.g., processing of payroll and a centralized home office accounting systems as grounds for finding that hospitals are not directly incurring the costs of the residency training programs, MACs have also found a home office to be a "related organization" and, as such, not entitled to pass-through treatment. In addition, regional offices of some chain organizations that provide some staff and services to hospitals operating allied health programs have been cited as reasons for finding that hospitals are not responsible for program curriculum and the salaries of program staff.

The PRRB has decided a number of allied health appeals in favor of MAC/CMS based on the specific facts of each case. For example, in *Health East 2007 Paramed ED-CPE CIRP Group v. NGS*, PRRB December 2018-D6, 2017 WL 6034230 (Nov. 21, 2017), the PRRB held that the home office operated the program because it controlled the curriculum, employed the staff and issued certificates of completion to successful residents. In *St. Vincent Charity Medical Center v. CGS*, PRRB December 2020 D-6, 2020 WL 5551968 (Aug. 14, 2020), the PRRB rejected the provider's argument that the hospital operated the program because the hospital was but one site where the program trained residents. The PRRB did not address the fact that historically, allied health programs have rotated residents to a number of hospitals – and reimbursement has been granted so long as the individual provider only claims the costs of the rotations at its hospital. In *Medical University Hospital Authority v. Palmetto*, PRRB December 2019 D-15, 2019 WL 1557539 (Feb. 19, 2019), the PRRB held that the hospital did not directly incur the costs of the program because it was reimbursed for the costs by another entity. Yet in the federal district court's review of the Administrator's affirmance of the PRRB's decision in this case, the court found the PRRB's review "too narrow," finding that if the costs of the operation of an allied health program ultimately were reflected on the provider's books and records, the costs were directly incurred. *Medical University Hospital Authority v. Becerra*, 2021 WL 1177860 (D. S.C. March 29, 2021). This court's approach to compliance with 45 C.F.R. Section 413.85(f) — supporting the provider's theory of the case — casts significant doubt on the PRRB's analytical approach to these cases. The court emphasized that the operation of the programs at the hospital level (i.e., a functional analysis) was essential to determining the "operator" of the program, suggesting that a literal interpretation of the applicable regulation would not necessarily answer this question.

The denials of pass-through treatment of these costs by MACs have been made to hospital cost reports for programs that have been granted pass-through treatment for decades and represents a dramatic change in agency policy lacking any notice to providers, CMS order, or any rulemaking mandated by the Medicare statute. Hospitals are appealing these denials.

G. Organ Acquisition Costs

The distinction between pre- and post-transplant services is critical from a Medicare reimbursement perspective. Medicare pays hospitals for the acquisition of organs used in kidney, heart, heart-lung, liver, lung, pancreas, kidney/pancreas and intestinal transplants on a cost-reimbursement basis. [42 C.F.R. Section 412.113(d); *Medicare Claims Processing Manual* (CMS Pub. 100-04), ch. 3, Section 90] In contrast, the organ transplants themselves and other post-transplant medical services are reimbursed on a prospective basis, whether under the inpatient prospective payment system, outpatient prospective payment system, or

the Medicare physician fee schedule.

The OIG has commented on multiple occasions regarding the allocation of transplant-related costs. Based on audit experience, the OIG became concerned that some providers were improperly treating certain costs, such as those associated with the activities of transplant coordinators, as organ acquisition costs when the activities did not actually occur pre-transplant. This may have occurred because the providers wanted more favorable cost-reimbursement treatment for the services. As a result, the OIG issued guidance on how providers should properly claim organ acquisition costs. The OIG's report regarding organ acquisition costs can be found on its website at http://oig.hhs.gov/oas/reports/region9/90500034a.pdf.

The OIG emphasizes that providers must allocate costs reasonably between different transplant programs, even those programs that share staff and space. Providers also must allocate costs reasonably between pre- and post-transplant costs in calculating acquisition costs. The OIG suggests that providers use time cards and/or time studies to assist with the proper allocation of costs. Again, providers must take into account that there is staff and space common to both pre- and post-transplant activities. If providers are unsure about how to properly allocate organ acquisition costs, they should seek guidance from their contractors or CMS.

CMS issued a proposed regulation on May 10, 2021 to address some of these concerns [86 Fed. Reg. 25070, 25656-25676], including codifying existing policy that acquisition costs incurred from a living donor or a cadaveric donor by the donor hospital or by an OPO qualify as organ acquisition costs. CMS proposed some definitional changes to ensure the use of more consistent terminology, addressed differences in coverage for living and cadaveric donors, and applied some elements of kidney acquisition costs to non-renal organs; all with a goal of ensuring proper allocation of costs to the appropriate payor. In view of the large number of comments received, CMS decided to address these issues in future rulemaking. [85 Fed. Reg. 44774, 44777 (Aug. 13, 2021)]

Compliance Tip: Providers must take into account that there is staff and space common to both pre- and post-transplant activities. Providers unsure about how to properly allocate organ acquisition costs should seek guidance from their MACs or CMS.

The 21st Century Cures Act amended the Social Security Act to allow all Medicare-eligible individuals with end stage renal disease (ESRD) to enroll in Medicare Advantage plans beginning Jan. 1, 2021. On May 21, 2020, CMS finalized rules requiring that Medicare Advantage be made available to ESRD-eligible Medicare beneficiaries as required by the statute. Historically, Medicare Advantage has been an option only for those qualifying for Medicare because of age or disability and those choosing to enroll in a Medicare Advantage Special Needs Plan. In the final rules, CMS clarified that, beginning in 2021, Medicare Advantage patients will be "counted" as Medicare patients in determining the Medicare percentage for kidney transplants, thereby assuring that Medicare Advantage patients' renal organ acquisition costs will be covered by Medicare.

H. Wage Index Data

Wage index reporting is a component of Medicare's prospective payment system for hospitals. CMS adjusts prospective payments by the wage index applicable to the area in which a hospital is located. CMS calculates different wage indexes for various designated geographic regions using cost report data from all hospitals participating in the Medicare prospective payment system. Wage index figures are based on cost data that is four years old in order to give CMS and contractors time to review and audit the data.

There are specific rules, largely contained in the Provider Reimbursement Manual, governing how hospitals must report wage data on their Medicare cost reports. Hospital compliance with these requirements has in the past been the subject of audit activities by the OIG. In early 2007, the OIG issued a report concluding that 21 hospitals reported roughly $378 million in wage data that did not comply with applicable requirements. According to the OIG, the hospitals erred in reporting wage data because they did not sufficiently review and reconcile their reported wage data to supporting documentation to ensure the accuracy of the data. *(See Office of Inspector General, "Review of Hospital Wage Data Used to Calculate Inpatient Prospective Payment System Wage Indexes," Report No. A-01-05-00504 (Feb. 26, 2007), available at* http://oig.hhs.gov/oas/reports/region1/10500504.pdf*.)* When hospitals overstate wage data, they receive greater Medicare reimbursement at the expense of hospitals that report wage data accurately. More recently, the OIG issued a report, citing numerous significant vulnerabilities in the wage index system. The vulnerabilities identified by the OIG were:

1. The lack of authority for CMS to penalize hospitals that submit inaccurate or incomplete wage or occupational mix data (in the absence of misrepresentation or falsification);
2. The limited-scope desk reviews performed by MACs, which do not always identify inaccurate wage data;
3. That the rural floor decreases wage index accuracy; and
4. That reclassification "hold-harmless" provisions decrease wage index accuracy.

(See Office of Inspector General, "Significant Vulnerabilities Exist in the Hospital Wage Index System for Medicare Payments," Report No. A-01-17-0050 (Nov. 21, 2018), available at https://oig.hhs.gov/oas/reports/region1/11700500.pdf*).*

For FFY 2020, FFY 2021, and FFY 2022, CMS has instituted a new area wage index policy that provides an area wage index (AWI) value bump to hospitals in the lowest quartile of AWI values nationally. CMS has decided to pay for this bump by cutting the standardized amount for all IPPS hospitals across the nation [84 Fed. Reg. 42044, 42325-42332 (Aug. 16, 2019), 85 Fed. Reg.58432, 58765 (Sept. 18, 2020), and 86 Fed. Reg. 44774, 45178 (Aug. 13, 2021)]. Despite this policy that manipulates the area wage index data, and given the OIG's focus on this issue, hospitals must strive to report wage data accurately on their costs reports. Although labor costs are not reimbursed to providers directly, they do factor into the Medicare payments hospitals receive. Accordingly, largely because of the Medicare cost report certification form, submitting a cost report with wage data not in compliance with Medicare rules could potentially give rise to false claims liability.

In its 2007 report on wage index issues, the OIG identified several problems with wage index reporting. Hospitals should be aware of these issues when preparing Medicare cost reports. Specifically, the OIG identified the following as problematic.

Overstated Pension and Other Post-Retirement Benefit Costs

Per CMS policy, hospitals must report pension and other post-retirement benefit costs on a cash basis. This means that pension and other benefit costs must be liquidated before a hospital claims such costs on its cost report, which differs from certain GAAP provisions. CMS and Medicare contractors consider it inappropriate for hospitals to claim unliquidated pension and benefit costs. *(See Office of Inspector General, "Review of Hospital Wage Data Used to Calculate Inpatient Prospective Payment System Wage Indexes," Report No. A-01-05-00504 (Feb. 26, 2007) available at* http://oig.hhs.gov/oas/reports/region1/10500504.pdf*.)* Although providers have attempted to challenge CMS' policy regarding the reporting of pension and other post-retirement costs, recent federal court decisions have upheld CMS' position [*Regents of the Univ. of California v. Burwell*, 155 F. Supp. 3d 31 (D.D.C. 2016), aff'd, 681 Fed.App. 5 (D.C. Cir. 2017); *Abington Mem'l Hosp. v. Burwell*, 216 F. Supp. 3d 110 (D.D.C. Oct. 26, 2016)].

Misstated Wages, Fringe Benefit Costs, Home Office Costs and Nonsalary Costs

The Medicare Provider Reimbursement Manual identifies several categories of salary and benefit costs that should not be claimed on the cost report for Part A cost reporting purposes. For example, hospitals are directed to exclude salary costs for skilled nursing facility services, rural health clinic services, and interns and residents. Certain advertising costs also should be excluded from wage index calculations. *(See Office of Inspector General, "Review of Hospital Wage Data Used to Calculate Inpatient Prospective Payment System Wage Indexes," Report No. A-01-05-00504 (Feb. 26, 2007); see also PRM-II (CMS Pub. 15-2), ch. 36, Section 3605.2; PRM-1 (CMS Pub. 15-1), ch.21, Section 2136.2.)* Hospitals must ensure that they do not report any of these excluded cost categories on their cost reports.

Misstated and Unsupported Costs for Contract Labor

The Medicare rules allow hospitals to report contract labor costs only for certain specified types of services. In general, any contract labor costs not directly related to patient care should not be claimed on a hospital's Medicare cost report. Hospitals must ensure that they claim contract labor costs related only to services that are recognized by the Medicare program as allowable, including nursing, diagnostic, therapeutic, rehabilitative services and certain management services. *(See Office of Inspector General, "Review of Hospital Wage Data Used to Calculate Inpatient Prospective Payment System Wage Indexes," Report No. A-01-05-00504 (Feb. 26, 2007); see also PRM-II (CMS Pub. 15-2), ch. 36, Section 3605.2.)*

Costs for Nonallowable Part B Services

Under Medicare statutes and regulations, the costs of services provided by nurse practitioners and physicians are covered by Medicare Part B (not Part A). The Provider Reimbursement Manual requires hospitals to exclude from reported wage index information physician, nurse practitioner and other services that the hospital claims for Part B reimbursement. A hospital may claim costs for physician services under Part A when those costs relate to administrative functions and not patient care that would otherwise be covered under Medicare Part B. However, the hospital must be able to adequately document the physician functions. Hospitals should be aware of the rules regarding physician and

nonphysician practitioner labor costs when preparing and submitting their cost reports. *(See Office of Inspector General, "Review of Hospital Wage Data Used to Calculate Inpatient Prospective Payment System Wage Indexes," Report No. A-01-05-00504 (Feb. 26, 2007); see also PRM-II (CMS Pub. 15-2), ch. 36, Section 3605 and ch. 21, Section 2108.)*

I. FQHCs and RHCs

The Medicare program reimburses Federally Qualified Health Centers (FQHC) and Rural Health Clinics (RHC) that are operated as part of a hospital on a cost basis. FQHCs are safety net providers, typically for outpatient services. FQHCs can include community health centers, migrant health centers, and health care for homeless health centers. (Federally Qualified Health Center," ICN MLN006397 Medicare Learning Network (January 2021).) RHCs provider outpatient services in rural, underserved areas "with a shortage of primary care providers, personal health services, or both." *(See Rural Health Clinics," ICN MLN006397 Medicare Learning Network (January 2021).)*

In general, reimbursement to FQHCs and RHCs is governed by the Medicare cost-based reimbursement principles discussed above. However, the Medicare regulations offer additional, specific guidance regarding the type of costs that generally are viewed as "reasonable" for FQHCs and RHCs [42 C.F.R. Section 405.2468(b)]. For example, costs that are viewed as reasonable for FQHCs and RHCs include:

1. Compensation for the services of health care providers such as physicians, physician assistants, nurse practitioners, and certified nurse-midwives;
2. Compensation for the duties of a supervising physician;
3. Costs of "services and supplies incident to the services of a physician;" (4) overhead costs for the administration of an FQHC or RHC; and
4. "Costs of services purchased by the RHC or FQHC."

[42 C.F.R. Section 405.2468(B)(1)-(4)]

In addition, CMS is authorized by statute to establish limits or screening guidelines regarding the amount of costs that are reasonable for FQHCs and RHCs to incur for particular items and services [42 C.F.R. Section 405.2468(c)]. The screening guidelines assess the costs of certain services, including but not limited to compensation for a physician's professional and supervisory services, administrative expenses, and staffing. [42 C.F.R. Section 405.2468(d)(2).] To bill costs exceeding the amounts established by the screening guidelines as allowable costs, the FQHC or RHC must provide a reasonable justification "satisfactory to the MAC." [42 C.F.R. Section 405.2468(d)(1).]

For the purposes of preparing their cost reports, providers that operate an FQHC or RHC should familiarize themselves with the specific guidance that CMS offers for these types of facilities, as well as the general Medicare rules for cost reporting.

J. Market-Based MS-DRG Relative Weight Estimation — Repealed

In August 2021, as part of the Fiscal Year (FY) 2022 Medicare Hospital Inpatient Prospective Payment System (IPPS) and Long Term Care Hospital (LTCH) Rates Final Rule, CMS repealed the "market-based data collection requirement" that it had adopted in the FY 2020 IPPS rule. [86 Fed. Reg. 44784, 45317-45319 (Aug. 13, 2021)] Under the repealed rule, hospitals would have been required to report median payer-specific rates negotiated with Medicare Advantage organization payers by Medicare severity diagnosis-related group ("MS-

DRG"). The repeal eliminates what CMS acknowledges would have been a large burden for hospitals. CMS also repealed the requirement to use payer-specific negotiated rate data in the MS-DRG relative weight methodology, starting in FY 2024. In its press release, CMS stressed that the repeal of this data collection and payment policy does not dilute the agency's commitment to hospital price transparency. Thus, it is possible that CMS will develop reporting requirements along similar lines in the coming years.

K. Other Common Cost Reporting Compliance Issues

For facilities that are reimbursed under Medicare or Medi-Cal on a reasonable cost basis for some of their services, there are many cost report compliance concerns. In summary, among the most common concerns are:

1. Costs are claimed that are not properly documented in the provider's records.
2. Costs are claimed that were not actually incurred either under generally accepted accounting principles or under specific reasonable cost rules.
3. Cost allocations are not supported by adequate documentation.
4. Cost allocations or cost apportionment is done in a manner that is inconsistent with Medicare-suggested or required methodologies or prior provider practices solely to enhance reimbursement.
5. Costs are claimed that are nonallowable because they are not related to patient care or are classified as nonallowable pursuant to a specific cost reimbursement rule.
6. Related organizations are not properly identified, and charges of related organizations are not reduced to the related organization's costs.
7. Nonallowable cost centers are not established when required by program guidelines or instructions or for an accurate determination of costs.
8. Interest expense is not reduced by investment income.
9. Home office cost allocations are not made in accordance with Medicare program requirements or are not supported by adequate documentation.
10. Physician administrative costs are not supported by time allocations or time studies.

IX. ACCOUNTING FOR COST REPORT ISSUES AS PART OF A COMPLIANCE PROGRAM

In designing and maintaining an effective compliance program *(see chapter 1)*, hospitals should attempt to fully account for the cost reporting issues addressed in this chapter. It is recommended that hospitals develop well-documented policies and procedures coupled with appropriate and effective controls.

Elements of a compliance program likely to have the greatest impact on cost reporting include:

1. Training and education;
2. Auditing and monitoring; and

3. Response and prevention.

These activities are discussed below.

A. Training and Education

Hospitals should strive to ensure that everyone involved in the cost report preparation process is adequately trained on all relevant laws, regulations, rules and internal policies. In addition, continuing education is imperative for any changes in applicable laws, controlling authorities or policies. It is important that hospitals document this training and education.

Effective training and education may include:

1. Internal meetings to review the organization's cost report policies, procedures, templates, methods, etc., with minutes documenting the agenda.
2. Access for cost report preparers to technical reference materials and resource information, including Medicare cost report instructions and regulations. When such resources are used, the resource document should be referenced in and/or filed with appropriate cost report work papers.
3. Written communication to cost report preparers that illustrates risk areas identified by the hospital or its compliance advisors.
4. Written communication to cost report preparers about OIG investigations of other providers, or other enforcement actions, that may provide useful guidance to the organization.
5. Cost report checklists and record-keeping requirements for related documentation.

B. Auditing and Monitoring

Hospitals must strive to ensure that proper cost reporting procedures are being followed. How best to accomplish this depends on the hospital and its organizational structure. CMS expects providers to undertake both proactive and reactive measures to monitor for overpayments. Regardless of how hospitals decide to audit and monitor cost report compliance, they should strive to document their efforts. If the government ever investigates a hospital for possible cost report compliance violations, a hospital will want to prove that its auditing and monitoring policies were effective by producing adequate documentation.

Compliance Tip: However a hospital decides to audit and monitor cost report compliance, it should strive to document its efforts. If the government ever investigates a hospital for possible violations, hospitals will need documentation to prove their auditing and monitoring policies were effective.

C. Response and Prevention

The detection and prevention of errors is one of the main goals of an effective compliance program. For cost reporting purposes, hospitals should review the cost report preparer's work, along with documented revisions in the cost report work papers, if appropriate. Documenting that cost reporting errors were corrected will help to demonstrate that a hospital's compliance efforts were indeed effective.

Compliance Tip: Documenting that cost reporting errors were corrected will help to demonstrate that a hospital's compliance efforts were indeed effective.

If an error in a current or prior cost report filing is detected, the hospital must follow the appropriate policy and procedure for investigation and disclosure or repayment *(see chapter 15, "Repayment and Self-Disclosure")*. It is more beneficial for hospitals to focus on correcting past mistakes than on undertaking disciplinary action for errors. However, disciplinary action may be appropriate in the event of intentional errors or failure to comply with policies and procedures.

Hospital and Hospital Health Care Complex Cost Report Certification and Settlement Summary

04-20 FORM CMS-2552-10 4090 (Cont.)

This report is required by law (42 USC 1395g; 42 CFR 413.20(b)). Failure to report can result in all interim payments made since the beginning of the cost reporting period being deemed overpayments (42 USC 1395g).

FORM APPROVED
OMB NO. 0938-0050
EXPIRES 03-31-2022

HOSPITAL AND HOSPITAL HEALTH CARE COMPLEX COST REPORT CERTIFICATION AND SETTLEMENT SUMMARY	PROVIDER CCN: _____	PERIOD FROM _____ TO _____	WORKSHEET S PARTS I, II & III

PART I - COST REPORT STATUS

Provider use only	1. [ ] Electronically filed cost report Date: _____ Time: _____ 2. [ ] Manually submitted cost report 3. [ ] If this is an amended report enter the number of times the provider resubmitted this cost report 4. [ ] Medicare Utilization. Enter "F" for full or "L" for low.		
Contractor use only	5. [ ] Cost Report Status (1) As Submitted (2) Settled without audit (3) Settled with audit (4) Reopened (5) Amended	6. Date Received:_____ 7. Contractor No.:_____ 8. [ ] Initial Report for this Provider CCN 9. [ ] Final Report for this Provider CCN	10. NPR Date:_____ 11. Contractor's Vendor Code: _____ 12. [ ] If line 5, column 1, is 4: Enter number of times reopened = 0-9.

PART II - CERTIFICATION

MISREPRESENTATION OR FALSIFICATION OF ANY INFORMATION CONTAINED IN THIS COST REPORT MAY BE PUNISHABLE BY CRIMINAL, CIVIL AND ADMINISTRATIVE ACTION, FINE AND/OR IMPRISONMENT UNDER FEDERAL LAW. FURTHERMORE, IF SERVICES IDENTIFIED IN THIS REPORT WERE PROVIDED OR PROCURED THROUGH THE PAYMENT DIRECTLY OR INDIRECTLY OF A KICKBACK OR WERE OTHERWISE ILLEGAL, CRIMINAL, CIVIL AND ADMINISTRATIVE ACTION, FINES AND/OR IMPRISONMENT MAY RESULT.

CERTIFICATION BY CHIEF FINANCIAL OFFICER OR ADMINISTRATOR OF PROVIDER(S)

I HEREBY CERTIFY that I have read the above certification statement and that I have examined the accompanying electronically filed or manually submitted cost report and submitted cost report and the Balance Sheet and Statement of Revenue and Expenses prepared by _____{Provider Name(s) and Number(s)} for the cost reporting period beginning _____ and ending _____ and to the best of my knowledge and belief, this report and statement are true, correct, complete and prepared from the books and records of the provider in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regulations regarding the provision of health care services, and that the services identified in this cost report were provided in compliance with such laws and regulations.

☐ I have read and agree with the above certification statement. I certify that I intend my electronic signature on this certification statement to be the legally binding equivalent of my original signature.

(Signed) _____
Chief FinancialOfficer or Administrator of Provider(s)

_____
Title

_____
Date

PART III - SETTLEMENT SUMMARY

		TITLE V	TITLE XVIII PART A	TITLE XVIII PART B	HIT	TITLE XIX	
		1	2	3	4	5	
1	HOSPITAL						1
1.01	*HOSPITAL-PARHM*						*1.01*
2	SUBPROVIDER - IPF						2
3	SUBPROVIDER - IRF						3
4	SUBPROVIDER (OTHER)						4
5	SWING BED - SNF						5
5.01	*SWING BED-PARHM (CAH ONLY)*						*5.01*
6	SWING BED - NF						6
7	SNF						7
8	NF, ICF/IID						8
9	HOME HEALTH AGENCY						9
10	HOSPITAL-BASED - RHC						10
11	HOSPITAL-BASED - FQHC						11
12	OUTPATIENT REHABILITATION PROVIDER (Specify)						12
200	TOTAL						200

The above amounts represent "due to" or "due from" the applicable program for the element of the above complex indicated.

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0050. The time required to complete this information collection is estimated 673 hours per response, including the time to review instructions, search existing resources, gather the data needed, and complete and review the information collection. If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Report Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850. Please do not send applications, claims, payments, medical records or any documents containing sensitive information to the PRA Reports Clearance Office. Please note that any correspondence not pertaining to the information collection burden approved under the associated OMB control number listed on this form will not be reviewed, forwarded, or retained. If you have questions or concerns regarding where to submit your documents, please contact 1-800-MEDICARE.

6 Physician Self-Referral Laws

I. Introduction 6.1

II. Federal Law 6.2

A. General Rule 6.2

B. Relationship to Other Laws 6.3

Relationship to the Federal Anti-Kickback Statute 6.3

C. Definitions 6.4

Designated Health Services 6.4

Entity 6.5

Immediate Family Member 6.5

Physician 6.6

Financial Relationship 6.6

Ownership and Investment Interests 6.6

Compensation Arrangements 6.7

Referral 6.9

Period of Disallowance 6.10

Stand in the Shoes 6.11

Value-Based Activity 6.11

D. Special Rules on Compensation 6.12

Set in Advance 6.12

Volume or Value Standard and Other Business Generated Standard 6.13

Writing and Signature Requirements 6.13

Physician Compensation Conditioned Upon Referrals 6.14

E. "Under Arrangements" Restriction 6.14

F. Exceptions Related to Both Ownership/Investment Interests and Compensation Arrangements 6.15

Physician Services 6.15

In-Office Ancillary Services 6.15

Managed Care Patients 6.19

Academic Medical Centers 6.19

Implants Furnished by an ASC 6.21

EPO and Other Dialysis-Related Drugs 6.21

Preventive Screening Tests and Vaccines 6.22

Eyeglasses and Contact Lenses Following Cataract Surgery 6.22

Intra-Family Rural Referrals 6.22

G. Exceptions Related to Ownership/Investment Interests 6.23
Publicly-Traded Securities 6.23
Mutual Funds 6.23
Hospital Ownership by Physician 6.23
Rural Providers 6.26
H. Exceptions Related to Compensation Arrangements 6.26
Rental of Office Space 6.26
Rental of Equipment 6.27
Bona Fide Employment Relationships 6.28
Personal Services Arrangements 6.29
Physician Recruitment 6.30
Limited Remuneration to Physician 6.36
Isolated Transactions 6.36
Certain Arrangements With Hospitals 6.37
Group Practice Arrangements With a Hospital 6.38
Purchase of Items/Services — Payments by a Physician to Laboratory or Other Entity 6.38
Charitable Donations by a Physician 6.39
De Minimis Exception (Nonmonetary Compensation) 6.39
Medical Staff Incidental Benefits 6.40
Fair Market Value Compensation 6.41
Compliance Training 6.43
Indirect Compensation Arrangements 6.43
Referral Services 6.44
Obstetrical Malpractice Insurance Subsidies 6.44
Professional Courtesy 6.46
Retention Payments in Underserved Areas 6.46
Community-Wide Health Information Systems 6.48
Electronic Prescribing Items and Services 6.49
Electronic Health Records Items and Services 6.50
Arrangements That Facilitate Value-Based Health Care Delivery and Payment 6.51
Cybersecurity Technology and Related Services 6.51
I. Exceptions To Prohibition/Temporary Non-Compliance 6.52
J. Sanctions for Violations of the Federal Physician Self-Referral Law 6.52
K. Waiver of the Stark Law for Accountable Care Organizations 6.53
L. Waiver of the Stark Law for Joint Replacement Model 6.54

M. Transition to Value-Based Care and Value-Based Arrangement Exceptions 6.54
Full Financial Risk Exception 6.54
Meaningful Downside Financial Risk to the Physician 6.55
Value-Based Arrangements Exception 6.55
N. Disclosing Stark Violations 6.57
O. Advisory Opinions 6.57

III. California Law 6.57
A. Introduction 6.57
B. General Rule and Definitions 6.57
Covered Health Care Professionals 6.58
Covered Services 6.58
C. Relevant Exceptions 6.59
Hospital Exception 6.59
Lease Exceptions (Rental Equipment and Space) 6.60
Personal Services 6.60
Managed Care Patients 6.61
Hospice Medical Director 6.61
Physician Recruitment 6.61
D. Patient Disclosure Requirement 6.62
E. Sanctions 6.62

FORMS & APPENDICES

HC 6-A Group Practice Definition

6 Physician Self-Referral Laws

I. INTRODUCTION

Physician self-referral is the practice of a physician referring a patient to a laboratory, imaging center, hospital or other entity with which the physician has a financial relationship. The financial relationship involved may be an ownership or investment interest, or a compensation arrangement.

The federal government is concerned about physician self-referrals because the financial relationship may encourage a physician to over-utilize services. Over-utilization increases health care costs to the Medicare program and may result in patients having tests or services they do not need.

Due to these concerns, Congress passed a law in 1989 prohibiting a physician with a financial relationship in a clinical laboratory from referring Medicare patients to that laboratory. This law is often referred to as the "Stark" law because it was authored by Congressman Pete Stark. The law included several exceptions to protect certain business arrangements between physicians and labs.

This law has been expanded many times, and complex regulations have been published to clarify it. The self-referral prohibition now applies to many types of health care services, including all inpatient and outpatient hospital services.

The most recent significant revisions occurred on Dec. 2, 2020, pursuant to a final rule published by the Centers for Medicare & Medicaid Services (CMS) that made substantial additions and modifications to the Stark law (the "2020 Final Rule"). Among other changes, the 2020 Final Rule created new Stark law exceptions for certain "value-based" arrangements and other activities, created new or revised definitions for fundamental terms, such as "fair market value," "commercially reasonable," and the so-called "volume or value" standard, that are used throughout the regulations and have caused some uncertainty, and otherwise made notable changes throughout the regulations. The 2020 Final Rule was published in the Federal Register at 85 Fed. Reg. 77492 (Dec. 2, 2020). It became effective Jan. 19, 2021 (with the exception of a few requirements applicable to group practices that are effective Jan. 1, 2022), and is reflected in this chapter. Most recently, in the CMS 2022 Physician Fee Schedule Final Rule, CMS revised the scope of indirect compensation arrangements, as addressed further herein.

Separately, on March 30, 2020, in response to the COVID-19 pandemic, CMS issued broad waivers to the Stark law, pursuant to its authority under Section 1135 of the Social Security Act. The waivers apply for "COVID-19 purposes," and are available to providers who furnish items and services in good faith but are unable to comply with one or more specified Stark law requirements as a result of consequences of the pandemic. Of note, the waivers apply only to some requirements — compliance with the non-waived requirements is still required. Providers should review these blanket waivers carefully before relying on them to ensure the proposed arrangement meets the requirements, and be aware that these waivers are only available only from March 1, 2020 through the end of the emergency declaration.

This chapter explains the prohibition on self-referral, the exceptions to the prohibition, and penalties for violations of the law. This chapter also describes related California laws, including the Physician Ownership and Referral Act (PORA), which is also known as the "Speier" law, after the state legislator (Jackie Speier) who authored it.

Key Chapter Compliance Tips:

1. Establish a process to assure that physicians do not begin providing services for the hospital until a written agreement signed by all parties is in place that qualifies under a self-referral exemption.
2. Establish a system for tracking the expiration dates for physician contracts so that contracts are renewed in a timely manner and gap periods without written agreements in place are avoided.
3. Where physicians are required to submit logs documenting services rendered, establish a process requiring review and approval of logs for each log period prior to making any payment for such services.
4. Require documentation of the fair market value of payments to or from physicians, whether provided by independent appraisals or determined internally, prior to entering into any financial arrangements with physicians.
5. Assure that all amendments to agreements with physicians are in writing and have a term of at least one year, unless a term of less than a year is approved by the hospital's legal counsel.
6. Check on physician ownership of vendors and suppliers.
7. Remember that financial relationships with a physician's "immediate family members" are attributed to the physician.

Note: While it is not required in all instances for all of these steps to be met to be considered in compliance with federal and California self-referral laws (e.g., a physician providing services before a written agreement is signed), as a general matter these compliance tips are a good practice to implement to reduce risk of non-compliance.

II. FEDERAL LAW

A. General Rule

The Stark law prohibits a physician from referring Medicare patients for designated health services (DHS) if the physician (or an immediate family member of the physician) has a financial relationship with the entity providing the DHS, unless an exception applies [42 U.S.C. Section 1395nn; 42 C.F.R. Section 411.350 *et seq.*].

If a prohibited referral is nevertheless made, the recipient of the referral (that is, the entity providing the DHS) may not bill the Medicare program, the patient, or anyone else for the services performed as a result of the prohibited referral. Significant financial penalties may

result if Medicare is billed, including up to $15,000 per violation. *(See J. "Sanctions for Violations of the Federal Physician Self-Referral Law," page 6.52.)*

The U.S. Department of Health and Human Services (DHHS) maintains a website with information about the Stark law at www.cms.gov/PhysicianSelfReferral. This website includes answers to frequently asked questions and advisory opinions, along with other helpful information.

Although the Stark law does not prohibit the referral of Medicaid patients, a separate law provides that federal matching payments will not be made to states for Stark-designated healthcare services that are furnished to Medicaid patients on the basis of a referral that would result in the denial of payment by Medicare under the Stark law if provided to a Medicare patient [42 U.S.C. Section 1396b(5)]. This statute has generally been interpreted to restrict payments to states, but not to apply the Stark law's prohibitions to Medicaid patients. However, the Department of Justice (DOJ) and *qui tam* relators have successfully taken the position in several district court cases that providers violate the False Claims Act when they submit claims to state Medicaid agencies for services rendered by entities with which they have a financial relationship, where those referrals would have been prohibited by the Stark law if made for a Medicare patient [*U.S. ex rel. Parikh v. Citizens Med. Ctr.*, 977 F. Supp.2d 654 (S.D. Tex. 2013); *U.S. and State of Fla. ex rel. Schubert v. All Children's Health Sys. Inc.*, third Amended *qui tam* Compl. Dkt. No. 45, Case 8:11-CV-01687 – JDW – EAJ (April 29, 2013); *U.S. ex. rel. Baklid – Kunz v. Halifax Med. Ctr.*, 2012 WL 921147 (M.D. Fla. March 29, 2012); *U.S. ex. rel. Osheroff v. Tenet Healthcare Corp.*, 2012 WL2871264 (S.D. Fla. July 12, 2012)]. The theories put forward are either that the Medicaid claims are themselves false claims, because they are passed from the state Medicaid program to the federal government, or that the provider is causing the state Medicaid program to submit false claims to the federal government. It is clearly now the position of the DOJ (though one could disagree with this position) that the submission of Medicaid claims which would have been prohibited if they were Medicare claims constitutes the submission of False Claims.

B. Relationship to Other Laws

Compliance with the Stark law as described in this chapter will not necessarily ensure compliance with other state or federal laws. For example, although a particular arrangement involving a physician's financial relationship with an entity may not prohibit the physician from making referrals to the entity under Stark, the arrangement may nevertheless violate the federal anti-kickback law *(see chapter 7, "Federal and State Anti-Kickback Laws")* or other laws enforced by DHHS, the Federal Trade Commission, the Securities and Exchange Commission, the Internal Revenue Service, or other federal or state agency.

It is essential for hospitals to analyze their business arrangements under both federal and state laws, as compliance with one law does not ensure compliance with other relevant laws. Hospitals are strongly encouraged to consult experienced legal counsel when contemplating proposed business transactions to be sure that all potential legal issues are identified and addressed.

Relationship to the Federal Anti-Kickback Statute

The Stark statute and the anti-kickback statute are two very different laws. Although both laws are directed at the problem of inappropriate financial incentives influencing medical decisions, the laws differ in scope and structural approach. Some of the major differences are:

1. The Stark law pertains only to physician referrals under Medicare. The anti-kickback statute applies to anyone who engages in business with a federal health care program, including providers, plans, vendors, and suppliers.
2. The Stark law is not a criminal law. It is a civil law and does not require a wrongful intent for an entity to violate the law. Billing for DHS rendered pursuant to a prohibited referral is punishable by the return of all Medicare payments made for services provided to patients referred by the physician. In addition, civil monetary penalties may be imposed for billing for DHS that the provider knew, or should have known, were rendered pursuant to a prohibited referral.
3. The anti-kickback statute is a felony criminal law that prohibits the "knowing and willful" payment or receipt of remuneration to compensate or induce referrals. Thus, an entity must have some wrongful intent to violate the law. A violation may be punishable by exclusion from federal health care programs, criminal fines, a prison sentence, and civil money penalties.
4. The Stark law contains many exceptions to the general referral prohibition. Compliance with an exception is required if a physician makes Medicare referrals to a DHS entity with which the physician has a financial relationship.
5. The anti-kickback law contains many "safe harbors." Compliance with a safe harbor is voluntary as transactions that do not meet a safe harbor do not necessarily violate the statute.

In each situation where the Stark law applies, the anti-kickback statute may apply also. An entity contemplating a proposed business arrangement with a physician should first determine whether it meets a Stark exception. If it does not, the arrangement will cause Medicare referrals from the physician to the entity to be prohibited. If the proposed business arrangement meets a Stark exception, then it should be analyzed under the anti-kickback statute. *(See chapter 7, "Federal and State Anti-Kickback Laws.")*

C. Definitions

The Stark law has more than 50 defined terms [42 C.F.R. Section 411.351]. Many of the terms used have obvious definitions, while others have fairly technical definitions. Many of the definitions are included in this chapter; however, it is important to review the definitions of terms prior to entering into a financial relationship with a physician so that important nuances are not overlooked. The following section summarizes some of the key definitions and concepts found throughout the Stark law. *(See CHA Appendix HC 6-A for the definition of "group practice," which was changed significantly effective Jan. 1, 2022, as part of the 2020 Final Rule))*

Designated Health Services

The Stark law applies to a broad range of services, called **"designated health services"** (DHS), which include:

1. All inpatient and outpatient hospital services;
2. Clinical laboratory services;
3. Physical therapy, occupational therapy, and outpatient speech-language pathology services;

4. Radiology and certain other imaging services, including MRI, CT, and ultrasound;
5. Radiation therapy services and supplies;
6. Durable medical equipment and supplies;
7. Parental and enteral nutrients, equipment and supplies;
8. Prosthetics, orthotics and prosthetic devices and supplies;
9. Home health services; and
10. Outpatient prescription drugs.

Lithotripsy is not itself a DHS, although lithotripsy services are covered by the Stark law when provided by a hospital as part of hospital inpatient or outpatient services.

A service furnished to inpatients by a hospital does not constitute a DHS if the service does not affect the amount Medicare pays to the hospital under a prospective payment system.

[42 C.F.R. Section 411.351]

CMS publishes a list each year of HCPCS and CPT codes for the following DHS to which the physician self-referral prohibition applies:

1. Clinical lab services,
2. Physical therapy services,
3. Occupational therapy services,
4. Speech-language pathology services,
5. Radiology and certain other imaging services, and
6. Radiation therapy services and supplies.

The list of HCPCS and CPT codes may be found at https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/List_of_Codes.html.

Entity

An **"entity"** to which referrals are made for purposes of the Stark law includes a physician's solo practice or a group practice, or any other person or entity that "furnishes" DHS. A person or entity is considered to be furnishing DHS if it:

1. Is the person or entity that has performed services that are billed as DHS; or
2. Is the person or entity that has presented a claim to Medicare for DHS (including claims submitted pursuant to a reassignment from another provider).

Immediate Family Member

As mentioned above, a physician may not refer a patient to a hospital or other entity providing DHS if he or she has a financial relationship with the hospital or other entity, unless an exception applies. A physician also may not refer a patient if the physician's immediate family member has the financial relationship.

An **"immediate family member"** includes a husband or wife; birth or adoptive parent, child or sibling; stepparent, stepchild, stepbrother or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law or sister-in-law; grandparent or grandchild; and a spouse of a grandparent or grandchild.

Physician

The term **"physician"** means a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, or a chiropractor. A physician and the professional corporation of which he or she is a sole owner are the same for Stark purposes.

Financial Relationship

A **"financial relationship"** is:

1. A direct or indirect ownership or investment interest by the physician (or an immediate family member) in the entity providing the DHS, or
2. A direct or indirect compensation arrangement between the physician (or an immediate family member) and the entity providing the DHS.

Ownership and Investment Interests

An ownership or investment interest may be through equity, debt, or other means. This may include, but is not limited to, stock, stock options (with an exception described below), partnership shares, limited liability company memberships, loans, bonds and other financial instruments that are secured with an entity's property or revenue.

An ownership or investment interest in a subsidiary company is not considered an ownership or investment interest in the parent company, nor in any other subsidiary of the parent, unless the subsidiary company itself has an ownership or investment interest in the parent or other subsidiary. It may, however, be part of an indirect financial relationship.

Ownership and investment interests do not include:

1. An interest in an entity through a retirement plan offered by the entity to a physician (or immediate family member) through employment with the entity;
2. Stock options and convertible securities received as compensation until the stock options are exercised or the convertible securities are converted to equity (however, before this time, the stock options or convertible securities are compensation arrangements);
3. An unsecured loan subordinated to a credit facility (which is a compensation arrangement);
4. An "under arrangements" contract between a hospital and an entity owned by one or more physicians (or a group of physicians) providing DHS "under arrangements" with the hospital (such a contract is a compensation arrangement); or
5. A security interest held by a physician in equipment sold by the physician to a hospital and financed through a loan from the physician to the hospital (such an interest is a compensation arrangement).
6. A titular ownership or investment interest that excludes the ability or right to receive the financial benefits of ownership or investment, including, but not limited to, the distribution of profits, dividends, proceeds of sale, or similar returns on investment.
7. An interest in an entity that arises from a qualified employee stock ownership plan.

Indirect Ownership or Investment Interest

An indirect ownership or investment interest exists if:

1. There is an unbroken chain of any number of persons or entities (but no less than one) having ownership or investment interests between the referring physician (or an immediate family member) and the entity furnishing DHS; and
2. The entity furnishing DHS has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician (or immediate family member) has some ownership or investment interest (through any number of intermediary ownership or investment interests) in the entity furnishing the DHS.

An indirect ownership or investment interest exists even though the entity furnishing DHS does not know of, or acts in reckless disregard or deliberate ignorance of, the precise composition of the unbroken chain or the specific terms of the ownership or investment interests that form the links in the chain.

Further, the Stark law and its regulations define an ownership or investment interest to include an interest in an entity that holds an ownership interest in an entity that furnishes DHS [42 U.S.C. Section 1395nn(a)(2); 42 C.F.R. Section 411.354(b)]. In other words, both direct and indirect ownership or investment interests trigger the prohibition on referrals unless an exception applies.

Compensation Arrangements

A **"compensation arrangement"** is any arrangement involving remuneration, direct or indirect, between a physician (or immediate family member) and an entity furnishing DHS.

Remuneration

"Remuneration" means any payment or other benefit made directly or indirectly, overtly or covertly, in cash or in kind, except that the following are not considered remuneration for purposes of this law:

1. The forgiveness of amounts owed for inaccurate tests or procedures, mistakenly performed tests or procedures, or the correction of minor billing errors.
2. The furnishing of items, devices, or supplies (not including surgical items, devices, or supplies) that are used for one or more of the following purposes:
    a. To collect, transport, process, or store specimens for the entity furnishing the items, devices, or supplies; or
    b. To order tests or procedures for the entity, or to communicate the results of tests or procedures for the entity.
3. A payment made by an insurer or a self-insured plan (or a subcontractor of the insurer or self-insured plan) to a physician to satisfy a claim, submitted on a fee-for-service basis, for the furnishing of health services by that physician to an individual who is covered by a policy with the insurer or by the self-insured plan, if:
    a. The health services are not furnished, and the payment is not made, under a contract or other arrangement between the insurer or the self-insured plan (or a subcontractor of the insurer or self-insured plan) and the physician;
    b. The payment is made to the physician on behalf of the covered individual and would otherwise be made directly to the individual; and

c. The amount of the payment is set in advance, does not exceed fair market value, and is not determined in a manner that takes into account directly or indirectly the volume or value of any referrals.

Types of Compensation Arrangements

Direct. A direct compensation arrangement exists if remuneration passes between the referring physician (or an immediate family member) and the entity furnishing DHS without any intervening persons or entities.

Indirect. An indirect compensation arrangement exists if each of the following three elements are present:

1. There is an unbroken chain of financial relationships (investment/ownership or compensation) between a referring physician (or immediate family member) and the DHS entity to which referrals are made and there is at least one intermediary person or entity between them (unless the only link in the "unbroken chain" is the physician's "physician organization";
2. Aggregate compensation to the referring physician (or immediate family member) from the closest link in the chain varies with the volume or value of referrals or other business generated by the referring physician for the DHS entity; andThe amount of compensation received per individual unit::
    a. Is not fair market value for items or services actually provided;
    b. Could increase as the number or value of the physician's referrals to, or other business generated for, the entity furnishing DHS increases, or could decrease as the number or value of the physician's referrals or other business generated decreases; or
    c. Is payment for the lease of office space or equipment or for the use of premises or equipment.
3. The DHS entity has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician's (or immediate family member's) aggregate compensation varies with the volume or value of referrals or other business generated by the referring physician for the DHS entity.

[42 C.F.R. Section 411.354(c)(2) (setting forth the elements of an indirect compensation arrangement, as well as a definition of "individual unit," which is defined broadly. For example, if a physician is paid fixed annual compensation, the individual unit is the yearly payment.]

NOTE: The analysis applied to determine the existence of an indirect compensation arrangement, particularly with respect to assessment of the compensation to the referring physician from the closest link in the chain, is a significant change under the CMS 2022 Physician Fee Schedule Rule (following on significant changes to the assessment included in the 2020 Final Rule).

For purposes of paragraph 2. above, if the financial relationship between the physician (or immediate family member) and the entity in the chain with which the referring physician (or immediate family member) has a direct financial relationship is an ownership/investment interest (as opposed to a compensation arrangement), the determination of whether the aggregate compensation meets the test set forth in paragraph 2 above will be measured by

the nonownership/noninvestment interest (that is, the compensation arrangement) closest to the referring physician (or immediate family member).

Additionally, CMS clarifies which exceptions apply to indirect compensation arrangements. [42 C.F.R. Section 411.354(c)(4)]

Example: If a referring physician has an ownership interest in company A, which owns company B, which has a compensation arrangement with company C, which has a compensation arrangement with entity D that furnishes DHS, government officials would look to the aggregate compensation between company B and company C and would determine if the compensation varies with the volume or value of referrals or other business generated by the physician for entity D and otherwise meets the test set forth in paragraph 2 above.

Referral

A **"referral"** means:

1. The request by a physician for, or ordering of, or the certifying or recertifying of the need for, any designated health service for which payment may be made under Medicare Part B, including a request for a consultation with another physician and any test or procedure ordered by or to be performed by (or under the supervision of) that other physician, but not including any designated health service personally performed or provided by the referring physician. A designated health service is not personally performed or provided by the referring physician if it is performed or provided by any other person, including, but not limited to, the referring physician's employees, independent contractors, or group practice members, and;
2. A request by a physician that includes the provision of any designated health service for which payment may be made under Medicare, the establishment of a plan of care by a physician that includes the provision of such a designated health service, or the certifying or recertifying of the need for such a designated health service, but not including any designated health service personally performed or provided by the referring physician. A designated health service is not personally performed or provided by the referring physician if it is performed or provided by any other person including, but not limited to, the referring physician's employees, independent contractors, or group practice members.

A referral does not include a request by a pathologist for clinical diagnostic laboratory tests and pathological examination services, by a radiologist for diagnostic radiology services, and by a radiation oncologist for radiation therapy or ancillary services necessary for, and integral to, the provision of radiation therapy if:

1. The request results from a consultation initiated by another physician (whether the request for a consultation was made to a particular physician or to an entity with which the physician is affiliated); and
2. The tests or services are furnished by or under the supervision of the referring pathologist, radiologist, or radiation oncologist; or under the supervision of a

pathologist, radiologist, or radiation oncologist, respectively, in the same group practice as the referring pathologist, radiologist, or radiation oncologist.

A referral is not an item or service for the purposes of the Stark regulations.

Commercially Reasonable

"Commercially reasonable" means that that the particular arrangement furthers a legitimate business purpose of the parties to the arrangement and is sensible, considering the characteristics of the parties, including their size, type, scope, and specialty. An arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties. [42 C.F.R. Section 411.351]

Fair Market Value and General Market Value

"Fair market value" is defined in general as the value in an arm's-length transaction, consistent with the general market value. With respect to the rental of equipment, fair market value is defined as the value in an arm's-length transaction of rental property for general commercial purposes (not taking into account its intended use), consistent with the general market value of the subject transaction. With respect to the rental of office space, fair market value is defined as the value in an arm's-length transaction of rental property for general commercial purposes (not taking into account its intended use), without adjustment to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee, and consistent with the general market value of the subject transaction. [42 C.F.R. Section 411.351]

"General market value" is defined as it relates to asset purchases, compensation for services, and equipment or office space. With respect to the purchase of an asset, it is the price that an asset would bring on the date of acquisition of the asset as the result of bona fide bargaining between a well-informed buyer and seller that are not otherwise in a position to generate business for each other. With respect to compensation for services, it is the compensation that would be paid at the time the parties enter into the service arrangement as the result of bona fide bargaining between well-informed parties that are not otherwise in a position to generate business for each other. With respect to the rental of equipment or the rental of office space, it is the price that rental property would bring at the time the parties enter into the rental arrangement as the result of bona fide bargaining between a well-informed lessor and lessee that are not otherwise in a position to generate business for each other. [42 C.F.R. Section 411.351]

Period of Disallowance

In the 2020 Final Rule, CMS eliminated the definition of a "period of disallowance," which had referred to the period during which Medicare referrals were prohibited when a physician had a compensation arrangement with an entity that did not comply with any exception under the Stark law. While CMS eliminated the bright-line rule in favor of a case-by-case basis analysis, it acknowledged the general concept of a period of disallowance saying it "should begin on the date when a financial relationship fails to satisfy all requirements of any applicable exception and end on the date when the financial relationship ends or satisfies all requirements of an applicable exception."

Stand in the Shoes

The "stand in the shoes" rules provide that a physician who has an ownership/investment interest in a physician organization through which the physician provides medical services is deemed to "stand in the shoes" of that physician organization. (A physician organization is typically a practice entity such as a professional corporation, a physician practice, or a group practice through which professional services are provided.) This means that:

1. Financial relationships with the physician organization are attributed to the physician with an ownership/investment interest. This means that the physician is deemed to have the same compensation arrangement with DHS entities as his or her physician organization.
2. The compensation arrangement between the DHS entity and the physician organization must, therefore, satisfy the requirements of a direct compensation exception.
3. The indirect compensation definition and exception may not be used by a physician with an ownership/investment interest in a physician organization to protect an arrangement between a DHS entity and the physician organization.

Thus, entities such as hospitals that have direct financial relationships with physician organizations are considered to have a direct financial relationship with each of the physician owners/investors of those organizations. [42 C.F.R. Section 411.354(c)(3)]

When applying compensation exceptions, the parties to the arrangement with respect to a signature requirement is the physician organization and certain physicians who elect to stand in the shoes of that physician organization [42 C.F.R. Section 411.354(c)(3)(i)(A)].

When determining whether a Stark exception applies to a "stand in the shoes" situation, the relevant referrals and other business generated "between the parties" are referrals and other business generated between the DHS entity and the physician organization (including all members, employees and independent contractor physicians).

As mentioned above, physicians who are owners or investors must stand in the shoes of their physician organization. Physicians who are not owners or investors may, but are not required to, stand in the shoes of their physician organizations. A physician who is not an owner or investor may be an employee or independent contractor, for example.

The "stand in the shoes" rules do not apply to any indirect compensation arrangement that satisfied the requirements of the indirect compensation exception as of Sept. 5, 2007, during the original term or current renewal term of the arrangement. The rules also do not apply to arrangements that satisfy the academic medical center exception *(see "Academic Medical Centers," page 6.19)*, or to a physician whose ownership or investment interest is titular only. **"Titular only"** means that the interest excludes the right to receive any financial benefits of ownership or investment, such as the distribution of profits, dividends, proceeds of sale or similar return on investment. [42 C.F.R. Section 411.354(c)(3)(ii)]

Value-Based Activity

Any of the following activities, provided that the activity is reasonably designed to achieve at least one value-based purpose of the value-based enterprise:

1. The provision of an item or service;

2. The taking of an action; or
3. The refraining from taking an action.

[42 C.F.R. Section 411.351]

Value-Based Arrangement
An arrangement for the provision of at least one value-based activity for a target patient population to which the only parties are the value-based enterprise (VBE) and one or more of its VBE participants or VBE participants in the same value-based enterprise. [42 C.F.R. Section 411.351]

Value-Based Enterprise
Two or more VBE participants collaborating to achieve at least one value-based purpose, each of which is a party to a value-based arrangement with at least one other VBE participant in the VBE that have an accountable body or person responsible for the financial and operational oversight of the VBE and that have a governing document that describes the VBE and how the VBE participants intend to achieve its value-based purpose(s).

[42 C.F.R. Section 411.351]

VBE Participant
A person or entity that engages in at least one value-based activity as part of a VBE. [42 C.F.R. Section 411.351]

Value-Based Purpose
Any of the following purposes:

1. Coordinating and managing the care of a target patient population;
2. Improving the quality of care for a target patient population;
3. Appropriately reducing the costs to or growth in expenditures of payors without reducing the quality of care for a target patient population; or
4. Transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population.

[42 C.F.R. Section 411.351]

Target Patient Population
An identified patient population selected by a VBE or its VBE participants based on legitimate and verifiable criteria that are set out in writing in advance of the commencement of the value-based arrangement and further the VBE's value-based purpose(s). [42 C.F.R. Section 411.351]

D. Special Rules on Compensation

Set in Advance
Compensation is deemed to be "set in advance" if the aggregate compensation, a time-based or per-unit of service-based (whether per-use or per-service) amount, or a specific formula for calculating the compensation is set out in writing before the furnishing of the items, services, office space, or equipment for which the compensation is to be paid. The

formula for determining the compensation must be set forth in sufficient detail so that it can be objectively verified. Compensation (or a formula for determining the compensation) may be modified at any time during the course of a compensation arrangement and satisfy the requirement that it is "set in advance" if all of the following conditions are met:

1. All requirements of an applicable exception are met on the effective date of the modified compensation (or the formula for determining the modified compensation).
2. The modified compensation (or the formula for determining the modified compensation) is determined before the furnishing of the items, services, office space, or equipment for which the modified compensation is to be paid.
3. Before the furnishing of the items, services, office space, or equipment for which the modified compensation is to be paid, the formula for the modified compensation is set forth in writing in sufficient detail so that it can be objectively verified.

Volume or Value Standard and Other Business Generated Standard

Compensation will be considered to take into account the volume or value of referrals, or other business generated between the parties when the formula by which compensation is calculated includes referrals or other business generated as a "variable," resulting in a change in compensation that correlates with the number or value of referrals or other business generated (with certain limited exceptions). If an arrangement does not fall squarely within this special rule (which effectively functions as a definition), then it does not take into account the volume or value of referrals or other business generated. [42. C.F.R. 411.354(d)(5) and (6)]

Prior to the 2020 Final Rule, no definition existed regarding whether compensation takes into account the volume or value of referrals or other business generated. Rather, the Stark law regulations included special rules whereby unit-based compensation (including time-based or per-unit-of-service-based compensation) would be "deemed" not to take into account the volume or value of referrals to, or other business generated for, the entity if the compensation was fair market value for services or items actually provided and did not vary during the course of the compensation arrangement in any manner that takes into account referrals of DHS. CMS added the new standard described above in an effort to provide an objective, bright-line standard for determining whether compensation takes into account the volume or value of referrals or other business generated. In doing so, CMS noted that the special rules for unit-based compensation "will be either unnecessary or inapplicable to deem unit-based compensation not to take into account the volume or value of a physician's referrals or other business generated by a physician," but are preserved in the regulations to assist parties, CMS, and law enforcement in applying the historical policies in effect at the time of the existence of a particular compensation arrangement. [85 Fed. Reg. at 77544]

Writing and Signature Requirements

Any compensation arrangement that is required to be in writing may satisfy such requirement by a collection of documents, including contemporaneous documents (such as letters or emails) evidencing the course of conduct between the parties. A signature requirement may be satisfied by an electronic or other signature valid under applicable federal or state law. A formal written contract is best practice, but less formal writings may suffice.

Additionally, temporary noncompliance with writing and signature requirements is permitted for up to 90 days after an arrangement begins if the arrangement otherwise fully complies with an applicable exception. [42 C.F.R. Section 411.354(e); 42 U.S.C. Section 1395nn(h)(1)(D)]

Physician Compensation Conditioned Upon Referrals

A physician's compensation from a bona fide employer *(see "Bona Fide Employment Relationships," page 6.28),* or under a managed care contract *(see "Managed Care Patients," page 6.19),* or other arrangement for personal services *(see "Personal Services Arrangements," page 6.29),* may be conditioned on the physician's referrals to a particular provider, practitioner, or supplier, provided that the compensation arrangement meets all of the following conditions. The compensation arrangement:

1. Is set in advance for the term of the agreement.
2. Is consistent with the fair market value of the physician's services.
3. Otherwise complies with an applicable Stark exception.
4. Complies with both of the following conditions:
    a. The requirement to make referrals to a particular provider, practitioner, or supplier is set forth in writing signed by the parties.
    b. The requirement to make referrals to a particular provider, practitioner, or supplier does not apply if the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgment.
5. The required referrals relate solely to the physician's services covered by the scope of the employment, personal services arrangement, or the contract, and the referral requirement is reasonably necessary to effectuate the legitimate business purposes of the compensation arrangement. In no event may the physician be required to make referrals that relate to services that are not provided by the physician under the scope of his or her employment or contract.
6. Regardless of whether the physician's compensation takes into account the volume or value of referrals by the physician as permitted, neither the existence of the compensation arrangement nor the amount of the compensation is contingent on the number or value of the physician's referrals to the particular provider, practitioner, or supplier. The requirement to make referrals to a particular provider, practitioner, or supplier may require that the physician refer an established percentage or ratio of the physician's referrals to a particular provider, practitioner, or supplier. [42 C.F.R. Section 411.354(d)(4)]

E. "Under Arrangements" Restriction

Changes to the Stark law have resulted in many so-called "under arrangements" relationships prohibiting the participating physicians from making Medicare referrals to the participating hospital. As a result, many "under arrangements" relationships have been restructured to avoid the referral prohibition.

In an **"under arrangements"** relationship, a physician, group practice, or other physician-owned entity provides services to hospital inpatients or outpatients pursuant to a contract with the hospital. The physician or group bills the hospital, and is paid by the hospital, for the services rendered. The hospital in turn bills Medicare. This practice has resulted in Medicare payment of hospital-level reimbursement rates for services that are actually provided by an

entity that is owned by referring physicians. Under the previous regulations, the definition of the "entity" to which referrals are made was limited to the entity that bills for the service, so referring physicians who owned an entity which provided non-DHS services "under arrangements" to a hospital were not considered to have an ownership/investment interest in a DHS entity, because they did not own the hospital that billed for the DHS services. In addition, the physicians' indirect compensation arrangements with the hospital resulting from the "under arrangements" relationship could usually be structured to fit within the indirect compensation exception.

However, the Stark regulations were changed to expand the definition of an "entity" to which a physician makes a referral to include not only an entity that bills for a service, but also the entity that actually performs the service, even though that entity does not bill for the service.

This means that physicians with an ownership/investment interest in, or a compensation arrangement with, an entity providing a service "under arrangements" to a hospital may not refer Medicare patients to the "under arrangements" entity unless a Stark exception applies and there is no Stark exception available for an ownership interest in an "under arrangements" entity.

The sole exception is lithotripsy services provided under arrangements to a hospital, which is still permissible.

F. Exceptions Related to Both Ownership/Investment Interests and Compensation Arrangements

The prohibition on referrals does not apply to the types of services described in this section, regardless of whether a physician has an ownership/investment interest in, or a compensation arrangement with, the entity to which the referrals are made [42 U.S.C. Section 1395nn(b); 42 C.F.R. Section 411.355].

Physician Services

A physician may refer a Medicare patient to another physician in the same group practice, even though the referring physician has a financial relationship with the group practice. This exception applies to physician services that are furnished:

1. Personally by another physician who is a member of the referring physician's group practice, or who is a physician in the same group practice as the referring physician; or
2. Under the supervision of another physician who is a member of the referring physician's group practice or who is a physician in the same group practice as the referring physician, provided that the supervision complies with all other applicable Medicare payment and coverage rules for the physician services.

It should be noted that independent contracting physicians may qualify as being "in the same group practice" without being a "member" of the group practice. *(See definitions of "physician in the group practice" and "member of a group practice" at 42 C.F.R. Section 411.351. See CHA Appendix HC 6-A for the definition of "group practice.")*

In-Office Ancillary Services

There is an exception for in-office ancillary services, including certain specific items of durable medical equipment (DME) *(see "Covered DME," page)* and infusion pumps that are DME (including external ambulatory infusion pumps), provided by an individual physician or by a

"group practice," as defined in the Stark law and regulations *(see CHA Appendix HC 6-A for the definition of "group practice")*, that meet the following conditions (**NOTE:** The exception does not protect referrals of all other DME and parenteral and enteral nutrients (PEN), equipment, and supplies (such as infusion pumps used for PEN)):

1. They are furnished personally by one of the following individuals:
    a. The referring physician.
    b. A physician who is a member of the same group practice as the referring physician.
    c. An individual who is supervised by the referring physician or, if the referring physician is in a group practice, by another physician in the group practice, provided that the supervision complies with all other applicable Medicare payment and coverage rules for the services.
2. They are furnished in one of the following locations:
    a. The same building, but not necessarily in the same space or part of the building, in which all of the conditions below are satisfied:
        - The referring physician, or his or her group practice (if any), has an office that is normally open to the physician's or group's patients for medical services at least 35 hours per week; and

          The referring physician, or one or more members of the referring physician's group practice, regularly practices medicine and furnishes physician services to patients at least 30 hours per week. The 30 hours must include some physician services that are unrelated to the furnishing of DHS payable by Medicare, any other federal health care payer, or a private payer, even though the physician services may lead to the ordering of DHS; or
        - The patient receiving the DHS usually receives physician services from the referring physician or members of the referring physician's group practice (if any);

          The referring physician or the referring physician's group practice owns or rents an office that is normally open to the physician's or group's patients for medical services at least eight hours per week [42 C.F.R. Section 411.355(b)(2)(i)(C)(2)]; and

          The referring physician regularly practices medicine and furnishes physician services to patients at least six hours per week. The six hours must include some physician services that are unrelated to the furnishing of DHS payable by Medicare, any other federal health care payer, or a private payer, even though the physician services may lead to the ordering of DHS; or
        - The referring physician is present and orders the DHS during a patient visit on the premises as set forth in 42 C.F.R. Section 411.355(b)(2)(i)(C)(2) or the referring physician, or a member of the referring physician's group

practice (if any), is present while the DHS is furnished during occupancy of the premises as set forth in 42 C.F.R. Section 411.355(b)(2)(i)(C)(2);

The referring physician, or the referring physician's group practice owns, or rents an office that is normally open to the physician's or group's patients for medical services at least eight hours per week; and

The referring physician, or one or more members of the referring physician's group practice, regularly practices medicine and furnishes physician services to patients at least six hours per week. The six hours must include some physician services that are unrelated to the furnishing of DHS payable by Medicare, any other federal health care payer, or a private payer, even though the physician services may lead to the ordering of DHS.

b. A **"centralized building,"** meaning all or part of a building that is owned or leased on a full-time basis for a term of at least six months, that is used by the group practice for the provision of some or all of the group practice's clinical laboratory services; or

c. A centralized building that is used by the group practice for the provision of some or all of the group practice's DHS (other than clinical laboratory services).

3. They are billed by one of the following:

   a. The physician performing or supervising the service.

   b. The group practice of which the performing or supervising physician is a member under a billing number assigned to the group practice.

   c. The group practice if the supervising physician is a physician in the group practice under a billing number assigned to the group practice.

   d. An entity that is wholly owned by the performing or supervising physician or by that physician's group practice under the entity's own billing number or under a billing number assigned to the physician or group practice.

   e. An independent third party billing company acting as an agent of the physician, group practice, or entity specified in paragraphs a. through d. above under a billing number assigned to the physician, group practice, or entity.

   For purposes of this paragraph, a group practice may have, and bill under, more than one Medicare billing number, subject to any applicable Medicare program restrictions.

It is important to remember that the in-office ancillary services exception protects only self-referrals by solo practitioners and intra-group referrals by members of medical groups and other physician organizations that meet the definition of a "group practice" (found in CHA Appendix HC 6-A, "Group Practice Definition"). A **"member of the group"** is an owner or employee physician. Although not directly relevant to hospital operations, it is worth noting that in the 2020 Final Rule, CMS made significant changes to the rules surrounding the distribution of "overall profits" by a "group practice" to member physicians. Effective Jan. 1, 2022, group practices must now aggregate all revenue and expenses from all DHS service

lines and then distribute profits using a uniform methodology (for the entire group or within pods of at least five physicians). So-called "split pooling" or aggregating DHS profits by service line prior to distribution is no longer permitted.

Covered DME

DME covered by the in-office ancillary services exception includes canes, crutches, walkers and folding manual wheelchairs, and blood glucose monitors that meet the following conditions:

1. The item is one that a patient requires for the purpose of ambulating, a patient uses in order to depart from the physician's office, or is a blood glucose monitor (including one starter set of test strips and lancets, consisting of no more than 100 of each). A blood glucose monitor may be furnished only by a physician or employee of a physician or group practice that also furnishes outpatient diabetes self-management training to the patient.
2. The item is furnished in a building that meets the "same building" requirements in the in-office ancillary services exception as part of the treatment for the specific condition for which the patient-physician encounter occurred.
3. The item is furnished personally by the physician who ordered the DME, by another physician in the group practice, or by an employee of the physician or the group practice.
4. A physician or group practice that furnishes the DME meets all Medicare DME supplier standards.
5. All other requirements of the in-office ancillary services exception.

A designated health service is "furnished" in the location where the service is actually performed upon a patient or where an item is dispensed to a patient in a manner that is sufficient to meet the applicable Medicare payment and coverage rules.

Special Rule for Home Care Physicians

In the case of a referring physician whose principal medical practice consists of treating patients in their private homes, the same building requirements are met if the referring physician (or a qualified person accompanying the physician, such as a nurse or technician) provides the DHS contemporaneously with a physician service that is not a DHS provided by the referring physician to the patient in the patient's private home. For purposes of this requirement, a private home does not include a nursing, long-term care, or other facility or institution, except that a patient may have a private home in an assisted living or independent living facility.

Disclosure Requirement for Certain Imaging Services

With respect to magnetic resonance imaging, computed tomography, and positron emission tomography services identified as "radiology and certain other imaging services" on the List of CPT/HCPCS Codes, the referring physician must provide written notice to the patient at the time of the referral that the patient may receive the same services from a person other than one described in paragraph 1 on page [42 U.S.C. Section 1395nn(b)(2); 42 C.F.R. Section 411.355(c)(7)].

The written notice must include a list of at least five other suppliers (which do not include hospitals) that accept Medicare patients, that provide the services for which the patient is being referred and which are located within a 25-mile radius of the referring physician's office location at the time of the referral. The notice should be written in a manner sufficient to be reasonably understood by all patients and should include for each supplier on the list, at a minimum, the supplier's name, address, and telephone number.

If there are fewer than five other suppliers located within the 25-mile radius, the physician must list all of the others. Providing the list of alternate suppliers is not required if no other suppliers exist within the 25-mile radius.

Managed Care Patients

Another exception under the Stark law permits physicians to refer Medicare managed care patients, including Medicare patients that are also patients of Medi-Cal managed care plans, for which Medicare or Medi-Cal makes payments on a pre-paid basis, to hospitals or other entities regardless of the existence of financial relationships between the hospital/entity and the physicians. This exception protects services to enrollees of such plans, whether rendered by direct contractors with the plans or by subcontractors. The exception reflects the fact that where prepayment on a capitated basis is made by Medicare or Medi-Cal, the concern about overutilization of services, which underlies the Stark law, does not exist. *(See "Physician Compensation Conditioned Upon Referrals," page 6.14.)*

Academic Medical Centers

A physician may refer a Medicare patient for DHS provided by an academic medical center with which the physician has a financial relationship if the following conditions are met:

1. The referring physician:
    a. Is a bona fide employee of a component of the academic medical center on a full-time or substantial part-time basis. (A **"component"** of an academic medical center means an affiliated medical school, faculty practice plan, hospital, teaching facility, institution of higher education, departmental professional corporation, or nonprofit support organization whose primary purpose is supporting the teaching mission of the academic medical center.) The components need not be separate legal entities;
    b. Is licensed to practice medicine in the state(s) in which he or she practices medicine;
    c. Has a bona fide faculty appointment at the affiliated medical school or at one or more of the educational programs at the accredited academic hospital; and
    d. Provides either substantial academic services or substantial clinical teaching services (or a combination of academic services and clinical teaching services) for which the faculty member receives compensation as part of his or her employment relationship with the academic medical center. Parties should use a reasonable and consistent method for calculating a physician's academic services and clinical teaching services. A physician will be deemed to meet this requirement if he or she spends at least 20 percent of his or her professional time or 8 hours per week providing academic services or clinical teaching services (or a combination of academic services or clinical teaching

services). A physician who does not spend at least 20 percent of his or her professional time or 8 hours per week providing academic services or clinical teaching services (or a combination of academic services or clinical teaching services) is not precluded from qualifying under this paragraph.

2. The compensation paid to the referring physician must meet all of the following conditions:
    a. The total compensation paid by each academic medical center component to the referring physician is set in advance.
    b. In the aggregate, the compensation paid by all academic medical center components to the referring physician does not exceed fair market value for the services provided.
    c. The total compensation paid by each academic medical center component is not determined in a manner that takes into account the volume or value of any referrals or other business generated by the referring physician within the academic medical center.
    d. If any compensation paid to the referring physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement must satisfy the special rule for directed referrals at 42 C.F.R. Section 411.354(d)(4).
3. The academic medical center must meet all of the following conditions:
    a. All transfers of money between components of the academic medical center must directly or indirectly support the missions of teaching, indigent care, research, or community service.
    b. The relationship of the components of the academic medical center must be set forth in one or more written agreements or other written documents that have been adopted by the governing body of each component. If the academic medical center is one legal entity, this requirement will be satisfied if transfers of funds between components of the academic medical center are reflected in the routine financial reports covering the components.
    c. All money paid to a referring physician for research must be used solely to support bona fide research or teaching and must be consistent with the terms and conditions of the grant.

The **"academic medical center"** consists of:

1. An accredited medical school (including a university, when appropriate) or an accredited academic hospital. An **"accredited academic hospital"** for purposes of this section means a hospital or a health system that sponsors four or more approved medical education programs;
2. One or more faculty practice plans affiliated with the medical school, the affiliated hospital(s), or the accredited academic hospital; and
3. One or more affiliated hospitals in which a majority of the physicians on the medical staff consists of physicians who are faculty members and a majority of all hospital admissions is made by physicians who are faculty members. The hospital may be

the same hospital that satisfies the requirement of paragraph 1. above. A **"faculty member"** is a physician who is either on the faculty of the affiliated medical school or on the faculty of one or more of the educational programs at the accredited academic hospital. Faculty from any affiliated medical school or accredited academic hospital education program may be aggregated, and residents and non-physician professionals do not need to be counted. Any faculty member may be counted, including courtesy and volunteer faculty. For purposes of determining whether the majority of physicians on the medical staff consists of faculty members, the affiliated hospital must include or exclude all individual physicians with the same class of privileges at the affiliated hospital (for example, physicians holding courtesy privileges).

Implants Furnished by an ASC

In general, a referral by a physician to an ASC with which the physician has a financial relationship is not a DHS referral under Stark. This is because DHS do not include services, such as ASC services, that are reimbursed by Medicare as part of a composite rate (except for services such as hospital services that are themselves DHS). A physician may refer a Medicare patient for implants furnished by an ASC with which the physician has a financial relationship, even though implants are separately reimbursed by Medicare and are not paid as part of a composite rate, if the conditions listed below are met (this exception includes, but is not limited to, cochlear implants, intraocular lenses, and other implanted prosthetics, implanted prosthetic devices, and implanted DME):

1. The implant is implanted by the referring physician or a member of the referring physician's group practice in an ASC that is certified by Medicare and with which the referring physician has a financial relationship.
2. The implant is implanted in the patient during a surgical procedure paid by Medicare to the ASC as an ASC procedure.
3. The arrangement for the furnishing of the implant does not violate the anti-kickback statute *(see chapter 7, "Federal and State Anti-Kickback Laws")*.

This exception does not apply to any financial relationships between the referring physician and any entity other than the ASC in which the implant is furnished to, and implanted in, the patient.

EPO and Other Dialysis-Related Drugs

A physician may refer a Medicare patient for EPO and other dialysis-related drugs furnished in or by an end stage renal disease (ESRD) facility with which the physician has a financial relationship if the following conditions are met:

1. The EPO and other dialysis-related drugs are furnished in or by an ESRD facility. **"EPO and other dialysis-related drugs"** are certain outpatient prescription drugs that are required for the efficacy of dialysis and identified as eligible for this exception on the List of CPT/HCPCS Codes. **"Furnished"** means that the EPO or dialysis-related drugs are administered to a patient in the ESRD facility or, in the case of EPO or Aranesp (or equivalent drug identified on the List of CPT/HCPCS Codes) only, are dispensed by the ESRD facility for use at home. *(See "Designated Health Services," page 6.4, regarding the list of codes.)*

2. The arrangement for the furnishing of the EPO and other dialysis-related drugs does not violate the anti-kickback statute *(see chapter 7, "Federal and State Anti-Kickback Laws")*.

This exception does not apply to a financial relationship between the referring physician and an entity other than the ESRD facility that furnishes the EPO and other dialysis-related drugs to the patient.

Preventive Screening Tests and Vaccines

A physician may refer a Medicare patient for preventive screening tests or vaccines to an entity with which the physician has a financial relationship if the following conditions are met:

1. The preventive screening test or vaccine must be covered by Medicare and listed as eligible for this exception on the List of CPT/HCPCS Codes *(see "Designated Health Services," page 6.4, regarding the list of codes)*.
2. The preventive screening test or vaccine is subject to a CMS-mandated frequency limit. However, if a COVID-19 vaccine Is identified on the List of CPT/HCPCS Codes and is not subject to a CMS-mandated frequency limit, this element does not apply. [42 C.F.R. Section 411.355(h)]

Eyeglasses and Contact Lenses Following Cataract Surgery

A physician may refer a Medicare patient for eyeglasses and contact lenses (covered by Medicare when furnished to patients following cataract surgery) provided by an entity with which the physician has a financial relationship if the following conditions are met:

1. The eyeglasses or contact lenses are provided in accordance with Medicare coverage and payment provisions.
2. The arrangement for the furnishing of the eyeglasses or contact lenses does not violate the anti-kickback statute *(see chapter 7, "Federal and State Anti-Kickback Laws")*.

Intra-Family Rural Referrals

Services provided pursuant to a referral from a referring physician to an immediate family member or to an entity furnishing DHS with which an immediate family member has a financial relationship are excepted from the Stark law's prohibition if all of the following conditions are met:

1. The patient who is referred resides in a rural area;
2. Except as provided in paragraph 3. below, in light of the patient's condition, no other person or entity is available to furnish the services in a timely manner within 25 miles of, or 45 minutes transportation time from, the patient's residence;
3. In the case of services furnished to patients where they reside (for example, home health services or DME), no other person or entity is available to furnish the services in a timely manner in light of the patient's condition; and
4. The referring physician or the immediate family member must make reasonable inquiries as to the availability of other persons or entities to furnish the DHS. However, neither the referring physician nor the immediate family member has any obligation to inquire as to the availability of persons or entities located farther than

25 miles of, or 45 minutes transportation time from (whichever test the referring physician utilized for purposes of paragraph 2. above), the patient's residence.

G. Exceptions Related to Ownership/Investment Interests

This section describes ownership or investment interests that a physician may hold without triggering the prohibition on referrals of Medicare patients. [42 U.S.C. Section 1395nn(c) and (d); 42 C.F.R. Section 411.356.]

Publicly-Traded Securities

A physician may own investment securities (including shares or bonds, debentures, notes, or other debt instruments) that, at the time the DHS referral was made, could be purchased on the open market and that meet the requirements below:

1. They are either:
    a. Listed for trading on the New York Stock Exchange, the American Stock Exchange, or any regional exchange in which quotations are published on a daily basis, or foreign securities listed on a recognized foreign, national, or regional exchange in which quotations are published on a daily basis; or
    b. Traded under an automated interdealer quotation system operated by the National Association of Securities Dealers; or
    c. Listed for trading on an electronic stock market or over-the-counter quotation system in which quotations are published on a daily basis and trades are standardized and publicly transparent.
2. They are in a corporation that had stockholder equity exceeding $75 million at the end of the corporation's most recent fiscal year or on average during the previous three fiscal years. **"Stockholder equity"** is the difference in value between a corporation's total assets and total liabilities.

Mutual Funds

A physician may own shares in a regulated investment company as defined in Section 851(a) of the Internal Revenue Code of 1986, if the company had, at the end of its most recent fiscal year, or on average during the previous three fiscal years, total assets exceeding $75 million.

Hospital Ownership by Physician

Since the Stark law was enacted there has been an exception for direct or indirect ownership or investment interest in a hospital if:

1. The referring physician is authorized to perform services at the hospital; and
2. The ownership interest is in the entire hospital and not merely in a distinct-part or department of the hospital.

[42 C.F.R. Section 411.356(c)(3)]

This exception protects referrals by a physician who has an ownership or investment interest in a hospital and is a member of that hospital's medical staff with clinical privileges at that hospital. The ownership exception protects both direct investments by physicians in hospitals and indirect investments, i.e., ownership in an entity that has ownership in a hospital. Such physicians may refer Medicare patients to the hospital.

However, ACA eliminated the hospital ownership exception other than for hospitals that had physician ownership or investment and a Medicare provider agreement in effect on Dec. 31, 2010 [42 U.S.C. Section 1395nn(i); 42 C.F.R. Section 411.362(b)(1)]. As a result of this change, a physician who is an owner of a hospital that does not meet these two criteria may not make Medicare referrals to that hospital. This change effectively ends the exception for any new physician-owned hospitals that did not have physician ownership and a Medicare provider agreement that was effective on or before Dec. 31, 2010. In addition, the hospital may not have been converted from an ASC to a hospital on or after March 23, 2010 [42 C.F.R. Section 411.362(b)(6)].

ACA also imposed significant limitations on existing physician-owned hospitals that continue to qualify for the physician ownership exception. Such hospitals may not increase the number of operating rooms, procedure rooms or beds beyond the number for which the hospital was licensed on March 23, 2010, the date of enactment of ACA. A **"procedure room"** is defined in the regulations as "a room in which catheterizations, angiographies, angiograms and endoscopies are performed, except such term shall not include an emergency room or department (exclusive of rooms in which catheterizations, angiographies, angiograms, and endoscopies are performed)" [42 C.F.R. Section 411.362(a)]. For hospitals that entered into a provider agreement between March 23, 2010 and Dec. 31, 2010, expansion cannot occur after the effective date of the provider agreement [42 C.F.R. Section 411.362(b)(2)]. Hospitals may increase the number of other types of procedure rooms. Moreover, CMS has made clear through its rule making that this facility expansion limitation is based upon the aggregate number of operating rooms, procedure rooms and beds, and therefore, a physician-owned hospital may reduce or increase the number of beds, operating rooms, or procedure rooms, so long as the aggregate number does not increase above the aggregate number for which the hospital was licensed on March 23, 2010, or the effective date of its provider agreement, as applicable [75 Fed. Reg. 72245]. In addition, under certain circumstances, a physician-owned hospital may potentially relocate some or all beds, operating rooms, and procedure rooms [75 Fed. Reg. 72245]. In order to determine the aggregate number of operating rooms or procedure rooms for which the hospital was licensed on March 23, 2010, the hospital may include operating rooms or procedures rooms that existed and were operational on that date, even if such rooms were not actively being used [CMS Advisory Opinion No. CMS-AO-2019-01 (August 2019)].

CMS has developed a process for hospitals to apply for an exception to the limitations described above. The exception process is available only to hospitals in high-growth areas located in states with low bed capacity and with an above-average proportion of Medicaid admissions, or to hospitals with the highest percentage of Medicaid admissions in their county. Physician-owned hospitals wishing to apply for an exception should visit the CMS web page for physician-owned hospitals for additional information at www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/index.html.

There are also restrictions related to physician investment. The percentage of the total value of physician ownership in the hospital entity (regardless of whether the physicians refer patients to the hospital) cannot exceed the percentage as of March 23, 2010 (e.g., the percentage may fluctuate over time, so long as it never exceeds the percentage as of March 23, 2010). In addition, physician investors generally may not be treated more favorably than non-physician investors. For example, any ownership or investment interest that a hospital

offers to a physician owner or investor may not be offered on more favorable terms than the terms offered to a non-physician owner or investor [42 C.F.R. Section 411.362(b)(4)((ii)]. The hospital may not condition any physician ownership or investment interests either directly or indirectly on the physician owner or investor making or influencing referrals to the hospital or otherwise generating business for the hospital [42 C.F.R. Section 411.362(b)((3)(ii)(B)]. In addition, specific restrictions and prohibitions regarding the financing of physician investment in the hospital (such as loans and guarantees) as well as restrictions on the distribution of investment returns were enacted in ACA and clarified in regulations published on Nov. 24, 2010 [75 Fed. Reg. 72260 (Nov. 24, 2010); 42 C.F.R. Section 411.362(b)(4)].

The hospital must comply with the following reporting and disclosure requirements by Sept. 23, 2011:

1. At such time and in such manner as specified by CMS, the hospital must submit an annual report containing a detailed description of the identity of each physician owner or investor and any other owners or investors of the hospital, and the nature and extent of all ownership and investment interests in the hospital.
2. The hospital must have procedures in place to require each referring physician owner or investor who is a member of the medical staff agree, as a condition of continued medical staff membership or admitting privileges, to disclose to any patient being referred, in time for the patient to make a meaningful decision regarding the receipt of care, the following information:
    a. The ownership or investment interest, as applicable, of the referring physician; and
    b. Any ownership or investment interest of any treating physician, which may be accomplished by providing the patient with a list of all other physician owners or investors in the hospital.

    This disclosure must be in writing. CMS states that a prominently displayed sign could potentially satisfy the disclosure requirement, although it would not if a patient is blind, unable to read, or is incapacitated. In such cases, another method of notification would be required.
3. The hospital must also disclose the fact that the hospital is owned or invested in by physicians on any public website for the hospital (which does not include social media websites, electronic patient payment portals, electronic patient care portals or electronic health information exchanges) and in any public advertising for the hospital. This disclosure requirement applies to print ads, television ads, radio ads, and any other **"public advertising,"** which is defined as any public communication paid for by the hospital that is primarily intended to persuade individuals to seek care at the hospital.
4. If the hospital admits a patient and does not have any physician available on the premises to provide services during all hours in which the hospital is providing services to the patient, the hospital must also disclose this fact to the patient, and, prior to providing services to the patient, obtain a signed acknowledgment that the patient understands that a physician may not be present during all hours that services are furnished to the patient. CMS has indicated in its final rule making that

the failure to provide this disclosure would result in noncompliance with the hospital exception's requirements, and therefore, as a matter of prudent business practice, a hospital should include a compliant notice with other documents that must be signed by the patient (or the patient's representative) at the time of registration so long as it is prior to the patient's admission. [75 Fed. Reg. 72251 (Nov. 24, 2010)]

5. Finally, the hospital must have the capacity to provide assessment and initial treatment for all patients, and the ability to refer and transfer patients to hospitals with the capability to treat their needs. [42 U.S.C. Section 1395nn(i); 42 C.F.R. Section 411.362; 75 Fed. Reg. 72260 (Nov. 24, 2010)]

Rural Providers

An exception protects ownership or investment interests in a rural provider, with respect to referrals of DHS furnished in a rural area [42 C.F.R. Section 411.356(c)(1)]. A **"rural provider"** is an entity that furnishes at least 75 percent of the DHS it furnishes to residents of a rural area. A **"rural area"** is an area that is not within a Metropolitan Area (MSA) or New England County Metropolitan Area (NECMA), as defined by the Executive Office of Management and Budget. A rural hospital owned by physicians must comply with the requirements added by ACA as outlined under "Hospital Ownership by Physician," page 6.23 [42 U.S.C. Section 1395nn(i); 42 C.F.R. Section 411.356(c)(l) and (c)(3)(iv)].

H. Exceptions Related to Compensation Arrangements

This section describes compensation arrangements that are not considered "financial relationships" and thus do not trigger the prohibition on referrals of Medicare patients *(see 42 U.S.C. Section 1395nn(e); 42 C.F.R. Section 411.357)*.

Rental of Office Space

A Stark exception protects payments for the use of office space made by a lessee to a lessor (for example, a physician renting office space from a hospital) if there is a rental or lease agreement that meets the following conditions:

1. The lease arrangement is set out in writing, is signed by the parties, and specifies the premises it covers.
2. The duration of the lease arrangement is at least one year. To meet this requirement, if the lease arrangement is terminated during the term with or without cause, the parties may not enter into a new lease arrangement during the first year of the original term of the lease arrangement.
3. The space rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease or rental and is used exclusively by the lessee when being used by the lessee (and is not shared with or used by the lessor or any person or entity related to the lessor). However, the lessee may make payments for the use of space consisting of common areas if the payments do not exceed the lessee's pro rata share of expenses for the space based upon the ratio of the space used exclusively by the lessee to the total amount of space (other than common areas) occupied by all persons using the common areas. In its 2020 Final Rule, CMS revised the "exclusive use" requirement to clarify that multiple lessees may use the space to the exclusion of the lessor.

4. The rental charges over the term of the lease arrangement are set in advance and are consistent with fair market value.
5. The rental charges over the term of the lease arrangement are not determined in any manner that takes into account the volume or value of referrals or other business generated between the parties; or using a formula based on:
    a. A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space; or
    b. Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.
6. The lease arrangement would be commercially reasonable even if no referrals were made between the lessee and the lessor.

A holdover month-to-month rental immediately following a lease arrangement of at least one year that continues to meet the conditions in paragraphs 1 through 6 above also complies with this exception, provided the holdover rental is on the same terms and conditions as the immediately preceding lease arrangement.

As set forth in requirement 5 above, payments based on units of service or a percentage of revenue are not permitted under the space lease exception. *(See "Rental of Equipment," page 6.27.)*

Example: A hospital enters into a written lease of space to a physician in a hospital-owned medical office building for a term of one year. The amount of space leased is reasonable and necessary for the physician's practice, and the rent is a fixed amount per month and consistent with the fair market value of the space. The lease meets the space lease exception.

Rental of Equipment

A Stark exception is also available to protect equipment leases. It is similar to the space lease exception. Payments made by a lessee to a lessor for the use of equipment are permissible if the following conditions are met:

1. The lease arrangement is set out in writing, is signed by the parties, and specifies the equipment it covers.
2. The equipment leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease arrangement and is used exclusively by the lessee when being used by the lessee (and is not shared with, or used by, the lessor or any person or entity related to the lessor). In its 2020 Final Rule, CMS revised the "exclusive use" requirement to clarify that multiple lessees may use the equipment to the exclusion of the lessor.
3. The duration of the lease arrangement is at least one year. To meet this requirement, if the lease arrangement is terminated during the term with or without cause, the parties may not enter into a new lease arrangement during the first year of the original term of the original lease arrangement.

4. The rental charges over the term of the lease arrangement are set in advance, are consistent with fair market value, and are not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties; or using a formula based on:
    a. A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated by the use of the equipment; or
    b. Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.
5. The lease arrangement would be commercially reasonable even if no referrals were made between the parties.

A holdover month-to-month rental immediately following the expiration of a lease arrangement of at least one year that continues to meet the conditions in paragraphs 1 through 5 above also complies with this exception, provided the holdover lease arrangement is on the same terms and conditions as the immediately preceding arrangement.

As with the space lease exception, payments based on units of service or percentage of revenue are not permitted under the equipment lease exception.

Example: A hospital enters into a written lease of a CT scanner from a physician and uses the scanner to perform procedures for hospital patients. The rental fee is a fixed amount per procedure performed and is consistent with fair market value. The leasing physician refers patients to the hospital for CT scans. The term of the lease is two years. Because the rental fee is on a per unit of service basis, the lease is not protected by the equipment lease exception.

In an opinion issued by the U.S. Court of Appeals for the District of Columbia Circuit on June 12, 2015 [*Council for Urological Interests v. Burwell*, 790 F.3d 212, (D.C. CIR. 2015)], the court determined that the prohibition on compensation based upon units of service or a percentage of revenue in equipment leases exceeded CMS' authority under the Administrative Procedure Act. The appellate court remanded the case to the district court with instructions to remand the case to CMS to consider with more care whether the prohibition is consistent with Congressional intent. The ruling created uncertainty as to whether the prohibition on these types of equipment leases, as well as the similar prohibition incorporated into the Stark exceptions for space leases, fair market value compensation and indirect compensation exceptions, were still effective. However, after re-examining its authority to establish the prohibitions on units of service or percentage of revenues compensation, CMS issued a new final rule re-establishing the prohibitions, effective Jan. 1, 2017.

Bona Fide Employment Relationships

There is an exception to the Stark law's referral prohibition for bona fide employment relationships. The employment exception permits compensation to be paid by an employer to an employed physician (or immediate family member) in a bona fide employment relationship if the following conditions are met:

1. The employment is for identifiable services;
2. The amount of the remuneration is consistent with fair market value and, except for a productivity bonus based on services performed personally by the physician (or immediate family member) is not determined in any manner that takes into account the volume or value of the physician's referrals;
3. The employee agreement would be commercially reasonable even if no referrals were made by the physician to the employer; and
4. If remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement satisfies the conditions of 42 C.F.R. Section 411.354(d)(4).

An **"employee"** is defined, for purposes of this exception, as an individual who, under the common law rules that apply in determining the employer-employee relationship, is considered to be employed by, or an employee of, an entity [42 C.F.R. Section 411.351].

While hospitals in California (with certain exceptions) cannot employ physicians to provide medical services, physicians may be employed to provide administrative and management services, such as those provided by department medical directors. Compensation under such employment arrangements is protected by this exception and will not prohibit the employed physician from referring Medicare patients to the hospital.

Personal Services Arrangements

There is an exception for personal services arrangements, where a physician furnishes personal services to a hospital. To satisfy this exception, the following requirements must be met:

1. The arrangement must be set out in writing, signed by the parties, and specify the services covered by the arrangement;
2. The arrangement must cover all of the services to be furnished by the physician (or immediate family member) to the entity. This requirement is met if all separate agreements incorporate each other by reference, or if they cross reference a master list of agreements that is maintained and updated centrally and is made available to the Secretary of the Department of Health and Human Services upon request. The master list must be maintained in a manner that preserves the historical record of contracts;
3. The aggregate services covered by the arrangement for may not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement;
4. The duration of the arrangement is for at least one year. To meet this requirement, if an arrangement is terminated during the term with or without cause, the parties may not enter into the same or substantially the same arrangement during the first year of the original term of the arrangement;
5. The compensation to be paid over the term of the arrangement must be set in advance, may not exceed fair market value, and, except in the case of a physician incentive plan as defined in 42 C.F.R. Section 411.351 may not be determined in any manner that takes into account the volume or value of any referrals or other business generated between the parties;

6. If remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement satisfies the conditions of 42 C.F.R. Section 411.354(d)(4); and
7. The services to be performed under the arrangement may not involve the counseling or promotion of a business arrangement or any activity that violates a federal or state law.

A holdover personal service arrangement following the expiration of an arrangement of at least one year that continues to meet the above conditions also complies with this exception, provided that the holdover personal service arrangement is on the same terms and conditions as the immediately preceding arrangement.

A physician or family member can furnish services through employees; through a wholly-owned entity; or through locum tenens physicians.

In order to document that service payments are consistent with fair market value of services actually rendered, it is advisable to maintain time records of the nature and extent of services provided by the physician.

Example 1: A physician and a hospital enter into a written agreement under which the physician is paid a fixed amount per month to serve as medical director of the hospital's cardiology department. The fixed amount is consistent with fair market value of the services to be rendered, and the term of the agreement is one year. The agreement is protected by the personal services exception.

Example 2: A hospital contracts with a physician to provide professional services in the hospital's outpatient primary care clinic and compensates the physician using a formula that includes a fixed monthly payment and an annual bonus that is calculated based on the physician's personal productivity (using a WRVU formula). The agreement is in writing and has a term of two years, and the total compensation paid is consistent with fair market value. The arrangement is protected by the personal services exception.

NOTE: CMS included commentary in the 2020 Final Rule clarifying that a compensation arrangement may be modified at any time, even during the first year of the arrangement, and does not need to remain in place for at least one year from the date of amendment, so long as the arrangement (as modified) satisfies all of the requirements of an applicable exception at the time of the amendment.

Physician Recruitment

The Stark law includes an exception for physician recruiting. Benefits provided by hospitals directly to a recruited physician in order to induce the physician to relocate to the geographic area served by the hospital and to become a member of the medical staff will not disqualify the physician from making Medicare referrals to the hospital if the following four conditions are met:

8. The arrangement is set out in writing and signed by both parties;
9. The arrangement is not conditioned on the physician's referral of patients to the hospital;
10. The hospital does not take into account the amount of the remuneration to the physician based on the volume or value of actual or anticipated referrals by the physician or other business generated between the parties; and
11. The physician is allowed to establish staff privileges at any other hospital(s) and to refer business to any other entities. However, referrals may be restricted under an employment or services contract that complies with 42 C.F.R. Section 411.354(d)(4. *(See "Physician Compensation Conditioned Upon Referrals," page 6.14)*.

The recruitment benefits must be intended to induce the physician to relocate and join the recruiting hospital's medical staff. Thus, the exception cannot be met if the recruited physician is a member of the recruiting hospital's medical staff before the recruitment occurs, even if all other requirements of the exception are met.

The **"geographic area served by the hospital"** is, essentially, the area composed of the lowest number of contiguous zip codes from which the hospital draws at least 75 percent of its inpatients. For rural hospitals, the geographic area served by the hospital may also be the area composed of the lowest number of contiguous zip codes from which the hospital draws at least 90 percent of its inpatients. *(See 42 C.F.R. Section 411.357(e)(2) for further explanation of the geographic area served by the hospital.*

A physician will be considered to have relocated his or her medical practice if it was located outside the geographic area served by the hospital; and:

1. The physician moves his or her medical practice at least 25 miles and into the geographic area served by the hospital; or
2. The physician moved his or her medical practice into the geographic area served by the hospital and the physician's new medical practice derives at least 75 percent of its revenues from professional services furnished to patients (including hospital inpatients) not seen or treated by the physician at his or her prior medical practice site during the preceding three years, measured on an annual basis (fiscal or calendar year). For the initial year of the recruited physician's practice, the 75 percent test will be satisfied if there is a reasonable expectation that the recruited physician's medical practice for the year will derive at least 75 percent of its revenues from professional services furnished to patients not seen or treated by the physician at his or her prior medical practice site during the preceding three years.

CMS has clarified that in order to meet the relocation requirement the physician must move his or her practice from outside of the geographic area served by the hospital into such geographic area.

Residents and physicians who have been in practice one year or less will not be subject to the relocation requirement, except that the recruited resident or physician must establish his or her medical practice in the geographic area served by the hospital. Special rules exist for recruiting physicians formerly employed by a federal or state prison system, the Department of Defense, the Department of Veterans Affairs, or an Indian Health Service facility. The Secretary of the Department of Health and Human Services may also issue an advisory opinion regarding a particular physician.

Where a hospital is recruiting a physician to join an existing medical group in the hospital's service area, the Stark law's recruiting exception requires amounts other than the actual costs incurred by the group in recruiting the physician to be paid to and retained by the recruited physician or to be passed through to the recruit. Further, the Stark exception allows income guarantees when only the actual additional incremental expenses incurred by the group that are attributed to the recruited physician are taken into account in determining the amount to be paid under the guarantee. Further, the group practice may not impose on the recruited physician practice restrictions that unreasonably restrict the physician's ability to practice medicine in the hospital's geographic area. [42 C.F.R. Section 411.357(e)(4)]

Specifically, in the case of remuneration provided by a hospital to a physician either indirectly through payments made to another physician practice, or directly to a physician who joins a physician practice, the following additional conditions must be met:

1. The writing is also signed by the physician practice, if the remuneration is provided indirectly to the physician through payments made to the physician practice and the physician practice does not pass directly through to the physician all of the remuneration from the hospital.
2. Except for actual costs incurred by the physician practice in recruiting the new physician, the remuneration is passed directly through to or remains with the recruited physician.
3. In the case of an income guarantee of any type made by the hospital to a recruited physician who joins a physician practice, the costs allocated by the physician practice to the recruited physician do not exceed the actual additional incremental costs attributable to the recruited physician. With respect to a physician recruited to join a physician practice located in a rural area or HPSA, if the physician is recruited to replace a physician who, within the previous 12-month period, retired, relocated outside of the geographic area served by the hospital, or died, the costs allocated by the physician practice to the recruited physician do not exceed either:
    a. The actual additional incremental costs attributable to the recruited physician; or
    b. The lower of a per capita allocation or 20 percent of the practice's aggregate costs.
4. Records of the actual costs and the passed-through amounts are maintained for a period of at least six years and made available to the Secretary upon request.
5. The remuneration from the hospital under the arrangement is not determined in a manner that takes into account (directly or indirectly) the volume or value of any actual or anticipated referrals by the recruited physician or the physician practice (or any physician affiliated with the physician practice) receiving the direct payments from the hospital.
6. The physician practice may not impose on the recruited physician practice restrictions that unreasonably restrict the recruited physician's ability to practice medicine in the geographic area served by the hospital.

Rural/FQHCs

Recruitment of a physician by a hospital located in a rural area to an area outside the geographic area served by the hospital is permitted under this exception if the Secretary determines in an advisory opinion that the area has a demonstrated need for the recruited physician and all other requirements of this exception are met.

This exception applies to remuneration provided by a federally qualified health center (FQHC) or a rural health clinic (RHC) in the same manner as it applies to remuneration provided by a hospital.

The geographic area served by a federally qualified health center or a rural health clinic is the area comprised of the lowest number of contiguous or noncontiguous zip codes from which the federally qualified health center or rural health clinic draws at least 90 percent of its patients, as determined on an encounter basis. The geographic area served by the federally qualified health center or rural health clinic may include one or more zip codes from which the federally qualified health center or rural clinic draws no patients, provided that such zip codes are entirely surrounded by zip codes in the geographic area described above from which the federally qualified health center or rural health clinic draws at least 90 percent of its patients.

Assistance to Compensate a Nonphysician Practitioner

The Stark law includes an exception for remuneration provided by a hospital to a physician to compensate a nonphysician practitioner (NPP) to provide NPP patient care services (defined below), if all of the following conditions are met:

1. The arrangement is set out in writing and signed by the hospital, the physician, and the NPP and commences before the physician (or the physician organization in whose shoes the physician stands) enters into the compensation arrangement.
2. The arrangement is not conditioned on the physician's referrals to the hospital, or the NPP's referrals (defined below) to the hospital.
3. The remuneration from the hospital:
    a. Does not exceed 50 percent of the actual compensation, signing bonus, and benefits paid by the physician to the NPP during a period not to exceed the first two consecutive years of the compensation arrangement between the NPP and the physician (or the physician organization in whose shoes the physician stands); and
    b. Is not determined in any manner that takes into account the volume or value of any actual or anticipated referrals by the physician (or any physician in the physician's practice) or NPP referrals by the NPP (or any NPP in the physician's practice) or other business generated between the parties.
4. The compensation, signing bonus, and benefits paid to the NPP by the physician does not exceed the fair market value of the NPP patient care services furnished by the NPP to patients of the physician's practice.
5. The NPP has not, within one year of the commencement of his or her compensation arrangement with the physician (or the physician organization in whose shoes the physician stands):

a. Furnished NPP patient care services in the geographic area served by the hospital; or

b. Been employed or otherwise engaged to provide NPP patient care services by a physician or a physician organization that has a medical practice site located in the geographic area served by the hospital, regardless of whether the NPP furnished NPP services at the medical practice site located in the geographic area served by the hospital.

6. The NPP has a compensation arrangement with the physician or the physician organization in whose shoes the physician stands, and substantially all of the NPP patient care services that the NPP furnishes to patients of the physician's practice are primary care services or mental health care services.

7. The physician does not impose practice restrictions on the NPP that unreasonably restrict the NPP's ability to provide NPP patient care services in the geographic area served by the hospital.

Records of the actual amount of remuneration provided by the hospital to the physician, and by the physician to the NPP, must be maintained for period of at least six years and made available to the Secretary upon request.

For the purposes of this exception, "NPP patient care services" means direct patient care services furnished by a NPP. that address the medical needs of specific patients or any task performed by a NPP that promotes the care of patients of the physician or physician organization with which the NPP has a compensation arrangement.

For the purposes of this exception, **"NPP referral"** means a request by a nonphysician practitioner that includes the provision of any designated health service for which payment may be made under Medicare, the establishment of any plan of care by a nonphysician practitioner that includes the provision of such a designated health service, or the certifying or recertifying of the need for such a designated health service, but does not include any DHS personally performed or provided by the NPP.

For purposes of this exception, a **"compensation arrangement"** between a physician (or the physician organization in whose shoes the physician stands) and a NPP means an employment, contractual, or other arrangement under which remuneration passes between the parties. A compensation arrangement does not include a NPP's ownership or investment interest in a physician organization.

This exception may be used by a hospital, federally qualified health center, or rural health clinic only once every three years with respect to the same referring physician.

This exception does not apply to remuneration provided by a hospital, federally qualified health center, or rural health clinic to a physician to compensate a NPP to provide patient care services if:

1. The NPP is replacing a NPP who terminated his or her employment or contractual arrangement to provide NPP patient care services with the physician (or the physician organization in whose shoes the physician stands) within one year of the commencement of the employment or contractual arrangement; and

2. The remuneration provided to the physician is provided during a period that does not exceed two consecutive years as measured from the commencement of the

compensation arrangement between the NPP who is being replaced and the physician (or the physician organization in whose shoes the physician stands).

Timeshare Arrangements

Remuneration provided under an arrangement for the use of premises, equipment, personnel, items, supplies, or services are protected by a timeshare exception if the following conditions are met:

1. The arrangement is set out in writing, signed by the parties, and specifies the premises, equipment, personnel, items, supplies, and services covered by the arrangement.
2. The arrangement is between a physician (or the physician organization in whose shoes the physician stands) and a hospital or physician organization of which the physician is not an owner, employee, or contractor.
3. The premises, equipment, personnel, items, supplies, and services covered by the arrangement are used predominately for the provision of evaluation and management services to patients, and on the same schedule.
4. The equipment covered by the arrangement is:
    a. Located in the same building where the evaluation and management services are furnished;
    b. Not used to furnish designated health services other than those incidental to the evaluation and management services furnished at the time of the patient's evaluation and management visit; and
    c. Not advanced imaging equipment, radiation therapy equipment, or clinical or pathology laboratory equipment (other than equipment used to perform CLIA-waived laboratory tests).
5. The arrangement is not conditioned on the referral of patients by the physician who is a party to the arrangement to the hospital or physician organization of which the physician is not an owner, employee, or contractor.
6. The compensation over the term of the arrangement is set in advance, consistent with fair market value, and not determined in any manner that takes into account the volume or value of referrals or other business generated between the parties, or using a formula based on:
    a. A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services provided while using the premises, equipment, personnel, items, supplies, or services covered by the arrangement; or
    b. Per-unit of service fees that are not time-based, to the extent that such fees reflect services provided to patients referred by the party granting permission to use the premises, equipment, personnel, items, supplies, or services covered by the arrangement to the party to which the permission is granted.
7. The arrangement would be commercially reasonable even if no referrals were made between parties.

8. The arrangement does not convey a possessory leasehold interest in the office space that is the subject of the arrangement.

Limited Remuneration to Physician

An entity may provide remuneration to a physician in an amount up to $5,000 in a calendar year (adjusted for inflation annually) for items or services provided by the physician to the entity. No writing is required, but all of these requirements must be satisfied:

1. The compensation may not be determined in any manner that takes into account the volume or value of referrals or other business generated by the physician.
2. The compensation does not exceed the fair market value of the items or services.
3. The arrangement would be commercially reasonable even if no referrals were made between the parties.
4. Compensation for the lease of office space or equipment is not determined using a formula based on a percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space or to the services performed on or business generated through the use of the equipment, or per unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.
5. Compensation for the use of premises or equipment is not determined using a formula based on a percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services provided while using the premises or equipment covered by the arrangement, or per-unit of service fees that are not time-based, to the extent that such fees reflect services provided to patients referred by the party granting permission to use the premises or equipment covered by the arrangement to the party to which the permission is granted.
6. If remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement satisfies the conditions of Section 411.354(d)(4). *(See "Physician Compensation Conditioned Upon Referrals," page 6.14)*.

NOTE: This exception provides additional flexibility for hospitals and other entities to pay physicians (up to a capped amount) without getting a signed writing, when certain conditions are met. For example, a hospital could use this exception to protect payments made to a physician providing call coverage when there wasn't sufficient time to get a signed writing in place.

Isolated Transactions

Payments to physicians that constitute an "isolated financial transaction" are protected if the following conditions are met:

1. The amount of remuneration is consistent with the fair market value and is not determined in any manner that takes into account the volume or value of referrals by the referring physician or other business generated between the parties.

2. The remuneration is provided under an arrangement that would be commercially reasonable even if the physician made no referrals to the entity.
3. There are no additional transactions between the parties for six months after the isolated transaction, except for commercially reasonable post-closing adjustments that do not take into account (directly or indirectly) the volume or value of referrals or other business generated by the referring physician and except for transactions that comply with the other Stark exceptions described in this chapter.
4. An isolated financial transaction that is an instance of forgiveness of an amount owed in settlement of a bona fide dispute is not part of the compensation arrangement giving rise to the bona fide dispute.

For purposes of this exception, a **"transaction"** is an instance of two or more persons or entities doing business, and an **"isolated financial transaction"** is a one-time transaction involving a single payment, or a one-time transaction that involves integrally related installment payments, provided that:

1. The total aggregate payment is fixed before the first payment is made and does not take into account the volume or value of referrals or other business generated by the referring physician; and
2. The payments are immediately negotiable, guaranteed by a third party, secured by a negotiable promissory note, or subject to a similar mechanism to ensure payment in the event of default by the purchaser or obligated party.

An isolated financial transaction includes a one-time sale of property or a practice, single instance of forgiveness of an amount owed in settlement of a bona fide dispute, or similar one-time transaction, but does not include a single payment for multiple or repeated services (such as payment for services previously provided but not yet compensated).

[42 C.F.R. Sections 411.357(f); 411.351]

NOTE: In the 2020 Final Rule, CMS modified the definitions of "transaction" and "isolated financial transaction" to make clear that it would not include a single payment for multiple services (like the provision of call coverage or other ongoing professional services arrangement), but could be used for a single instance of forgiveness of an amount owed in settlement of a bona fide dispute. Although couched as a clarification, this is a significant departure from how many in the industry interpreted this exception historically and should be reviewed closely. While the isolated transaction exception has arguably become narrower, it is also worth noting that CMS provided additional flexibility in other changes appearing in the 2020 Final Rule, such as the expanded temporary non-compliance exception (90 days for writing and signature requirement) and the new limited remuneration to physician exception.

Certain Arrangements With Hospitals

Remuneration provided by a hospital to a physician falls within this exception if the remuneration does not relate, directly or indirectly, to the furnishing of DHS. To qualify as unrelated remuneration it must be wholly unrelated to the furnishing of DHS and must not in any way take into account the volume or value of a physician's referrals. Remuneration relates to the furnishing of DHS if it:

1. Is an item, service, or cost that could be allocated in whole or in part to Medicare or Medicaid under cost reporting principles;
2. Is furnished, directly or indirectly, explicitly or implicitly, in a selective, targeted, preferential, or conditioned manner to medical staff or other persons in a position to make or influence referrals; or
3. Otherwise takes into account the volume or value of referrals or other business generated by the referring physician.

Group Practice Arrangements With a Hospital

An arrangement between a hospital and a group practice under which DHS are furnished by the group but are billed by the hospital is an exception from the referral prohibition if the following conditions are met:

1. With respect to services furnished to an inpatient of the hospital, the arrangement is pursuant to the provision of inpatient hospital services "under arrangements" with the hospital.
2. The arrangement began before, and has continued in effect without interruption since Dec. 19, 1989.
3. With respect to the DHS covered under the arrangement, at least 75 percent of these services furnished to patients of the hospital are furnished by the group under the arrangement.
4. The arrangement is in accordance with a written agreement that specifies the services to be furnished by the parties and the compensation for services furnished under the agreement.
5. The compensation paid over the term of the agreement is consistent with fair market value, and the compensation per unit of service is fixed in advance and is not determined in any manner that takes into account the volume or value of referrals or other business generated between the parties.
6. The compensation is provided in accordance with an agreement that would be commercially reasonable even if no referrals were made to the entity.
7. If remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement satisfies the conditions of 42 C.F.R. Section 411.354(d)(4).

The definition of "group practice" is found in CHA Appendix HC 6-A.

Purchase of Items/Services — Payments by a Physician to Laboratory or Other Entity

An exception exists for payments made by a physician (or immediate family member) to a laboratory in exchange for the provision of clinical laboratory services. This exception also applies to payments made by a physician (or immediate family member) to an entity as compensation for any other items or services that:

1. Are furnished at a price that is consistent with fair market value;
2. To which the following Stark law exceptions are not applicable: rental of office space, rental of equipment, bona fide employment relationships, personal service

arrangements, physician recruitment, isolated transactions, certain arrangements with hospitals, and group practice arrangements with a hospital.

"Services," for purposes of this exception, means services of any kind (not merely those defined as "services" for purposes of the Medicare program).

NOTE: Prior to the 2020 Final Rule, the regulation stated that the services could not be specifically excepted by any other provision in 42 C.F.R. Sections 411.355-411.357. The revised regulation now provides that only the exceptions at 42 C.F.R. Sections 411.357(a)-(h), a narrower category, cannot apply. This change is significant, since it now clearly permits reliance on this exception even when payments by a physician do not meet the fair market value compensation exception. [42 C.F.R. Section 411.357(i)].

Example: A physician has an in-office laboratory and occasionally purchases laboratory supplies from a nearby hospital. The compensation arrangement would be protected by this exception as long as the physician pays fair market value for those supplies.

Charitable Donations by a Physician

Bona fide charitable donations made by a physician (or immediate family member) may be made to an entity if the following conditions are met:

1. The charitable donation is made to an organization exempt from taxation under the Internal Revenue Code (or to a supporting organization);
2. The donation is neither solicited, nor offered, in any manner that takes into account the volume or value of referrals or other business generated between the physician and the entity.

De Minimis Exception (Nonmonetary Compensation)

The Stark law provides an exception for compensation in the form of items or services that does not exceed a certain aggregate amount. The limit is adjusted each calendar year for inflation; for calendar year 2022, the amount was increased to $452. (Current annual limits may be found at https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/CPI-U_Updates.html.) The exception does not apply to compensation in the form of cash or cash equivalents. Additional requirements are the following:

1. The compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician.
2. The compensation may not be solicited by the physician or the physician's practice (including employees and staff members).

This exception can be used to protect incidental benefits provided by a hospital to its medical staff members, such as meals, transportation reimbursement, etc., as long as the specified value limit is not exceeded. CMS has taken the position that the value of a gift provided to a medical group that is of general benefit to the group, such as a painting for the group's waiting room, should be attributed to each physician in the group, and the value of the gift may not be prorated among group members.

Examples of nonmonetary compensation to physicians are nonworking lunches, gift baskets, flowers upon death of a family member, physician appreciation events, golf outings and tickets to sporting events. Note that medical staff incidental benefits in excess of the annual limit *(see "Medical Staff Incidental Benefits," page 6.40)* should be included as nonmonetary compensation.

In addition to nonmonetary compensation up to the limit described above, an entity that has a formal medical staff may provide one local medical staff appreciation event per year for the entire medical staff. Any gifts or gratuities provided in connection with the medical staff appreciation event are subject to the limit above.

Hospitals should develop a system to require reporting of, and tracking of, all items or services provided to a physician, to ensure that the annual limit is not exceeded. The system should track all items, even seemingly innocuous items. One method commonly used is to require all hospital departments to report to the hospital's compliance officer or compliance office detailed information regarding any nonmonetary compensation, including medical staff incidental benefits in excess of the annual limit. The information should include the market value of the items or services to be provided and copies of receipts or other documentation of the costs of the items or services. It is important that the information be reported prior to provision of any compensation, so that the compensation can be withheld if it will cause the limit to be exceeded. The compliance office then maintains a log of all reports of nonmonetary compensation, by physician, in order to monitor compliance with the annual limit.

Inadvertently Exceeding the Limit

If an entity inadvertently provides nonmonetary compensation to a physician in excess of the limit above, the compensation will be deemed to be within the limit if:

1. The value of the excess nonmonetary compensation is no more than 50 percent of the limit; and
2. The physician returns an amount equal to the value of the excess nonmonetary compensation by the end of the calendar year in which the excess was received, or within 180 consecutive calendar days following the date the excess was received by the physician, whichever is earlier.

The recovery of excess nonmonetary compensation may be used by an entity only once every three years with respect to the same referring physician.

Medical Staff Incidental Benefits

An exception for medical staff incidental benefits protects items and services (not cash or cash equivalents) provided by a hospital to its medical staff members if the following conditions are met:

1. The compensation is offered to all members of the medical staff practicing in the same specialty (but not necessarily accepted by every member to whom it is offered) and is not offered in a manner that takes into account the volume or value of referrals or other business generated between the parties.
2. Except with respect to identification of medical staff on a hospital website or in hospital advertising, the compensation is provided only during periods when the

medical staff members are making rounds or are engaged in other services or activities that benefit the hospital or its patients.

3. The compensation is provided by the hospital and used by the medical staff members only on the hospital's campus. Compensation, including, but not limited to, Internet access, pagers or two-way radios, used away from the campus only to access hospital medical records or information, or to access patients or personnel who are on the hospital campus, as well as the identification of the medical staff on a hospital website or in hospital advertising, meets the on campus requirement.
4. The compensation is reasonably related to the provision of, or designed to facilitate directly or indirectly the delivery of, medical services at the hospital.
5. The compensation is of low value with respect to each occurrence of the benefit (for example, each meal given to a physician while he or she is serving patients who are hospitalized must be of low value). The amount considered low value is adjusted annually for inflation; in calendar year 2022, the low value threshold was increased to less than $39 (Current annual limits may be found at https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/CPI-U_Updates.html.)
6. The compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated between the parties.

Other facilities and health care clinics (including, but not limited to, FQHCs) that have bona fide medical staffs may provide compensation under this exception also.

This exception permits hospitals to provide general benefits of nominal value to their medical staff members, or to all medical staff members in a particular specialty, without having to include those benefits under the de minimis exception discussed above, provided that each of the requirements is met.

Fair Market Value Compensation

The Stark law provides an exception for any arrangement in which compensation is paid at fair market value (FMV). This exception can protect both payments by a hospital to a physician (or immediate family member), and payments by a physician (or immediate family member) to a hospital, for items and services or for the lease of office space or equipment. This exception also applies to any group of physicians, regardless of whether the group meets the definition of a group practice.

The requirements of this exception are practically identical to the requirements of the personal services exception *(see "Personal Services Arrangements," page 6.29).* The major difference between the FMV exception and the personal services exception is that the FMV exception does not require a written agreement with a term of at least 12 months. In addition, the FMV exception requires the compensation to be consistent with fair market value, while the personal services exception requires that compensation not exceed fair market value (so compensation may be less than fair market value). Another difference is that unlike the personal services exception, the FMV exception does not provide for holdover arrangements after expiration. In a departure from prior interpretation, in the 2020 Final Rule CMS also clarified that the FMV exception can be used for arrangements involving the lease of space or equipment.

The FMV exception requires the following:

1. The arrangement must be in writing, signed by the parties, and cover only identifiable items or services, office space, or equipment.
2. The writing must specify the items, services, office space, or equipment covered under the arrangement, the compensation to be provided, and the time frame for the arrangement, which can be for any period of time and contain a termination clause. An arrangement may be renewed any number of times if the terms of the arrangement and the compensation for the same items or services do not change. Other than an arrangement that satisfies all of the conditions of acceptable limited remuneration to a physician, the parties may not enter into more than one arrangement for the same items, services, office space, or equipment during the course of a year.
3. The compensation must be set in advance, consistent with fair market value, and not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician. Compensation for the rental of office space or equipment may not be determined using a formula based on:
    a. A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space or to the services performed on or business generated through the use of the equipment; or
    b. Per-unit-of-service rental charges, to the extent that such charges reflect services provided to patients referred between the parties. *(See "Rental of Equipment," page 6.27.)*
4. The arrangement would be commercially reasonable even if no referrals were made between the parties.
5. The arrangement must not violate the anti-kickback statute *(see chapter 7, "Federal and State Anti-Kickback Laws")*.
6. The services to be performed under the arrangement must not involve the counseling or promotion of a business arrangement or other activity that violates a federal or state law.
7. Arrangements must satisfy the requirements related to special rules on compensation in 42 C.F.R. Section 411.354(d) as related to remuneration to the physician that is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, or remuneration paid to the group of physicians that is conditioned on one or more of the group's physicians' referrals to a particular provider, practitioner, or supplier.

Example: A hospital contracts in writing with a physician for consulting services related to its neonatal intensive care unit. The agreement is for a period of three months, and the hourly rate paid is consistent with fair market value. The arrangement is protected by the fair market value compensation exception as long as the hospital and physician do not enter into a new agreement for the same services until at least 12 months after the effective date of the original agreement.

NOTE: CMS included commentary in the 2020 Final Rule clarifying that a compensation arrangement may be modified at any time, even during the first year of the arrangement, and does not need to remain in place for at least one year from the date of amendment, so long as the arrangement (as modified) satisfies all of the requirements of an applicable exception at the time of the amendment. Risk-Sharing Arrangements

An exception is provided for compensation paid directly or indirectly by a managed care organization or an independent practice association to a physician pursuant to a risk-sharing arrangement (including, but not limited to, withholds, bonuses, and risk pools) for services provided by the physician to enrollees of a health plan.

Compliance Training

Compliance training provided by a hospital or other entity to a physician (or to the physician's immediate family member or office staff) who practices in the entity's local community or service area is an exception, provided that the training is held in the local community or service area.

For purposes of this exception, **"compliance training"** means training regarding the basic elements of a compliance program (for example, establishing policies and procedures, training of staff, internal monitoring, or reporting); specific training regarding the requirements of federal and state health care programs (for example, billing, coding, reasonable and necessary services, documentation, or unlawful referral arrangements); or training regarding other federal, state, or local laws, regulations, or rules governing the conduct of the party for whom the training is provided.

Compliance training may include programs that offer continuing medical education credit, provided that compliance training is the primary purpose of the program.

Indirect Compensation Arrangements

An exception for many indirect compensation arrangements is provided by the Stark regulations. The definition of an indirect compensation arrangement is found at "Types of Compensation Arrangements," page 6.8. The following conditions must be met:

1. The compensation received by the referring physician (or immediate family member) represents fair market value for services and items actually provided and is not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician for the DHS entity. Compensation for the rental of office space or equipment may not be determined using a formula based on:

a. A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space, or to the services performed on or business generated through the use of the equipment; or

b. Per-unit-of-service rental charges, to the extent that such charges reflect services provided to patients referred between the parties. *(See "Rental of Equipment," page 6.27.)*

2. The compensation arrangement is set out in writing, signed by the parties, and specifies the services covered by the arrangement, except in the case of a bona fide employment relationship between an employer and an employee, in which case the arrangement need not be set out in writing, but must be for identifiable services and be commercially reasonable even if no referrals are made to the employer; and

3. If remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the compensation arrangement described in 42 C.F.R. Section 411.354(c)(2)(ii) satisfies the conditions of special rules on compensation in 42 C.F.R. Section 411.354(d)(4).

This exception contains a "volume or value" test. However, unlike the standard under the definition for indirect compensation arrangement itself *(see "Types of Compensation Arrangements," page 6.8)*, the test under the exception for indirect compensation arrangements does not include the word "aggregate," and is otherwise phrased in a different manner so that the standard applied to compensation under the definition and the compensation requirement under the exception have different meanings. Under the 2020 Final Rule, it is anticipated that fewer financial relationships with physicians will be considered an indirect compensation arrangement in the first instance moving forward. [42 C.F.R. Section 411.354(p)]

Referral Services

A Stark exception exists that permits physician referral services, if the requirements of the referral services safe harbor under the anti-kickback law are met. *(See chapter 7, "Federal and State Anti-Kickback Laws.")*

Obstetrical Malpractice Insurance Subsidies

A Stark exception exists to permit remuneration to a physician in the form of obstetrical malpractice insurance subsidies if specified conditions are met.

If all of the conditions of the safe harbor under the anti-kickback law for obstetrical malpractice insurance subsidies *(see chapter 7, "Federal and State Anti-Kickback Laws")* are met, then the remuneration is permitted.

If all of the conditions of the safe harbor are not met, then a payment from a hospital, federally qualified health center (FQHC), or rural health clinic (RHC) that is used to pay for some or all of the costs of malpractice insurance premiums for a physician who engages in obstetrical practice as a routine part of his or her medical practice is permitted, if all of the following conditions are met:

1. The physician's medical practice is located in a rural area, a primary care HPSA, or an area with demonstrated need for the physician's obstetrical services as determined by the Secretary in an advisory opinion or at least 75 percent of the

physician's obstetrical patients reside in a medically underserved area or are members of a medically underserved population.

2. The arrangement is set out in writing, is signed by the physician and the hospital, FQHC or RHC providing the payment, and specifies the payment to be made by the hospital, FQHC or RHC and the terms under which the payment is to be provided.
3. The arrangement is not conditioned on the physician's referral of patients to the hospital, FQHC or RHC providing the payment.
4. The hospital, FQHC or RHC does not determine the amount of the payment in any manner that takes into account the volume or value of referrals by the physician or any other business generated between the parties.
5. The physician is allowed to establish staff privileges at any hospital(s), FQHC(s) or RHC(s) and to refer business to any other entities (except as referrals may be restricted under an employment arrangement *(see "Bona Fide Employment Relationships," page 6.28)* or services arrangement *(see "Personal Services Arrangements," page 6.29)*.
6. The payment is made to a person or organization (other than the physician) that is providing malpractice insurance (including a self-funded organization).
7. The physician treats obstetrical patients who receive medical benefits or assistance under any federal health care program in a nondiscriminatory manner.
8. The insurance is a bona fide malpractice insurance policy or program, and the premium, if any, is calculated based on a bona fide assessment of the liability risk covered under the insurance.
9. For each coverage period (not to exceed one year), at least 75 percent of the physician's obstetrical patients treated under the coverage of the obstetrical malpractice insurance during the prior period (not to exceed one year):

    a. Resided in a rural area, HPSA, medically-underserved area, or an area with a demonstrated need for the physician's obstetrical services as determined by the Secretary in an advisory opinion; or

    b. Were part of a medically-underserved population.

    For the initial coverage period (not to exceed one year), these requirements will be satisfied if the physician certifies that he or she has a reasonable expectation that at least 75 percent of the physician's obstetrical patients treated under the coverage of the malpractice insurance will reside in a rural area, HPSA, medically-underserved area, or an area with a demonstrated need for the physician's obstetrical services as determined by the Secretary in an advisory opinion, or be part of a medically-underserved population.

For purposes of this exception, **"costs of malpractice insurance premiums"** means:

1. For physicians who engage in obstetrical practice on a full-time basis, any costs attributable to malpractice insurance; or

2. For physicians who engage in obstetrical practice on a part-time or sporadic basis, the costs attributable exclusively to the obstetrical portion of the physician's malpractice insurance, and related exclusively to obstetrical services provided:

    a. In a rural area, primary care HPSA, or an area with demonstrated need for the physician's obstetrical services, as determined by the Secretary in an advisory opinion; or

    b. In any area, provided that at least 75 percent of the physician's obstetrical patients treated in the coverage period (not to exceed one year) resided in a medically-underserved area or were part of a medically-underserved population.

Professional Courtesy

Professional courtesy (the provision of free or discounted health care items or services to a physician or his or her immediate family members or office staff) offered by a hospital or other entity with a formal medical staff is considered an exception if all of the following conditions are met:

1. The professional courtesy is offered to all physicians on the entity's bona fide medical staff or in such entity's local community or service area, and the offer does not take into account the volume or value of referrals or other business generated between the parties;
2. The health care items and services provided are of a type routinely provided by the entity;
3. The entity has a professional courtesy policy that is set out in writing and approved in advance by the entity's governing body;
4. The professional courtesy is not offered to a physician (or immediate family member) who is a federal health care program beneficiary (for example, a Medicare beneficiary), unless there has been a good faith showing of financial need.

Retention Payments in Underserved Areas

A hospital, FQHC or RHC may provide retention payments to physicians in underserved areas without triggering the prohibition on referrals if the physician has a bona fide written offer from another entity, or if the physician provides a written certification, if the following conditions are met. (The term "hospital" is used below for simplicity; the exception applies in the same manner to FQHCs and RHCs.)

Bona Fide Written Offer

There is an exception for remuneration provided by a hospital directly to a physician on the hospital's medical staff to retain the physician's medical practice in the geographic area served by the hospital, if the following conditions are met:

1. The physician has a bona fide firm, written recruitment offer or offer of employment from a hospital, academic medical center or physician organization that is not related to the hospital making the payment, and the offer specifies the remuneration being offered and requires the physician to move the location of his or her medical practice at least 25 miles and outside of the geographic area served by the hospital making the retention payment.

2. The four requirements for payments to a physician under the physician recruitment exception are satisfied. *(See "Physician Recruitment," page 6.30.)*
3. Any retention payment is subject to the same obligations and restrictions, if any, on repayment or forgiveness of indebtedness as the written recruitment offer or offer of employment.
4. The retention payment does not exceed the lower of:
    a. The amount obtained by subtracting the physician's current income from physician and related services from the income the physician would receive from comparable physician and related services in the written recruitment or employment offer, provided that the respective incomes are determined using a reasonable and consistent methodology, and that they are calculated uniformly over no more than a 24-month period; or
    b. The reasonable costs the hospital would otherwise have to expend to recruit a new physician to the geographic area served by the hospital to join the medical staff of the hospital to replace the retained physician.
5. The requirements described in "Additional Requirements," page 6.48, are satisfied.

Written Certification From Physician

There is also an exception for remuneration provided by a hospital directly to a physician on the hospital's medical staff to retain the physician's medical practice in the geographic area served by the hospital if the following conditions are met:

1. The physician furnishes to the hospital before the retention payment is made a written certification that the physician has a bona fide opportunity for future employment by a hospital, academic medical center or physician organization that requires the physician to move the location of his or her medical practice at least 25 miles and outside the geographic area served by the hospital. The certification contains at least the following:
    a. Details regarding the steps taken by the physician to effectuate the employment opportunity;
    b. Details of the physician's employment opportunity, including the identity and location of the physician's future employer or employment location or both, and the anticipated income and benefits (or a range for income and benefits);
    c. A statement that the future employer is not related to the hospital making the payment;
    d. The date on which the physician anticipates relocating his or her medical practice outside of the geographic area served by the hospital; and
    e. Information sufficient for the hospital to verify the information included in the written certification.
2. The hospital takes reasonable steps to verify that the physician has a bona fide opportunity for future employment that requires the physician to relocate outside the geographic area served by the hospital.

3. The four requirements for payments to a physician under the physician recruitment exception are satisfied. *(See "Physician Recruitment," page 6.61.)*
4. The retention payment does not exceed the lower of:
    a. An amount equal to 25 percent of the physician's current income (averaged over the previous 24 months), using a reasonable and consistent methodology that is calculated uniformly; or
    b. The reasonable costs the hospital would otherwise have to expend to recruit a new physician to the geographic area served by the hospital to join the medical staff of the hospital to replace the retained physician.
5. The requirements described in "Additional Requirements," page 6.48, are satisfied.

Additional Requirements

Both the "bona fide written offer" exception and the "written certification from physician" exception described above must meet the following additional requirements:

1. The physician's current medical practice is located in a rural area or Health Professional Shortage Areas (HPSA) (regardless of the physician's specialty) or is located in an area with demonstrated need for the physician as determined by the Secretary in an advisory opinion; or at least 75 percent of the physician's patients reside in a medically-underserved area or are members of a medically-underserved population.
2. The hospital does not enter into a retention arrangement with a particular referring physician more frequently than once every five years.
3. The amount and terms of the retention payment are not altered during the term of the arrangement in any manner that takes into account the volume or value of referrals or other business generated by the physician.

Waiver by Secretary

The Secretary may waive the relocation requirement for retention payments made to physicians practicing in a HPSA or an area with demonstrated need for the physician through an advisory opinion, if the retention payment arrangement otherwise complies with all of the conditions of this section.

Community-Wide Health Information Systems

An exception exists for items or services of information technology provided by a hospital or other entity to a physician that allow access to, and sharing of, electronic health care records and any complementary drug information systems, general health information, medical alerts, and related information for patients served by community providers and practitioners, in order to enhance the community's overall health, provided that:

1. The items or services are available as necessary to enable the physician to participate in a community-wide health information system, are principally used by the physician as part of the community-wide health information system, and are not provided to the physician in any manner that takes into account the volume or value of referrals or other business generated by the physician;
2. The community-wide health information systems are available to all providers, practitioners, and residents of the community who desire to participate; and

Electronic Prescribing Items and Services

Nonmonetary remuneration (consisting of items and services in the form of hardware, software, or information technology and training services) necessary for and used solely to receive and transmit electronic prescription information does not trigger the referral prohibition if all of the following conditions are met:

1. The items and services are provided by:
    a. A hospital to a physician who is a member of its medical staff;
    b. A group practice to a physician who is a member of the group; or
    c. A Prescription Drug Program (PDP) sponsor or Medicare Advantage (MA) organization to a prescribing physician.
2. The items and services are provided as part of, or are used to access, an electronic prescription drug program that meets the applicable standards under Medicare Part D at the time the items and services are provided.
3. The donor, or any person on the donor's behalf, does not take any action to limit or restrict the use or compatibility of the items or services with other electronic prescribing or electronic health records systems.
4. For items or services that are of the type that can be used for any patient without regard to payer status, the donor does not restrict, or take any action to limit, the physician's right or ability to use the items or services for any patient.
5. Neither the physician nor the physician's practice (including employees and staff members) makes the receipt of items or services, or the amount or nature of the items or services, a condition of doing business with the donor.
6. Neither the eligibility of a physician for the items or services, nor the amount or nature of the items or services, is determined in a manner that takes into account the volume or value of referrals or other business generated between the parties.
7. The arrangement is set forth in a written agreement that:
    a. Is signed by the parties;
    b. Specifies the items and services being provided and the donor's cost of the items and services; and
    c. Covers all of the electronic prescribing items and services to be provided by the donor. This requirement is met if all separate agreements between the donor and the physician (and the donor and any family members of the physician) incorporate each other by reference or if they cross-reference a master list of agreements that is maintained and updated centrally and is available for review by the Secretary upon request. The master list must be maintained in a manner that preserves the historical record of agreements.
8. The donor does not have actual knowledge of, and does not act in reckless disregard or deliberate ignorance of, the fact that the physician possesses or has obtained items or services equivalent to those provided by the donor.

Electronic Health Records Items and Services

Nonmonetary remuneration (consisting of items and services in the form of software or information technology and training services, including cybersecurity software and services) necessary and used predominantly to create, maintain, transmit, receive, or protect electronic health records, meets this exception if all of the following conditions are met:

1. The items and services are provided to a physician by an entity that is not a laboratory company.
2. The software is interoperable at the time it is provided to the physician. For purposes of this exception, software is deemed to be interoperable if, on the date it is provided to the physician, it is certified by a certifying body authorized by the National Coordinator for Health Information Technology to certification criteria identified in the then-applicable version of 45 C.F.R. Part 170.
3. Before receipt of the initial donation of items and services or the donation of replacement items and services, the physician pays 15 percent of the donor's cost for the items and services. With respect to items and services received from the donor after the initial donation, the physician may pay 15 percent of the donor's cost for the items and services at reasonable intervals. The donor (or any party related to the donor) does not finance the physician's payment or loan funds to be used by the physician to pay for the items and services.
4. Neither the physician nor the physician's practice (including employees and staff members) makes the receipt of items or services, or the amount or nature of the items or services, a condition of doing business with the donor.
5. Neither the eligibility of a physician for the items or services, nor the amount or nature of the items or services, is determined in any manner that directly takes into account the volume or value of referrals or other business generated between the parties. The determination is deemed not to directly take into account the volume or value of referrals or other business generated between the parties if any one of the following conditions is met:
    a. The determination is based on the total number of prescriptions written by the physician (but not the volume or value of prescriptions dispensed or paid by the donor or billed to the program);
    b. The determination is based on the size of the physician's medical practice (for example, total patients, total patient encounters or total relative value units);
    c. The determination is based on the total number of hours that the physician practices medicine;
    d. The determination is based on the physician's overall use of automated technology in his or her medical practice (without specific reference to the use of technology in connection with referrals made to the donor);
    e. The determination is based on whether the physician is a member of the donor's medical staff, if the donor has a formal medical staff;
    f. The determination is based on the level of uncompensated care provided by the physician; or

g. The determination is made in any reasonable and verifiable manner that does not directly take into account the volume or value of referrals or other business generated between the parties.

6. The arrangement is set forth in a written agreement that:

   a. Is signed by the parties;

   b. Specifies the items and services being provided, the donor's cost of the items and services, and the amount of the physician's contribution; and

   c. Covers all of the electronic health records items and services to be provided by the donor.

   This requirement is met if all separate agreements between the donor and the physician (and the donor and any family members of the physician) incorporate each other by reference or if they cross-reference a master list of agreements that is maintained and updated centrally and is available for review by the Secretary upon request. The master list must be maintained in a manner that preserves the historical record of agreements.

7. For items or services that are of the type that can be used for any patient without regard to payer status, the donor does not restrict, or take any action to limit, the physician's right or ability to use the items or services for any patient.

8. The items and services do not include staffing of physician offices and are not used primarily to conduct personal business or business unrelated to the physician's medical practice.

Arrangements That Facilitate Value-Based Health Care Delivery and Payment

The 2020 Final Rule established three new exceptions at 42 C.F.R. Section 411.357(aa), referred to respectively as "full financial risk," "meaningful downside financial risk to the physician," and "value-based arrangements" with no risk. *(See M. "Transition to Value-Based Care and Value-Based Arrangement Exceptions," page 6.54, for more information.)*

Cybersecurity Technology and Related Services

Nonmonetary remuneration (consisting of technology and services) necessary and used predominantly to implement, maintain, or reestablish cybersecurity does not trigger the referral prohibition if all of the following conditions are met:

1. Neither the eligibility of a physician, nor the amount or nature of the technology or services, is determined in any manner that directly takes into account the volume or value of referrals or other business generated between the parties;

2. Neither the physician nor the physician's practice (including employees and staff members) makes the receipt of technology or services, or the amount or nature of the technology or services, a condition of doing business with the donor; and

3. The arrangement is documented in writing.

Unlike the electronic health record items and services exception, the physician is not required to contribute 15% to the cost of the cybersecurity technology and services.

[42 C.F.R. Section 411.357(bb)

I. Exceptions To Prohibition/Temporary Non-Compliance

The Stark law's prohibition does not apply under certain narrow circumstances. First, payment may be made to an entity for DHS, regardless of any financial relationship that may exist with the referring physician, if the entity did not have actual knowledge of, and did not act in reckless disregard or deliberate ignorance of, the identity of the physician who made the referral of DHS to the entity and the claim or bill complies with all other applicable federal and state laws. [42 C.F.R. Section 411.353(e)]

In addition, there is a temporary non-compliance exception where the financial relationship between the entity and the referring physician complied with an exception that requires a writing signed by the parties, for at least 180 consecutive days prior to the date that the relationship became non-compliant, the relationship fell out of compliance with the exception for reasons beyond the control of the entity furnishing the DHS, the entity promptly took steps to rectify the non-compliance, and the claim or bill complies with all other applicable laws. This exception applies only for a period of 90 days from the date the relationship became non-compliant. This exception may be used only once every three years with respect to the same referring physician, and does not apply if the exception with which the financial relationship previously complied was the nonmonetary compensation exception or the medical staff incidental benefits exception. [42 C.F.R. Section 411.353(f)]

Also, a special rule for reconciling compensation exists where an entity may submit a claim or bill and payment may be made for DHS no later than 90 consecutive calendar days following the expiration or termination of a compensation arrangement, the entity and the physician (or immediate family member of a physician) reconcile all discrepancies in payments such that the entire amount of remuneration for items or services has been paid and the compensation arrangement complies with an applicable exception.

Additional flexibilities also apply with respect to temporary non-compliance with the signature or writing requirements of an applicable exception. *(See "Writing and Signature Requirements," page 6.13.)* [42 C.F.R. Section 411.353(h)]

NOTE: In the 2020 Final Rule, CMS explicitly recognized the concept of imperfect performance — referring to a situation where the parties to an arrangement did not perfectly follow the written terms of a compensation arrangement during its term. The regulations now include a clear process to cure imperfect performance that may have occurred during the term of an agreement for a grace period of up to 90 days after expiration or termination.

J. Sanctions for Violations of the Federal Physician Self-Referral Law

Stark law violations may result in nonpayment of Medicare claims, as well as an obligation to refund any amounts already paid for services rendered pursuant to a prohibited referral. In addition, civil money penalties of up to $15,000 per violation can be imposed where claims are submitted for a service by a provider who knows or should have known that the service was rendered pursuant to a prohibited referral. A physician or other entity that enters into a circumvention scheme to violate the Stark law is subject to a civil money penalty of up to $100,000 for each scheme.

A **"circumvention scheme"** is defined as an arrangement or scheme, such as a cross-referral arrangement, which the physician or entity entering into the arrangement knows or should have known has the principal purpose of assuring referrals by the physician to an entity which, if the physician directly made referrals to the entity, such referrals would violate the Stark law.

Violations of the Stark law can also result in liability under the federal False Claims Act (FCA). The FCA is particularly troublesome for Stark law violations, since the FCA allows private parties to bring enforcement actions and share in any recovery under its whistleblower provisions. *(See chapter 3, "Federal and State False Claims Acts.")*

Finally, a physician or other entity may be subject to exclusion from the Medicare program for Stark law violations.

K. Waiver of the Stark Law for Accountable Care Organizations

The development and operation of accountable care organizations (ACOs), which were established as part of the 2011 health care reform's shared savings program (SSP) for Medicare fee-for-service beneficiaries, can implicate the Stark law and its prohibitions [42 U.S.C. Section 1395jjj]. It is therefore critical that a potential ACO and its participants carefully consider the application of the Stark law with respect to both the ACO's development and its operation.

An ACO is a group of providers and suppliers of services (e.g., hospitals, physicians and others involved in patient care) who work together to coordinate care for the Medicare beneficiaries they serve, agree to be accountable for the quality and cost of care for a defined group of Medicare fee for service beneficiaries and share in savings (and potentially losses) associated with the care for those assigned beneficiaries. The formation and operation of an ACO likely requires the ACO and its various providers and participants (including hospitals and physicians) to enter into arrangements that could implicate the Stark law, such as arrangements and/or agreements that relate to the ACO's:

1. Creation and infrastructure,
2. Network development,
3. Clinical management,
4. Information technology, and
5. Provider and supplier participation agreements.

As part of the final ACO regulation process, CMS and the OIG issued an interim final rule, effective Nov. 2, 2011, that included five separate fraud and abuse waivers that protect a broad range of ACO activities from the reach of the federal anti-kickback statute, certain civil monetary penalties law provisions and the Stark law [76 Fed. Reg. 67992 (Nov. 2, 2011)]. CMS and OIG subsequently issued a final rule finalizing the waivers effective Oct. 29, 2015 [80 Fed. Reg. 66726 (Oct. 29, 2015)]. If the applicable requirements are met, these five waivers protect an ACO's activities from the reach of the Stark law with respect to its:

1. Pre-participation or start-up activities,
2. Distribution of shared savings,
3. Financial relationships among participants,
4. Arrangements between participants, and
5. Incentives offered to patients.

See https://www.cms.gov/medicare/physician-self-referral/fraud-and-abuse-waivers for other waivers issued by CMS for similar models and programs, including Next Generation ACOs.

L. Waiver of the Stark Law for Joint Replacement Model

Effective April 1, 2016, CMS established the Comprehensive Care for Joint Replacement Model (CJR Model), which is intended to enhance the quality and efficiency of hip and knee replacement surgeries for Medicare patients. Under the CJR Model, hospitals physicians and other providers are held jointly accountable for the quality and cost of a joint replacement "episode of care," which begins with the hospital admission and ends 90 days after discharge.

Recognizing that the CJR Model calls for distributions of Medicare payments among hospitals and physicians that could create risk under the Stark law, on Nov. 16, 2015, DHHS issued a "Notice of Waivers of Certain Fraud and Abuse Laws in Connection with the Comprehensive Care for Joint Replacement Model."

The CMS notice includes waivers to protect the following arrangements among providers under the CJR Model from violation of the Stark law:

1. Payments under sharing arrangements between hospitals and other providers; and
2. Payments from physician groups to other providers.

There are numerous specific requirements that must be met to be protected by each of the waivers, which can be found in the notice at www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/2015-CJR-Model-Waivers.pdf.

M. Transition to Value-Based Care and Value-Based Arrangement Exceptions

In its 2020 Final Rule, CMS finalized provisions that remove regulatory barriers for healthcare providers entering into innovative arrangements to improve quality outcomes, produce health system efficiencies, and lower costs. The provisions pertain to "value-based arrangements" involving a "value-based enterprise" (VBE) engaged in at least one "value-based activity" to achieve a "value-based purpose" for a "target patient population." *(See C. "Definitions," page 6.4.)*

CMS has established three exceptions to protect remuneration paid under value-based arrangements. These exceptions are listed below, based on the required level of risk (ranging from full financial risk to no risk). The less risk that is required, the more requirements that apply under the applicable exception.

Full Financial Risk Exception

An exception exists for remuneration paid under a value-based arrangement where the value-based enterprise is at full financial risk (or is contractually obligated to be at full financial risk within the 12 months following the commencement of the value-based arrangement) during the entire duration of the value-based arrangement, and the following conditions are met:

1. The remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population.
2. The remuneration is not an inducement to reduce or limit medically necessary items or services to any patient.
3. The remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement.

4. If remuneration paid to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the value-based arrangement complies with both of the following conditions:
    a. The requirement to make referrals to a particular provider, practitioner, or supplier is set out in writing and signed by the parties.
    b. The requirement to make referrals to a particular provider, practitioner, or supplier does not apply if the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgment.
5. Records must be kept of the methodology for determining the remuneration, and the actual amount of remuneration paid under the value-based arrangement. These records must be maintained for a period of at least 6 years and made available to the Secretary upon request.

For purposes of this exception "full financial risk" means that the value-based enterprise is financially responsible on a prospective basis for the cost of all patient care items and services covered by the applicable payor for each patient in the target patient population for a specified period of time. [42 C.F.R. Section 411.357(aa)(1)]

Meaningful Downside Financial Risk to the Physician

An exception exists for remuneration paid under a value-based arrangement where the physician is at meaningful downside financial risk for failure to achieve the value-based purposes of the VBE during the entire duration of the value-based arrangement, if the following conditions are met, in addition to the conditions required under the exception for full financial risk:

1. A description of the nature and extent of the physician's downside financial risk is set forth in writing.
2. The methodology used to determine the amount of the remuneration is set in advance of the undertaking of value-based activities for which the remuneration is paid.

For purposes of this exception, **"meaningful downside financial risk"** means that the physician is responsible to repay or forgo no less than 10 percent of the total value of the remuneration the physician receives under the value-based arrangement. [42 C.F.R. Section 411.357(aa)(2)]

Value-Based Arrangements Exception

An exception exists for remuneration paid under a value-based arrangement that does not require the parties to take on downside risk at all, if the following conditions are met, in addition to the conditions required under the exceptions for full financial risk and meaningful downside financial risk:

1. The arrangement is set forth in writing and signed by the parties, and includes a description of:
    a. The value-based activities to be undertaken under the arrangement;

b. How the value-based activities are expected to further the value-based purpose(s) of the VBE;

c. The target patient population for the arrangement;

d. The type or nature of the remuneration;

e. The methodology used to determine the remuneration; and

f. The outcome measures against which the recipient of the remuneration is assessed, if any.

2. The outcome measures against which the recipient of the remuneration is assessed, if any, are objective, measurable, and selected based on clinical evidence or credible medical support.

3. Any changes to the outcome measures against which the recipient of the remuneration will be assessed are made prospectively and set forth in writing.

4. The arrangement is commercially reasonable.

5. No less frequently than annually, or at least once during the term of the arrangement if the arrangement has a duration of less than one year, the VBE or one or more of the parties monitor:

   a. Whether the parties have furnished the value-based activities required under the arrangement;

   b. Whether and how continuation of the value-based activities is expected to further the value-based purpose(s) of the VBE; and

   c. Progress toward attainment of the outcome measure(s), if any, against which the recipient of the remuneration is assessed.

6. If the monitoring indicates that a value-based activity is not expected to further the value-based purpose(s) of the VBE, the parties must terminate the ineffective value-based activity. Following completion of monitoring that identifies an ineffective value-based activity, the value-based activity is deemed to be reasonably designed to achieve at least one value-based purpose of the VBE:

   a. For 30 consecutive calendar days after completion of the monitoring, if the parties terminate the arrangement; or

   b. For 90 consecutive calendar days after completion of the monitoring, if the parties modify the arrangement to terminate the ineffective value-based activity.

7. If the monitoring indicates that an outcome measure is unattainable during the remaining term of the arrangement, the parties must terminate or replace the unattainable outcome measure within 90 consecutive calendar days after completion of the monitoring.

For purposes of this paragraph, **"outcome measure"** means a benchmark that quantifies:

8. Improvements in or maintenance of the quality of patient care; or

9. Reductions in the costs to or reductions in growth in expenditures of payors while maintaining or improving the quality of patient care. [42 C.F.R. Section 411.357(aa)(3)]

N. Disclosing Stark Violations

The ACA also required CMS to establish a disclosure protocol for Stark law violations, and for the first time authorized CMS to reduce the amount owed for violations below the amount specified in the Stark law. CMS published the Self-Referral Disclosure Protocol (SRDP) on Sept. 23, 2010, and revised the protocol on May 6, 2011 and again on March 27, 2017. Regulations implementing the SRDP, which include procedures for submitting requests, fees for requests, the process for withdrawing requests and the range of advisory opinions issued, are found at 42 C.F.R. Sections 411.370-411.389. *(See chapter 15, "Repayment and Self-Disclosure," for a full discussion of the SRDP.)*

O. Advisory Opinions

CMS issues opinions upon request to advise whether a physician's referrals are prohibited by the Stark law. In an advisory opinion, CMS determines whether the business arrangement described in the request appears to constitute a financial arrangement that could potentially restrict a physician's referrals of DHS and whether any of the Stark law's exceptions apply.

III. CALIFORNIA LAW

A. Introduction

Like Congress, the California Legislature has enacted a law prohibiting physician self-referral. This state law is known as the Physician Ownership and Referral Act (PORA) or the Speier law (named after the legislator who sponsored it). The general purpose and thrust of the state and federal laws is the same: to remove financial incentives that may encourage physicians to refer patients inappropriately. Unfortunately, the state law contains different definitions and different exceptions from the federal law. In addition, unlike the federal law, PORA applies to referrals of all patients, not just Medicare patients.

California has also enacted a separate law that contains generally similar, although not identical, self-referral restrictions that apply to referrals of workers' compensation patients (the Workers' Compensation Referral Law).

This chapter describes the requirements of PORA and the Workers' Compensation Referral Law (collectively, the California Referral Laws). It is essential for hospitals to analyze their business arrangements under both federal and state laws, as compliance with one law does not necessarily ensure compliance with other relevant laws. Hospitals are strongly encouraged to consult experienced legal counsel when contemplating proposed business transactions to be sure that all potential legal issues are identified and addressed.

B. General Rule and Definitions

The California Referral Laws prohibit referrals by physicians (and certain other health care professionals) for specified services to an entity in which the physician or immediate family has a financial interest. [Business and Professions Code Section 650.01 *et seq.*; Labor Code Section 139.3 *et seq.*]

A hospital cannot bill for services it performs for any patient as a result of a referral which is prohibited by PORA or for services it performs for workers' compensation patients as a result of a referral prohibited by the Workers' Compensation Referral Law. [Business and Professions Code Section 650.01(d); Labor Code Section 139.3(d)]. Further, although the

laws are not clear on the point, a hospital could be required to make refunds if it were to improperly bill for services where the bills were prohibited by the California Referral Laws.

Covered Health Care Professionals

The California Referral Laws use the term licensee to refer to those health care professionals subject to its self-referral prohibitions. The term **"licensee"** includes physicians and surgeons holding an M.D. or D.O. degree, psychologists, acupuncturists, optometrists, dentists, podiatrists, chiropractic practitioners, nurse practitioners and certified nurse-midwives [Business and Professions Code Section 650.01(b)(4).

Covered Services

PORA does not prohibit the referral of patients for hospital inpatient and outpatient services per se, but it does prohibit referrals of many types of services which are provided by hospitals, including the following:

1. Laboratory services
2. Diagnostic nuclear medicine
3. Radiation oncology services
4. Physical therapy
5. Physical rehabilitation
6. Psychometric testing
7. Home infusion therapy
8. Diagnostic imaging goods or services

The Workers' Compensation Referral Law includes the above services and also includes outpatient surgery.

Under the California Referral Laws the following definitions apply:

"Immediate family" includes the spouse and children of the licensee, the parents of the licensee, and the spouses of the children of the licensee.

"Financial interest" includes, but is not limited to, any type of ownership interest, debt, loan, lease, compensation, remuneration, discount, rebate, refund, dividend, distribution, subsidy, or other form of direct or indirect payment, whether in money or otherwise, between a licensee and a person or entity to whom the licensee refers a person for a good or service listed above. A financial interest also exists if there is an indirect financial relationship between a licensee and the referral recipient including, but not limited to, an arrangement whereby a licensee has an ownership interest in an entity that leases property to the referral recipient. Any financial interest transferred by a licensee to any person or entity or otherwise established in any person or entity for the purpose of avoiding the prohibition of this law shall be deemed a financial interest of the licensee. A **"direct or indirect payment"** does not include a royalty or consulting fee received by a physician who has completed a recognized residency training program in orthopedics from a manufacturer or distributor as a result of his or her research and development of medical devices and techniques for that manufacturer or distributor.

"Consulting fees" means those fees paid by the manufacturer or distributor to a physician and surgeon who has completed a recognized residency training program in orthopedics only for his or her ongoing services in making refinements to his or her medical devices or techniques marketed or distributed by the manufacturer or distributor, if the manufacturer or distributor does not own or control the facility to which the physician is referring the patient. The Workers' Compensation Referral Law does not include the above exception for consulting fees.

C. Relevant Exceptions

Like the Stark law, the California Referral Laws include a number of exceptions that permit referrals even where a financial interest is held by the referring physician or immediate family. Exceptions commonly applicable to hospital-physician arrangements are described below.

Hospital Exception

The most significant exception for hospitals applies to referrals by physicians to health facilities. The PORA states as follows:

> A licensee may refer a person to a health facility, as defined in Section 1250 of the Health and Safety Code, or to any facility owned or leased by a health facility, if the recipient of the referral does not compensate the licensee for the patient referral, and any equipment lease arrangement between the licensee and the referral recipient complies with [certain requirements set forth elsewhere in the statute] ... [Business and Professions Code Section 650.02(c)(1)]

This same exception exists for referrals of workers' compensation patients by Labor Code Section 139.31(c)(1).

Health facilities as defined in Health and Safety Code Section 1250 include general acute care hospitals, acute psychiatric hospitals, and special hospitals. Thus, referrals by physicians to these types of hospitals are exempt from the California Referral Laws, despite any financial arrangements the physician may have with the hospital. In essence, all that this exception requires is that:

1. If there are any equipment lease arrangements between the hospital and the physician, each arrangement must satisfy certain specific requirements set forth in the equipment lease exception (described below), and
2. The physician must not be compensated for his or her referrals.

Example: A hospital enters into an agreement with a physician to provide medical services to patients in its emergency room. Payments are made in accordance with a fee schedule which significantly exceeds the fair market value of the physician's services, as the physician refuses to provide coverage for less compensation. The physician has no equipment lease with the hospital. While this arrangement would not be protected by an exception under the Stark law, it is nevertheless protected by the health facilities exception under the California Referral Laws, so referrals of non-Medicare patients to the hospital by the physician are permitted under PORA. (However, payments in excess of fair market value can also create risk under federal and state anti-kickback laws; *see chapter 7*.)

The Workers' Compensation Referral Law has an additional pre-authorization provision that must be met, which states as follows:

> A physician may refer a patient to a health facility for any service classified as an emergency under subdivision (a) or (b) of Section 1317.1 of the Health and Safety Code. For nonemergency outpatient diagnostic imaging services performed with equipment which, when new, has a commercial retail price of four hundred thousand dollars ($400,000) or more, the referring physician shall obtain a service pre-authorization from the insurer.

Accordingly, where a physician refers a workers' compensation patient to a hospital for non-emergency outpatient diagnostic imaging, such as CT or MRI services, and the equipment used by the hospital to provide the service has a retail price of $400,000 or more, the physician must obtain pre-authorization from the workers' compensation insurer for the referral.

However, the requirement for pre-authorization does not apply to a patient for whom the physician or group accepts payment on a capitated basis [Labor Code Section 139.31(g)].

Lease Exceptions (Rental Equipment and Space)

An exception under each of the California Referral Laws protects leases of space or equipment if the following conditions are met:

1. The lease is written.
2. The lease has commercially reasonable terms.
3. The lease has a fixed periodic rental payment.
4. The lease has a term of one year or more.
5. The lease payments are not affected by either party's referral of any person or the volume of services provided by either party.

[Business and Professions Code Section 650.02(b)(2); Labor Code Section 139.31(b)(2)]

Thus, lease arrangements between hospitals and physicians must meet these requirements, including the requirement that there be fixed periodic rent. As was noted above, leases must meet these requirements even under the broad hospital referral exception. Unlike the Stark law, the lease exception under the California Referral Laws does not permit unit-of-service based payments, but only fixed payments.

Personal Services

The California Referral Laws also include a personal services arrangements exception which is very similar to the personal services arrangements exception under the Stark law *(see "Personal Services Arrangements," page 6.29)*. This exception protects personal services arrangements if the following conditions are met:

1. The arrangement is set out in writing and is signed by the parties;
2. The writing specifies all of the services to be provided by the physician;
3. The aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate purpose of the arrangement;

4. A person who is referred by a physician is informed in writing of the personal services arrangement that includes information on where a person may go to file a complaint against the physician;
5. The term of the agreement is for at least one year;
6. The compensation to be paid over the term of the arrangement is set in advance, does not exceed fair market value, and is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties; and
7. The services to be performed under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates any state or federal law.

[Business and Professions Code Section 650.02(b)(6); Labor Code Section 139.3(b)(4)]

Note that this exception for services agreements applies only where the physician is providing services, and not where the physician is purchasing services. However, there is generally little need to rely on this exception for hospital-physician arrangements since service arrangements can be protected under the less restrictive hospital referral exception discussed above.

Managed Care Patients

Similar to the Stark law, the California Referral Laws exclude from their prohibitions those services provided to an enrollee of a licensed health care service plan pursuant to the Knox-Keene Health Care Services Plan Act [Business and Professions Code Section 650.02(i); Labor Code Section 139.31(h)]. This exception represents the recognition that providers have no incentive to over-utilize services for patients where providers are compensated on a capitated basis or other prepaid, fixed payment basis rather than on a fee-for-service basis.

Hospice Medical Director

PORA contains a special exception to permit compensation to hospice medical directors. Specifically, PORA states that a financial interest does not include the receipt of remuneration by a medical director of a hospice for specified services if the following conditions are met:

1. The agreement is set out in writing, and specifies all services to be provided by the medical director;
2. The term of the arrangement is for at least one year; and
3. The compensation to be paid over the term of the arrangement is set in advance, does not exceed fair market value, and is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

However, there is no comparable exception under the Workers' Compensation Referral Law.

Physician Recruitment

The California Referral Laws do not contain any express exception for physician recruitment. However, the health facilities exception discussed under "Hospital Exception," page , should apply to protect recruitment payments. Although not technically included within the California Referral Laws, hospital districts are required to make a finding that any prospective

recruitment will be in the best interests of the public health of the communities served by the district prior to entering into physician recruitment agreements [Health and Safety Code Section 32121.3].

D. Patient Disclosure Requirement

The California Referral Laws require a physician who refers a patient to an entity in which the physician has a financial interest to disclose the financial interest to the patient in writing at the time of the referral. If the referral is between physicians who contract with a medical foundation under Section 1206(l) of the California Business and Professions Code, or between members of the same medical practice, and the services referred are rendered on the same physical premises, or under the same medical practice name, this disclosure requirement may be met by posting a conspicuous disclosure statement at the registration area. [Business and Professions Code Section 654.2]

A separate California law prohibits physicians or any other licensed healthcare professionals from charging or billing a patient on behalf of, or from referring a patient to, an organization in which the licensee, or the licensee's immediate family, has a significant beneficial interest, unless the licensee first discloses in writing to the patient that there is such an interest and advises the patient that the patient may choose any organization to obtain the services ordered by the licensee [Business & Professions Code Section 654.2]. This requirement can be met by posting a conspicuous sign in an area likely to be seen by all patients, or by providing the patient with a written disclosure statement. For purposes of this statute, a **"significant beneficial interest"** means any financial interest that is equal to or greater than the lesser of five percent of the whole or five thousand dollars. **"Immediate family"** includes spouses, children, parents of the licensee and spouse, and spouses of children.

E. Sanctions

Violations of the California Referral Laws are misdemeanors. They are subject to civil penalties of up to $5,000 for each offense. In addition, either the submission of claims to third party payers for services furnished in violation of the California Referral Laws, or entering into an arrangement or scheme, such as a cross-referral arrangement, that the physician or other licensee knows or should know has a principal purpose of ensuring referrals by the licensee to a particular entity that, if the licensee directly made referrals to that entity, would violate the California Referral Laws, is a public offense punishable by fines up to $15,000 for each violation.

Violations of the California Referral Laws can also lead to disciplinary action (including revocation of license) against the physician or other licensee making prohibited referrals. [Business and Professions Code Section 650.01(g); Labor Code Section 139.3(g)]

APPENDIX HC 6-A

Group Practice Definition

For purposes of the federal physician self-referral law (Stark), a group practice is a physician practice that meets the following conditions:

(a) **Single legal entity.** The group practice must consist of a single legal entity operating primarily for the purpose of being a physician group practice in any organizational form recognized by the state in which the group practice achieves its legal status, including, but not limited to, a partnership, professional corporation, limited liability company, foundation, nonprofit corporation, faculty practice plan, or similar association. The single legal entity may be organized by any party or parties, including, but not limited to, physicians, health care facilities, or other persons or entities (including, but not limited to, physicians individually incorporated as professional corporations). The single legal entity may be organized or owned (in whole or in part) by another medical practice, provided that the other medical practice is not an operating physician practice (and regardless of whether the medical practice meets the conditions for a group practice under this section). For purposes of this subpart, a single legal entity does not include informal affiliations of physicians formed substantially to share profits from referrals, or separate group practices under common ownership or control through a physician practice management company, hospital, health system, or other entity or organization. A group practice that is otherwise a single legal entity may itself own subsidiary entities. A group practice operating in more than one state will be considered to be a single legal entity notwithstanding that it is composed of multiple legal entities, provided that:

(1) The states in which the group practice is operating are contiguous (although each state need not be contiguous to every other state);

(2) The legal entities are absolutely identical as to ownership, governance, and operation; and

(3) Organization of the group practice into multiple entities is necessary to comply with jurisdictional licensing laws of the states in which the group practice operates.

(b) **Physicians.** The group practice must have at least two physicians who are members of the group (whether employees or direct or indirect owners), as defined at 42 C.F.R. Section 411.351.

(c) **Range of care.** Each physician who is a member of the group, as defined at 42 C.F.R. Section 411.351, must furnish substantially the full range of patient care services that the physician routinely furnishes, including medical care, consultation, diagnosis, and treatment, through the joint use of shared office space, facilities, equipment, and personnel.

(d) **Services furnished by group practice members.**

(1) Except as otherwise provided in paragraphs (d)(3) through (6) of this section, substantially all of the patient care services of the physicians who are members of the group (that is, at least 75 percent of the total patient care services of the group practice members) must be furnished through the group and billed under a billing number assigned to the group, and the amounts received must be treated as receipts of the group. Patient care services must be measured by one of the following:

(i) The total time each member spends on patient care services documented by any reasonable means (including, but not limited to, time cards, appointment schedules, or personal diaries). (For example, if a physician practices 40 hours a week and spends 30

hours a week on patient care services for a group practice, the physician has spent 75 percent of his or her time providing patient care services for the group.)

(ii) Any alternative measure that is reasonable, fixed in advance of the performance of the services being measured, uniformly applied over time, verifiable, and documented.

(2) The data used to calculate compliance with this "substantially all" test and related supportive documentation must be made available to the Secretary upon request.

(3) The "substantially all" test set forth in paragraph (d)(1) of this section does not apply to any group practice that is located solely in a HPSA, as defined at 42 C.F.R. Section 411.351.

(4) For a group practice located outside of a HPSA (as defined at 42 C.F.R. Section 411.351), any time spent by a group practice member providing services in a HPSA should not be used to calculate whether the group practice has met the "substantially all" test, regardless of whether the member's time in the HPSA is spent in a group practice, clinic, or office setting.

(5) During the start-up period (not to exceed 12 months) that begins on the date of the initial formation of a new group practice, a group practice must make a reasonable, good faith effort to ensure that the group practice complies with the "substantially all" test requirement set forth in paragraph (d)(1) of this section as soon as practicable, but no later than 12 months from the date of the initial formation of the group practice. This paragraph (d)(5) does not apply when an existing group practice admits a new member or reorganizes.

(6) (i) If the addition to an existing group practice of a new member who would be considered to have relocated his or her medical practice under 42 C.F.R. Section 411.357(e)(2) would result in the existing group practice not meeting the "substantially all" test set forth in paragraph (d)(1) of this section, the group practice will have 12 months following the addition of the new member to come back into full compliance, provided that:

(A) For the 12-month period the group practice is fully compliant with the "substantially all" test if the new member is not counted as a member of the group for purposes of 42 C.F.R. Section 411.352 (this law); and

(B) The new member's employment with, or ownership interest in, the group practice is documented in writing no later than the beginning of his or her new employment, ownership, or investment.

(ii) This paragraph (d)(6) does not apply when an existing group practice reorganizes or admits a new member who is not relocating his or her medical practice.

(e) **Distribution of expenses and income.** The overhead expenses of, and income from, the practice must be distributed according to methods that are determined before the receipt of payment for the services giving rise to the overhead expense or producing the income. Nothing in this section prevents a group practice from adjusting its compensation methodology prospectively, subject to the restrictions on the distribution of revenue from DHS under paragraph (i) of this section.

(f) **Unified business.**

(1) The group practice must be a unified business having at least the following features:

(i) Centralized decision making by a body representative of the group practice that

maintains effective control over the group's assets and liabilities (including, but not limited to, budgets, compensation, and salaries); and

(ii) Consolidated billing, accounting, and financial reporting.

(2) Location and specialty-based compensation practices are permitted with respect to revenues derived from services that are not DHS and may be permitted with respect to revenues derived from DHS under paragraph (i) of this section.

(g) **Volume or value of referrals.** No physician who is a member of the group practice directly or indirectly receives compensation based on the volume or value of his or her referrals, except as provided in paragraph (i) of this section.

(h) **Physician-patient encounters.** Members of the group must personally conduct no less than 75 percent of the physician-patient encounters of the group practice.

(i) **Special rules for profit shares and productivity bonuses.**

(1) Overall profits.

(i) Notwithstanding paragraph () of this section, a physician in the group may be paid a share of overall profits that is not directly related to the volume or value of the physician's referrals.

(ii) "Overall profits: means the profits derived from all the designated health services of any component of the group that consists of at least five physicians, which may include all physicians in the group. If there are fewer than five physicians in the group, "overall profits" means the profits derived from all the designated health services of the group.

(iii) Overall profits must be divided in a reasonable and verifiable manner. The share of overall profits will be deemed not to relate directly to the volume or value of referrals if one of the following conditions is met:

(A) Overall profits are divided per capita (for example, per member of the group or per physician in the group).

(B) Overall profits are distributed based on the distribution of the group's revenues attributed to services that are not designated health services and would not be considered designated health services if they were payable by Medicare.

(C) Revenues derived from designated health services constitute less than 5 percent of the group's total revenues, and the portion of those revenues distributed to each physician in the group constitutes 5 percent or less of his or her total compensation from the group.

(2) Productivity bonuses.

(i) Notwithstanding paragraph (g) of this section, a physician in the group may be paid a productivity bonus based on services that he or she has personally performed, or services "incident to" such personally performed services. that is not directly related to the volume or value of the physician's referrals (except that the bonus may directly relate to the volume or value of the physician's referrals if the referrals are for services "incident to" the physician's personally performed services).

(ii) A productivity bonus must be calculated in a reasonable and verifiable manner. A productivity bonus will be deemed not to relate directly to the volume or value of referrals if one of the following conditions is met:

(A) The productivity bonus is based on the physician's total patient encounters or relative value units (RVUs) personally performed by the physician.

(B) The services on which the productivity bonus is based are not designated health services and would not be considered designated health services if they were payable by Medicare.

(C) Revenues derived from designated health services constitute less than 5 percent of the group's total revenues, and the portion of those revenues to each physician in the group constitutes 5 percent or less of his or her total compensation from the group.

(3) **Value-based enterprise participation.** Notwithstanding paragraph (g) of this section, profits from designated health services that are directly attributable to a physician's participation in a value-based enterprise, as defined at 42 C.F.R. Section 411.351, may be distributed to the participating physician.

(4) **Supporting documentation.** Supporting documentation verifying the method used to calculate the profit share or productivity bonus under paragraphs (i)(1), (2), and (3) of this section, and the resulting amount of compensation, must be made available to the Secretary upon request.

[42 C.F.R. Section 411.352]

In an answer to a frequently asked question on its website, CMS has clarified that:

> A **"physician practice"** is a medical practice comprised of two or more physicians organized to provide patient care services (regardless of its legal form or ownership). For example, a "physician practice" may be a group of physicians that practice together but do not meet all of the requirements of Section 411.352 for "group practices" for purposes of satisfying the requirements of the physician services and in-office ancillary services exceptions. We note that the provision of patient care services by employed or contracted physicians does not automatically cause an entity to become or be considered a "physician practice" (and, thus, a "physician organization"). For example, a hospital, which, in general terms, is an institution that provides medical, surgical, or psychiatric care and treatment for the sick or the injured, is not considered a "physician practice" or "physician organization" even though it employs or contracts with two or more physicians to provide patient care services to its inpatients and outpatients.

7 Federal and State Anti-Kickback Laws

I. Introduction 7.1

II. The Federal Anti-Kickback Statute 7.3

A. General Rule 7.3

B. Definition of "Federal Health Care Program" 7.3

C. Types of Remuneration Prohibited 7.4

D. Definition of "Induce"; "Knowing and Willful" Standard 7.4

E. Statutory Exceptions 7.5

III. The Federal Anti-Kickback Safe Harbors 7.6

A. General 7.6

B. Arrangements That Implicate More Than One Safe Harbor 7.7

IV. The Safe Harbors 7.8

A. Investment Interests 7.8

Large Publicly Traded Entities 7.8

Small Business Entities 7.8

Special Fraud Alert 7.9

B. Space Rental 7.10

Lease Term 7.11

Special Fraud Alert 7.12

C. Equipment Rental 7.12

D. Personal Services and Management Contracts 7.13

Contract Term 7.15

Fraud Alerts 7.16

E. Sale of Practice 7.17

F. Referral Services 7.18

Documentation 7.19

G. Warranties 7.19

H. Discounts 7.21

Buyer Requirements 7.21

Seller Requirements 7.22

Offeror Requirements 7.23

Definitions 7.23

I. Employees 7.24

J. Group Purchasing Arrangements 7.25

K. Waiver of Beneficiary Copayment, Coinsurance and Deductible Amounts 7.26

Hospital Standards 7.26

Federally Qualified Health Center (FQHC) Standards 7.26

L. Increased Coverage, Reduced Cost-Sharing or Reduced Premiums Offered by Health Plans 7.29

M. Price Reductions Offered to Health Plans 7.29

Risk-Based Plan with Government Contract 7.30

Cost-Based Plan with Government Contract 7.30

Non-Risk-Based Private Plan 7.30

Risk-Based Private Plan 7.31

Definitions 7.32

N. Practitioner Recruitment 7.32

O. Obstetrical Malpractice Insurance Subsidies 7.34

P. Investments in Group Practices 7.35

Q. Cooperative Hospital Service Organizations 7.36

R. Ambulatory Surgical Center Investment 7.36

Hospital/Physician ASCs 7.37

Surgeon-Owned ASCs 7.38

Single-Specialty ASCs 7.38

Multi-Specialty ASCs 7.39

S. Referral Arrangement for Specialty Services 7.40

T. Price Reductions Offered to Eligible Managed Care Organizations 7.41

U. Price Reductions Offered by Contractors With Substantial Financial Risk to Managed Care Organizations 7.41

V. Ambulance Replenishing 7.42

General Replenishing 7.43

Fair Market Value Replenishing 7.44

Government-Mandated Replenishing 7.44

Definitions 7.44

W. Donations to Federally Qualified Health Centers 7.45

X. Electronic Prescribing Items and Services 7.46

Selection of Recipients 7.48

Y. Electronic Health Records Items and Services 7.48

Definitions 7.50

Z. Federally-Qualified Health Centers and Medicare Advantage Organizations 7.51

AA. Drug Discounts Under the Medicare Coverage Gap Discount Program 7.52

AB. Local Transportation 7.52

Definitions 7.53

AC. Point-of-Sale Reductions in Price for Prescription Pharmaceutical Products 7.53
Definition 7.54
AD. Pharmacy Benefit Manager Service Fees 7.54
AE. Care Coordination Arrangements to Improve Quality, Health Outcomes, and Efficiency 7.55
Definitions 7.57
AF. Value-Based Arrangements With Substantial Downside Financial Risk 7.59
Definitions 7.60
AG. Value-Based Arrangements with Full Financial Risk 7.61
Definitions 7.62
AH. Arrangements for Patient Engagement and Support to Improve Quality Health Outcomes, and Efficiency 7.62
Definitions 7.64
AI. CMS-Sponsored Model Arrangements and CMS-Sponsored Model Patient Incentives 7.64
Definitions 7.65
AJ. Cybersecurity Technology and Related Services 7.66
Definitions 7.67
AK. ACO Beneficiary Incentive Program 7.67

V. HHS Waivers of the AKS 7.67
A. AKS Waivers for Accountable Care Organizations 7.69
B. AKS Waiver for Joint Replacement Model 7.70

VI. Federal Enforcement and Penalties 7.71
A. Criminal Penalties 7.71
B. Civil Penalties 7.71

VII. Relationship to False Claims Act 7.72

VIII. Relationship to Physician Self-Referral (Stark) Laws 7.72

IX. Consequences for Tax-Exempt Status 7.73

X. Steps to Take Upon Discovering a Possible Anti-Kickback Violation 7.73

XI. Advisory Opinions, Fraud Alerts and Other Resources 7.73

XII. Remuneration to Beneficiaries 7.74

XIII. Federal Eliminating Kickbacks in Recovery Act of 2018 (EKRA) 7.76

XIV. California Anti-Kickback Laws 7.76
A. General Rule 7.76
B. Exceptions 7.77
Payments for Services 7.77
Ownership Interest/Investments 7.78
Hardware, Software and Information Technology 7.78
Payments for Advertising; Internet-Based Service Providers..... 7.79
C. Relationship to Federal Anti-Kickback Statute and Safe Harbors 7.79
D. Penalties 7.80
E. Other Applicable State Laws 7.80

FORMS & APPENDICES

HC 7-A Sample Disclosure Regarding Ambulance Replenishing

7 Federal and State Anti-Kickback Laws

I. INTRODUCTION

The federal anti-kickback law was enacted in 1972 to protect patients and federally-funded health care programs from fraud and abuse by ending "the corrupting influence of money on health care decisions,"[1] according to the Office of Inspector General (OIG). The OIG states that kickbacks can distort medical decision making, cause overutilization, increase costs, and result in unfair competition by freezing out competitors who are unwilling to pay kickbacks. Kickbacks can also adversely affect the quality of patient care by incentivizing physicians to order services or supplies based on profit rather than the patient's best medical interests.

In brief, the anti-kickback law makes it illegal to receive or pay anything of value to induce the referral of federally-funded health care program business, including Medicare, Medicaid, and other programs. The Bipartisan Budget Act of 2018 (Budget Act), enacted on Feb. 9, 2018, significantly increased criminal and civil penalties that can be imposed for violating the anti-kickback statute and other laws related to federal health care programs. The criminal fine for violating the anti-kickback statute quadrupled from $25,000 to $100,000, and the maximum imprisonment for a felony conviction doubled to 10 years. A violator is potentially subject to both fines and imprisonment [42 U.S.C. Section 1320a-7b(b)]. In addition to criminal fines, the Budget Act increased potential civil monetary penalties to $100,000 per violation, plus up to three times the amount of the remuneration (regardless of whether a portion of the remuneration was for a lawful purpose) [42 U.S.C. Section 1320a-7a(a)(7)]. Violators of the federal anti-kickback law also may be excluded from participation in the Medicare and Medicaid programs, as well as other federal health care programs.

The federal anti-kickback law is very broad. Accordingly, some seemingly innocuous, or even beneficial, business or payment arrangements may be prohibited under a strict interpretation of the law. Responding to concerns from health care providers, in 1987 Congress authorized the federal Department of Health and Human Services (DHHS) to promulgate regulations establishing "safe harbors" for specified business or payment practices that, while potentially prohibited by a strict reading of the law, will not be subject to civil or criminal sanctions. There are currently 36 safe harbors (two of which do not take effect until Jan. 1, 2023).

California also has adopted anti-kickback laws. Similar to the federal law, California's anti-kickback laws prohibit the giving or receipt of money or other consideration of any kind in exchange for the referral of patients, clients or customers. However, the California laws apply with regard to any patient, not just patients covered by government health care programs. Violations of the state law are punishable by imprisonment, fines or both. Criminal convictions under state law also may result in exclusion from participation in Medicare and Medicaid.

1 OIG Fact Sheet: Federal Anti-Kickback Law and Regulatory Safe Harbors, Nov. 18, 1999.

This chapter provides a general discussion of complex anti-kickback laws. It describes the elements of the federal and state laws, relevant safe harbors, how the laws are enforced, and potential consequences for violations. Compliance officers and others are strongly encouraged to contact an experienced health care lawyer if they believe they have a possible anti-kickback issue.

On Dec. 2, 2020, the OIG published a final rule that created significant new anti-kickback safe harbors for a number of arrangements, including "value-based" arrangements, and eased the burden of compliance with existing safe harbors (referred to in this chapter as the "2020 Final Rule"). These new regulations were the result of an Aug. 27, 2018, Request for Information (RFI) seeking public comment on how to address regulatory provisions that may act as "barriers to coordinated care or value-based care" and recognizing that the "broad reach" of the federal anti-kickback law (also known as the anti-kickback statute or AKS) and the beneficiary inducement civil monetary penalties were potential impediments to arrangements that advance coordinated care. The 2020 Final Rule was published in the Federal Register at 85 Fed. Reg. 77684 (Dec. 2, 2020). With the exception of certain pharmacy related amendments in the 2020 Final Rule, it became effective Jan. 19, 2021 and is reflected in this chapter.[2]

Separately, and more specific to the COVID-19 pandemic, on April 3, 2020, the OIG issued a Policy Statement to notify providers that the OIG would not impose administrative sanctions for conduct that is protected under certain blanket waivers to the Stark law that CMS issued on March 30, 2020, in response to the COVID-19 pandemic.[3] The broad waivers to the Stark law were issued by CMS pursuant to its authority under Section 1135 of the Social Security Act. The waivers apply for "COVID-19 purposes," and are available to providers who furnish items and services in good faith but are unable to comply with one or more specified Stark law requirements as a result of consequences of the pandemic. Of note, the waivers apply only to some requirements — compliance with the non-waived requirements is still required. Also, these waivers are available only from March 1, 2020, through the end of the emergency declaration, which, as of the date of this publication, is still in effect. Before relying on these waivers, providers should confirm that the emergency declaration and related blanket waivers remain in effect, and review these blanket waivers carefully before relying on them to ensure the proposed arrangement meets the requirements.

---

2 The 2020 Final Rule final regulations concerning the pharmacy industry were challenged in federal court in January 2021 (*Pharm. Care Mgmt. Ass'n v. U.S. Dep't of Health and Human Serv. et al.*, 2021 WL 624229 (D.D.C. Jan. 30, 2021)). As a result, the effective date of the following provisions of the 2020 Final Rule have been extended to Jan. 1, 2023: (1) amendments to 42 C.F.R Section 1001.952(h)(5) to remove safe harbor protection for reductions in price for prescription pharmaceutical products provided to plan sponsors under Part D; (2) new safe harbor at 42 C.F.R. Section 1001.952(cc) for certain point-of-sale reductions in price offered by manufacturers on prescription pharmaceutical products that are payable under Medicare Part D or by Medicaid managed care organizations that meet certain criteria; (3) new safe harbor at 42 C.F.R.Section 1001.952(dd) for fixed fees that manufacturers pay to pharmacy benefit managers (PBMs) for services rendered to the manufacturers that meet specified criteria; and (4) new paragraphs (h)(6) through (9) to 42 C.F.R. Section 1001.952, defining certain terms. Those provisions are now scheduled to take effect on Jan. 1, 2023.

3 https://oig.hhs.gov/coronavirus/OIG-Policy-Statement-4.3.20.pdf.

II. THE FEDERAL ANTI-KICKBACK STATUTE

A. General Rule

The federal anti-kickback law provides civil and criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit or receive remuneration in order to induce business reimbursed under a federally-funded health care program. The prohibited conduct includes not only remuneration intended to induce referrals of patients, but remuneration intended to induce the purchasing, leasing, ordering, or arranging for any good, facility, service, or item paid for by a federally-funded health care program.

Specifically, the anti-kickback statute states, in pertinent part:

> (b) Illegal remunerations
>
> (1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind -
>
> (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $100,000 or imprisoned for not more than ten years, or both.
>
> (2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person -
>
> (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $100,000 or imprisoned for not more than ten years, or both.
>
> [42 U.S.C. Section 1320a-7b(b), as updated by the Bipartisan Budget Act of 2018, 115 P.L. 123]

B. Definition of "Federal Health Care Program"

The term **"federal health care program"** includes any plan or program that provides health benefits (whether directly, through insurance, or otherwise) which is funded directly, in whole or in part, by the U.S. government, other than the health insurance program provided to federal employees. This definition includes programs such as Medicare, managed Medicare, TRICARE, Veterans Administration, Indian Health Services, health services for Peace Corps volunteers, Railroad Retirement Benefits, Black Lung Program and services to federal prisoners. [42 U.S.C. Section 1320a-7b(f)]

The term "federal health care program" also includes state health care programs that are at least partially funded by the U.S. government, such as Medicaid (Medi-Cal in California), managed Medicaid (Med-Cal), Maternal and Child Health Services block grant program,

block grants to states for social services and State Children's Health Insurance Program (SCHIP) [42 U.S.C. Section 1320a-7b(f), 1320a-7(h)].

The term "federally-funded health care programs" is used throughout this chapter to refer to all of these programs.

C. Types of Remuneration Prohibited

The anti-kickback statute prohibits "remuneration" in exchange for, or to induce, referrals. Although the word **"remuneration"** is not defined in the AKS or its implementing regulations, the OIG has stated that it means "anything of value in any form" [56 Fed. Reg. 35952, 35958 (July 29, 1991)]. Thus, remuneration can take forms other than cash, such as gifts, meals, trips, entertainment, rebates, discounts, consultant fees, grants, debt write-offs, reduced space or equipment rent, excessive payments for items or services, supplies, equipment, subsidized continuing education, subsidized parking (where others are charged) and long-term credit arrangements.

D. Definition of "Induce"; "Knowing and Willful" Standard

Section 1320a-7b(b)(2) prohibits remuneration intended "to induce" referrals. The word **"induce"** is not defined in the AKS or its implementing regulations. The OIG has stated that the meaning of the term is found in the ordinary dictionary definition, "to lead or move by influence or persuasion" (American Heritage Dictionary) [56 Fed. Reg. 35952, 35958 (July 29, 1991)].

Courts around the country have interpreted the anti-kickback statute very broadly, and have held that the statute may be violated if merely one purpose of a payment arrangement is to induce referrals. Under this standard, it is irrelevant that there are other legitimate reasons for the remuneration. If one purpose is to induce referrals, then the AKS is violated. Even a payment at fair market value could violate the anti-kickback statute if the payment is intended, at least in part, to induce referrals. [*United States v. Greber*, 760 F.2d 68 (3rd Cir. 1985), cert. den. 474 U.S. 988 (1985); *United States v. Kats*, 871 F.2d 105 (9th Cir. 1989); *United States v. McClatchey*, 217 F.3d 823 (10th Cir. 2000), cert. den. 531 U.S. 1015 (2000)]

However, in *Hanlester Network v. Shalala*, 51 F.3d 1390 (9th Cir. 1995), the United States Court of Appeals for the Ninth Circuit, which includes California, indicated that the offering of the possibility of profit for referrals does not in itself result in an illegal inducement. *Hanlester* involved three clinical laboratories operated by physician-owned limited partnerships. In considering whether profit distributions received by the physician owners constituted kickbacks, the court analyzed the question of when offers of investment opportunities violate the anti-kickback statute. The court made it clear that not all financial influences rise to the level of prohibited "inducement." The *Hanlester* court stated that "mere encouragement would not violate the statute," and interpreted the term "to induce" to require "an intent to exercise influence over the reason or judgment of another in an effort to cause the referral of program-related business." Where profit is distributed based on investors' ownership share, the fact that a high number of referrals results in potential higher return on investment is not enough to prove a violation of the AKS. To result in illegal inducement, the Ninth Circuit concluded that there would have to be a closer relationship between remuneration and referrals than a return on investment that can be affected by referrals.

Importantly, the *Hanlester* court also stated that for conduct to be considered "knowing and willful" for purposes of the anti-kickback statute, the parties must know that the conduct is

prohibited by the anti-kickback statute and proceed with the conduct with a specific intent to disobey the law. This is a very high standard for the government to meet.

However, the Patient Protection and Affordable Care Act (ACA) of 2010 addressed the "knowing and willful" standard as established in *Hanlester*. The anti-kickback statute was amended to specifically provide that a person need not have either actual knowledge of the statute, or specific intent to violate the statute, in order to violate it [42 U.S.C. Section 1320a-7b(h)]. Nevertheless, despite this change, other case law appears to indicate that in order to violate the anti-kickback statute a person must still believe his or her conduct violates the law, although not specifically the anti-kickback statute.

The United States Supreme Court has not addressed the different interpretations among the circuits. As a result of *Hanlester*, providers in the Ninth Circuit, including California, can enter into various joint ventures with more certainty about what constitutes an AKS violation than providers outside the Ninth Circuit. However, providers in the Ninth Circuit must consider the possibility of a future United States Supreme Court ruling on this subject.

E. Statutory Exceptions

The anti-kickback statute now contains 11 exceptions from the statute's prohibitions [42 U.S.C. Section 1320a-7b(b)(3)]. These eleven exceptions are for:

1. Discounts obtained by a provider and properly disclosed and appropriately reflected in costs claimed or charges made to the federal health care program.
2. Compensation paid to a bona fide employee by an employer for employment in the provision of covered items or services.
3. Amounts paid to a group purchasing organization by a vendor if there is a written contract specifying the amount paid to the group purchasing organization and certain disclosure requirements are met.
4. Waivers of coinsurance by federally qualified health centers (FQHCs).
5. Remuneration paid as part of a risk-sharing arrangement that places an entity at substantial financial risk for the cost or utilization of items or services the entity provides.
6. Provision of hardware, software, or information technology and training services used to receive and transmit electronic prescription information.
7. Provision of goods, items, services, donations, loans, or a combination thereof, to FQHCs.
8. Waivers or reductions by pharmacies of any cost sharing imposed under Medicare Part D if certain conditions are met.
9. Remuneration between an FQHC and a Medicare Advantage organization.
10. Discounts on drugs furnished by a manufacturer to a beneficiary under the Medicare coverage gap discount program (established at 42 U.S.C. Section 1395w-114a) which provides premium and cost sharing subsidies for low-income persons.
11. Incentive payments to Medicare fee for service beneficiaries by an ACO under a program (an ACO Beneficiary Incentive Program) established to allow ACOs to

pay patients if they make primary-care appointments if certain requirements and conditions are met.

Each of these statutory exceptions are also now the subject of regulatory safe harbors adopted by the OIG over time. It is not completely clear how the statutory exceptions and the respective regulatory safe harbors discussed below relate to each other. The OIG has indicated that the regulatory safe harbors subsume the statutory exceptions [59 Fed. Reg. 37202, 37206 (July 21, 1994), 64 Fed. Reg. 63518, 63527-63528 (Nov. 19, 1999)]. However, it is not clear that the OIG has authority to impose requirements beyond those of a statutory exception, and the only published judicial opinion addressing the scope of a statutory exception rejects the OIG's position [*United States v. Shaw*, 106 F.Supp.2d 103 (D. Mass. 2000)].

III. THE FEDERAL ANTI-KICKBACK SAFE HARBORS

A. General

As noted above, the federal anti-kickback law is very broad. Accordingly, some relatively innocuous, or even beneficial, business arrangements may be prohibited by a strict interpretation of the law. Responding to concerns from health care providers, in 1987 Congress authorized DHHS to promulgate regulations establishing safe harbors for specified business and payment practices that will not be treated as violations of the anti-kickback statute. As noted above, there are currently 36 safe harbors (two of which do not take effect until Jan. 1, 2023), which are found at 42 C.F.R. Section 1001.952. In the 2020 Final Rule, OIG/HHS created eight new anti-kickback safe harbors, including some for certain value-based arrangements, CMS-sponsored models and other activities.

If arrangements are structured to fit within a safe harbor, there should be no risk of being prosecuted or sanctioned for violating the AKS.[4] However, failure to comply with a safe harbor does not mean that an arrangement is necessarily illegal. Instead, it means that an analysis of the arrangement under the anti-kickback statute must be undertaken to determine whether the AKS is violated. Thus, compliance with safe harbors is voluntary.

Where a safe harbor is not available, the OIG's Supplemental Compliance Program Guidance for Hospitals (available at https://oig.hhs.gov/fraud/complianceguidance.asp) states that:

> [t]he general rule of thumb is that any remuneration flowing between hospitals and physicians should be at fair market value for actual and necessary items furnished or services rendered based upon an arm's length transaction and should not take into account, directly or indirectly, the value or volume of any past or future referrals or other business generated between the parties. [70 Fed. Reg. 4858, 4866 (Jan. 31, 2005)]

More particularly, the OIG indicates that hospitals should consider (without limitation) whether:

1. The arrangement is commercially reasonable and necessary to serve a purpose other than obtaining referrals;

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4 There is some suggestion in court opinion dicta that formal compliance with a safe harbor might not be absolute protection, and that there must be no intent to induce referrals, and at least one court has held that a sham arrangement that nominally meets a safe harbor's requirements does not get safe harbor protection. See, e.g., *United States v. Goss* (96 Fed. Appx. 365) (6th Cir. 2004), *United States v. Shaw*, 106 F.Supp.2d 103 (D. Mass. 2000), and *U.S. ex rel. Westmoreland v. Amgen, Inc.* (812 F. Supp. 2d 39 (D. Ma. 2011)).

2. The compensation is at fair market value and does not vary with the volume or value of referrals, and the hospital could not obtain the items or services elsewhere at a lower price;

3. The fair market valuation methodology used can be documented as being reasonable; and

4. The physicians in the arrangement have not been selected because of their referrals.

[70 Fed. Reg. 4858, 4866-4867]

The OIG periodically solicits proposals and recommendations for developing new, and modifying existing, safe harbors. Factors that the OIG considers in evaluating proposals and recommendations include the effect on access to care, quality of care, patient freedom of choice among providers, competition among providers, costs to federally-funded health care programs, potential for overutilization of services, and the ability of providers to provide services in medically-underserved areas or to medically-underserved populations. In addition, the OIG will consider the existence of potential financial benefit to providers that may affect the decision to order a health care item or service or to make a referral to a particular provider. It is reasonable to assume that the OIG may consider these factors in evaluating arrangements in general.

B. Arrangements That Implicate More Than One Safe Harbor

The OIG has clarified how it expects health care providers to comply with the safe harbor provisions when engaging in a business arrangement that may be covered by two or more safe harbors.

The first situation arises where a payment practice serves a single purpose (e.g., compensation for personal services), but potentially fits into more than one safe harbor (e.g., the employer-employee safe harbor and the personal services and management contracts safe harbor). In this situation, if the payment practice fits into either one of the safe harbors, it is exempt from criminal prosecution and civil sanctions. In the example given, if the payment practice does not qualify as a bona fide employment relationship, it still may receive safe harbor protection under the personal services and management contract safe harbor.

The second situation arises where a payment practice serves multiple purposes (e.g., a payment to compensate another party for personal services and equipment rental). Under these circumstances, it is necessary to examine each aspect of the payment practice to determine compliance with each respective safe harbor provision. A person engaged in a multi-purpose payment practice who seeks protection will need to document separately his or her compliance with the safe harbor applicable to each purpose being served by the payment practice. Compliance with one provision (for one of the purposes of the payment practice) does not protect the entire payment practice from criminal prosecution or civil sanction, where another purpose of the payment practice is implemented in a manner that violates the anti-kickback statute.

[56 Fed. Reg. 35952 (July 29, 1991)]

IV. THE SAFE HARBORS

A. Investment Interests

For purposes of the AKS, "remuneration" does not include any payment that is a return on an investment, such as a dividend or interest income, made to an investor as long as all of the applicable standards are met [42 C.F.R. Section 1001.952(a)]. The applicable standards for different categories of investments are discussed below.

Large Publicly Traded Entities

An investment interest safe harbor protects investment interests in large public companies where such investments are available to the general public (for example, purchasing stock in Johnson & Johnson). This safe harbor protects return on investment to investors in an entity that possesses more than $50 million in undepreciated net tangible assets related to the furnishing of health care items or services if the following conditions are met:

1. If the investment interest is an equity security, the security is registered with the Securities and Exchange Commission;
2. The investment interest of an investor who is in a position to make referrals to, or generate business for, the entity is obtained on terms and at a price equally available to the public when trading on a registered securities exchange;
3. Neither the entity nor any investor markets or furnishes items or services to passive investors differently than to non-investors;
4. Neither the entity nor any investor loans funds to or guarantees a loan for an investor who is in a position to make referrals to or otherwise generate business for the entity if the loan is used to obtain the investment interest; and
5. The amount of return on investment is directly proportional to the amount of an investor's capital investment.

Small Business Entities

The investment interests safe harbor also protects physician investments in certain small business entities, including joint ventures between hospitals and physicians, if its requirements are met.

The key requirement of the safe harbor is the so-called "40-40 rule," which provides as follows:

1. No more than 40 percent of the value of each class of investment interests may be held by investors who are in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity.
2. No more than 40 percent of the entity's gross revenue may come from referrals or business otherwise generated from investors.

However, the "40-40 rule" is not applicable to investment interests in any entity located in an "underserved area." Instead, for underserved areas, there is a "50-75 rule" in which the 40% threshold in the first prong is increased to 50%, and the second prong requires that at least 75% of the dollar volume of the entity's business be derived from the service of persons who reside in an underserved area or are members of medically underserved populations.

These restrictions often pose significant problems for hospital-physician joint ventures unless a significant portion of the investment interests are held by non-physicians. Hospitals are also subject to these limitations if they either provide items or services to the joint venture or generate business in any manner for the joint venture.

In addition to the 40-40 rule (or the 50-75 rule respecting underserved areas), the safe harbor also requires that:

1. The investment interest is offered to investors who can refer to, furnish items and services to, or generate business for, the entity on the same terms as are offered to other investors, and the terms of the offer are not related to previous or expected referrals, items or services furnished, or business generated;
2. There is no requirement that an investor refer to, furnish items or services to, or generate business for the entity as a condition of investment;
3. Neither the entity nor any investor may market or furnish items or services of the entity (or those of another entity under a cross-referral scheme) to investors differently than non-investors;
4. Neither the entity nor any investor may loan funds to, or guarantee a loan for, an investor who may refer to, furnish items or services to, or generate business for, the entity, if any part of the loan is used to obtain the investment interest; and
5. Each investor's return on investment is directly proportional to the amount of the investor's capital investment.

Special Fraud Alert

In addition to the investment interests safe harbor discussed above, further guidance regarding joint ventures was provided in a Special Fraud Alert issued by the OIG in 1989 (available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html), in which the OIG described a variety of joint venture arrangements that it believes may violate the AKS.

The Special Fraud Alert identified the following "questionable features, which separately or taken together, may result in a business arrangement that violates the anti-kickback statute":

1. Investors are chosen because they are in a position to make referrals.
2. Physicians who are expected to make a large number of referrals are offered a greater investment opportunity in the joint venture than those expected to make fewer referrals.
3. Physician investors are actively encouraged to make referrals to the joint venture, or are encouraged to divest their ownership interest if they fail to sustain an "acceptable" level of referrals.
4. The joint venture tracks its sources of referrals, and distributes this information to the investors.
5. Investors are required to divest their ownership interest if they cease to practice in the service area; for example, if they move, become disabled, or retire.
6. Investment interests are non-transferable.
7. The structure of some joint ventures may be suspect. For example, one of the

parties may be an ongoing entity, already engaged in a particular line of business. That party may act as the reference laboratory or equipment supplier for the joint venture. In some of these cases, the joint venture can be best characterized as a "shell."

8. The amount of capital invested by the physician is disproportionately small and the returns on investment disproportionately large when compared with a typical investment in a new business enterprise.
9. Physician investors invest only a nominal amount, such as $500 to $1,500.
10. Physician investors are permitted to "borrow" the amount of the "investment" from the entity and pay it back through deductions from profit distributions, thus eliminating the need to contribute cash to the partnership.
11. Investors are paid extraordinary returns on the investment in comparison with the risk involved.

The concerns reflected in this Special Fraud Alert are basically threefold. First, the OIG believes profit distributions received from a joint venture may constitute kickbacks if they are excessive when compared to those realized in non-health care ventures involving similar risks. Second, regardless of profit distributions, the OIG believes that the opportunity to invest in a joint venture may constitute a kickback if it is offered on terms related to referrals or if the investment opportunity is offered on what do not appear to be arm's-length terms. Third, independent of the reasonableness of the amount invested or the rate of return projected or realized, the OIG believes that features of an investment such as those described in the Fraud Alert may suggest it is intended to improperly encourage investing physicians to refer for services offered by the joint venture.

B. Space Rental

Hospitals commonly lease space to physicians who refer Medicare or Medi-Cal patients to the hospital, and sometimes physicians lease space to hospitals or hospital-affiliated entities. Such lease arrangements could potentially implicate the AKS. The OIG has stated that "[w]hile many rental arrangements are legitimate, many situations exist where rental payments are simply a device used to mask illegal payments intended to induce referrals" [56 Fed. Reg. 35952 (July 29, 1991)]. To protect legitimate space rental arrangements, a safe harbor was created [42 C.F.R. Section 1001.952(b)]. (The terms "lease" and "rent" are used synonymously.)

For purposes of the AKS, "remuneration" does not include any payment made by a lessee to a lessor for the use of premises, as long as all of the following six standards are met:

1. The lease agreement is set out in writing and signed by the parties.
2. The lease covers all of the premises leased between the parties for the term of the lease and specifies the premises covered by the lease.
3. If the lease is intended to provide the lessee with access to the premises for periodic intervals of time, rather than on a full-time basis for the term of the lease, the lease specifies exactly the schedule of such intervals, their precise length, and the exact rent for such intervals.
4. The term of the lease is for not less than one year.

5. The aggregate rental charge is set in advance, is consistent with fair market value in arm's-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under a federally-funded health care program. **"Fair market value"** means the value of the rental property for general commercial purposes (not adjusted to reflect any additional value that either party to the lease would attribute to the property as a result of proximity to sources of referrals or business otherwise generated for which payment may be made by a federally-funded health care program).
6. The aggregate space rented does not exceed that which is reasonably necessary to accomplish the commercially reasonable business purpose of the rental.

Example: A hospital enters into a written lease with a medical group under which the group leases space in a medical office building owned by the hospital. The lease rate is a fixed monthly amount and at fair market value, and the term of the lease is two years. After six months, the rent may be increased up to 5 percent by the hospital if certain tenant improvements are completed. The lease does not meet the requirements of the safe harbor, since the aggregate rental charge, meaning the total amount the lessee will be required to pay under the lease, is not set in advance.

Lease Term

The OIG recognizes that some providers may enter into short-term leases for legitimate business reasons and not for referral opportunities. For example, an academic physician who spends one semester or school year at another medical university may need to rent office space from the medical university for less than a year.

The one-year term requirement ensures that protected leases or contracts cannot be readjusted frequently based on the number of referrals between the parties. The OIG has stated that the one-year contract requirement restricts the period within which contract terms may not be changed, and not the time within which services under a contract may be performed. So long as contract terms are not altered within a one-year period, an agreement that is performed in less than one year's time will meet the one-year requirement in the safe harbor provision. [56 Fed. Reg. 35952, 35973 (July 29, 1991); 64 Fed. Reg. 63518, 63526 (Nov. 19, 1999)]

In addition, the OIG has acknowledged the customary use of early termination clauses in contracts for tax and other legitimate business purposes. The legitimacy of an early termination clause in a lease or contract that otherwise meets the conditions of the safe harbor depends on the parties' intent. Termination "for cause" clauses drafted in compliance with Internal Revenue Service or other legal or regulatory requirements should not jeopardize safe harbor status, if the purpose of the termination clause is to comply with those requirements, and not to facilitate renegotiation of contract terms. The OIG has stated that a "for cause" termination clause that (i) specifies the conditions under which the contract may be terminated "for cause," and (ii) operates in conjunction with an absolute prohibition on any renegotiation of the lease or contract or further financial arrangements between the parties for the duration of the original one-year term, would satisfy the one-year term requirement.

If a contract is terminated in accordance with a legally enforceable termination clause, the failure to renew the contract provides evidence that the termination was effectuated for a legitimate purpose. [56 Fed. Reg. 35952, 35974 (July 29, 1991); 64 Fed. Reg. 63518, 63526 (Nov. 19, 1999)]

The OIG remains concerned, however, that "without cause" termination clauses could be used by unscrupulous parties to create sham contracts, so safe harbor protection is likely not available for an agreement that is terminated in less than a year without cause [64 Fed. Reg. 63518, 63526 (Nov. 19, 1999)].

Special Fraud Alert

In February 2000, the OIG issued a Special Fraud Alert on the rental of office space in physician offices by persons or entities to which physicians refer (available at https://oig.hhs.gov/fraud/docs/alertsandbulletins/office%20space.htm). Although this fraud alert focused more particularly on suppliers that provide services in the rented space for patients referred or sent to the supplier by the physician-landlord (e.g. mobile diagnostic equipment suppliers, outpatient rehabilitation service providers and durable medical equipment (DME) suppliers), the alert nevertheless includes helpful guidance on methods to apportion exclusive office space, interior office common space and building common space, which guidance can also be applied to hospital-owned medical office building (MOB) space leased on a part-time basis to physicians. For example, where a supplier rents an examination room for four hours one afternoon per week in a physician's office that has four examination rooms of equal size and is open eight hours a day, five days a week, the alert provides the following formula for calculating the supplier's prorated annual rent for the exclusive office space (which formula could also be used for part-time physician leases in hospital owned MOBs):

Physician Office Rent Per Day		% of Physician Office Space Rented by Supplier		% of Each Day Rented by Supplier		No. of Days Rented by Supplier Per Year		
annual rent of primary lease / no. of work days per year	x	sq. ft. exclusively occupied by supplier / total office sq. ft.	x	4 hours / 8 hours	x	52 days (i.e., 1 day per week)	=	Supplier's annual rent for exclusive space

In addition to the above allocation for *exclusive* space rent, if the supplier/tenant's patients also use the common areas (e.g. waiting rooms, restrooms), then a pro rata portion of the rent for the interior office common space should also be allocated to the supplier tenant, based on the amount of exclusive space used by the supplier to the total amount of space (other than common space) occupied by all persons using such common space. This allocation formula should also apply to part-time physician leases in hospital MOBs.

C. Equipment Rental

For purposes of the AKS, "remuneration" does not include any payment made by a lessee of equipment for the use of the equipment if the same six standards that apply to space rental, above, are met (but substituting the word "equipment" for the word "premises") [42 C.F.R. Section 1001.952(c)].

Because the safe harbor requires that the aggregate rental charge be set in advance, equipment rental arrangements between parties in a position to make and accept referrals do not receive safe harbor protection if the payments are based on utilization (a "per use," "per procedure" or "percentage of revenues" lease or contract, also sometimes known as a "wear and tear" clause). These types of arrangements also may violate the AKS statute because

the payments are directly tied to the volume of business or amount of revenue generated, providing an improper incentive to refer.

The OIG recognizes that equipment becomes less valuable the more it is used, and that its owner deserves compensation for such wear and tear. However, the OIG believes that it is a relatively easy matter to disguise a wear and tear payment as a payment for referrals. Thus, the OIG will examine the intent of the parties on a case-by-case basis if payments are based on utilization. [56 Fed. Reg. 35952, 35955 (July 29, 1991)] This does not mean, however, that percentage or per-use leases and contracts that are based on overall volume (including business from referral sources that have no financial interest in the entity to which referrals are made) always violate the statute. The OIG, as mentioned above, recognizes that legitimate considerations, such as the depreciation of equipment, could result in some part of the payment being based on a percentage or "per use" payment arrangement without these payments influencing, or being influenced by, Medicare or Medicaid referrals. However, the more the payments appear to reflect the volume of referrals from the financially-interested party, the more suspect the arrangement becomes and the more likely it will be examined carefully by the OIG. [56 Fed. Reg. 35952, 35955 (July 29, 1991)]

D. Personal Services and Management Contracts

The safe harbor for personal services and management contracts can protect arrangements where payment is being made for services rendered. The standards in this safe harbor are intended to limit the opportunity to provide financial incentives in exchange for referrals. This safe harbor does not apply to bona fide employment arrangements. [42 C.F.R. Section 1001.952(d)] *(See I. "Employees," page 7.24, for a safe harbor applicable to employment arrangements.)*

For purposes of the AKS, remuneration does not include any payment made as compensation for services as long as all of the following seven standards are met:

1. The agreement is set out in writing and signed by the parties.
2. The agreement covers all services provided for the term of the agreement and specifies the services to be provided.
3. The term of the agreement is for not less than one year.
4. The methodology for determining the compensation paid over the term of the agreement is set in advance, is consistent with fair market value in arm's-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under a federally-funded health care program.
5. The services performed under the agreement do not involve the counseling or promotion of a business arrangement or other activity that violates any state or federal law.
6. The aggregate services contracted for do not exceed those that are reasonably necessary to accomplish the commercially reasonable business purpose of the services.

When each of the above elements is present, an arrangement will not be prosecuted or sanctioned for violating the federal anti-kickback law.

In the 2020 Final Rule, the OIG significantly relaxed the requirements of the personal services and management contracts safe harbor and removed the prior requirements that:

1. Aggregate compensation be set in advance (now only the methodology for determining compensation must be set in advance); and
2. That part-time arrangements must specify the exact schedule for the services being performed.

The safe harbor is now much more closely aligned with its Stark law equivalent.

Example No. 1: A hospital enters into a full-time agreement with a physician, under which the physician will provide medical administrative services as director of the hospital's emergency room. The physician is paid a fixed amount per month, and the amount paid is consistent with fair market value. The agreement is protected by the personal services safe harbor.

Example No. 2: Same as Example No. 1, except the agreement is not on a full-time basis, but requires the physician to work 10 hours per week in the emergency room. The specific hours of work during the week are not set forth in the agreement. Prior to the implementation of the 2020 Final Rule, the safe harbor requirements would not have been met because the exact intervals of time services will be provided are not specified in the agreement, but this arrangement now meets the terms of the revised safe harbor.

In the 2020 Final Rule, the OIG expanded this safe harbor to protect certain outcomes-based payments as long as the following additional requirements are met:

1. The arrangement achieves one or more legitimate outcome measures that are selected based on clinical evidence or credible medical support, and have benchmarks used to quantify (i) improvements in (or the maintenance of improvements in) the quality of care, or (ii) a material reduction in cost to or growth of expenditures of payors (or both).
2. The agreement between the parties is set out in writing and signed by the parties in advance of, or contemporaneously with, the commencement of the terms of the outcomes-based payment arrangement. The writing must state, at a minimum, a general description of the services to be performed by the parties for the term of the agreement, the outcome measure(s) the agent must achieve to receive an outcomes-based payment, the clinical evidence or credible medical support relied upon by the parties to select the outcome measure(s), and the schedule for the parties to regularly monitor and assess the outcome measure(s).
3. The agreement neither limits any party's ability to make decisions in their patients' best interest nor induces any party to reduce or limit medically necessary items or services.

4. For each outcome measure under the agreement, the parties regularly monitor and assess the agent's performance (including the impact of the outcomes-based payment arrangement on patient quality of care) and periodically assess and revise as necessary benchmarks and remuneration under the arrangement to ensure that the remuneration is consistent with fair market value in an arm's length transaction.
5. The parties have policies and procedures to promptly address and correct identified material performance failures or material deficiencies in quality of care resulting from the outcomes-based payment arrangement.

Arrangements involving outcomes-based payments still must satisfy the other elements of the safe harbor, including that the arrangement has a term of at least one year, the methodology for determining the aggregate compensation is set in advance, and compensation is consistent with fair market value, commercially reasonable and not determined in a manner that directly takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part by a federal health care program.

It is important to note that the safe harbor does not protect outcome-based payments if the payment is:

1. Made directly or indirectly by a pharmaceutical manufacturer, distributor, or wholesaler, a pharmacy benefit manager, a laboratory company, a pharmacy that primarily compounds drugs or primarily dispenses compounded drugs, a manufacturer of a device or medical supply, a medical device distributor or wholesaler that is not otherwise a manufacturer of a device or medical supply, or an entity or individual that sells or rents DME, prosthetics, orthotics, or supplies covered by a federal health care program (other than a pharmacy or a physician, provider, or other entity that primarily furnishes services); or
2. Related solely to the achievement of internal cost savings; or
3. Based solely on patient satisfaction or patient convenience measures.

[85 Fed. Reg. 77684 (Dec. 2, 2020)]

Contract Term

As with the term of leases, the OIG recognizes that some contracts for the performance of activities or services take less than one year to fulfill. The one-year term requirement ensures that protected contracts cannot be readjusted frequently based on the number of referrals between the parties. The OIG has stated that the one-year contract requirement restricts the period within which contract terms may not be changed, and not the time within which services under a contract may be performed. So long as contract terms are not altered within a one-year period, an agreement that is performed in less than one year's time will meet the one-year requirement in the safe harbor provision. [56 Fed. Reg. 35952, 35973 (July 29, 1991); 64 Fed. Reg. 63518, 63526 (Nov. 19, 1999)]

In addition, the OIG has acknowledged the customary use of early termination clauses in contracts for tax and other legitimate business purposes. The legitimacy of an early termination clause in a contract that otherwise meets the conditions of the safe harbor depends on the parties' intent. Termination for cause clauses drafted in compliance with

Internal Revenue Service or other legal or regulatory requirements should not jeopardize safe harbor status, if the purpose of the termination clause is to comply with those requirements, and not to facilitate renegotiation of contract terms. The OIG has stated that an agreement with a for cause termination clause satisfies the one-year term requirement if it:

1. Specifies the conditions under which the contract may be terminated for cause, and
2. Operates in conjunction with an absolute prohibition on any renegotiation of the lease or contract or further financial arrangements between the parties for the duration of the original one-year term.

If a contract is terminated in accordance with a legally enforceable termination clause, the failure to renew the contract provides evidence that the termination was effectuated for a legitimate purpose. [56 Fed. Reg. 35952, 35974 (July 29, 1991); 64 Fed. Reg. 63518, 63526 (Nov. 19, 1999)]

The OIG remains concerned that without cause termination clauses could be used by unscrupulous parties to create sham contracts. This could occur, for example, where the parties enter into an agreement to pay a sum of money up front for services to be performed over a period of time. Parties could disguise payments for referrals by terminating the agreement without cause after payment, but before performance of any services. A one-year prohibition on renegotiation or further financial arrangements would be meaningless in such circumstances. [64 Fed. Reg. 63518, 63526 (Nov. 19, 1999)] Accordingly, in order to assure the protection of the safe harbor, agreements should not include without cause termination provisions.

Fraud Alerts

On June 9, 2015, the OIG issued a Fraud Alert: Physician Compensation Arrangements May Result in Significant Liability. The purpose of the Fraud Alert was to warn physicians that compensation arrangements such as medical directorships may violate the federal anti-kickback law if one purpose of the arrangement is to compensate the physician for past or future referrals. The OIG noted that a number of settlements have been reached with individual physicians due to medical directorships and other compensation arrangements that resulted in improper remuneration, because payments took into account the volume or value of referrals, payments exceeded the fair market value of services rendered, or the physician did not actually provide the services called for under the agreements.

On Nov. 16, 2020, the OIG published a Special Fraud Alert on Speaker Programs in which the OIG described the fraud and abuse risks associated with the offer, payment, solicitation, or receipt of remuneration relating to speaker programs by pharmaceutical and medical device companies. The Special Fraud Alert identified the following “suspect characteristics” involving payments to health care professionals (HCPs) which, separately or taken together, may result in a business arrangement that violates the anti-kickback statute:

1. The company sponsors speaker programs where little or no substantive information is actually presented;
2. Alcohol is available or a meal exceeding modest value is provided to the attendees of the program (the concern is heightened when the alcohol is free);

3. The program is held at a location that is not conducive to the exchange of educational information (e.g., restaurants or entertainment or sports venues);
4. The company sponsors a large number of programs on the same or substantially the same topic or product, especially in situations involving no recent substantive change in relevant information;
5. There has been a significant period of time with no new medical or scientific information nor a new FDA-approved or cleared indication for the product;
6. HCPs attend programs on the same or substantially the same topics more than once (as either a repeat attendee or as an attendee after being a speaker on the same or substantially the same topic);
7. Attendees include individuals who don't have a legitimate business reason to attend the program, including, for example, friends, significant others, or family members of the speaker or HCP attendee; employees or medical professionals who are members of the speaker's own medical practice; staff of facilities for which the speaker is a medical director; and other individuals with no use for the information;
8. The company's sales or marketing business units influence the selection of speakers or the company selects HCP speakers or attendees based on past or expected revenue that the speakers or attendees have or will generate by prescribing or ordering the company's product(s) (e.g., a return on investment analysis is considered in identifying participants);
9. The company pays HCP speakers more than fair market value for the speaking service or pays compensation that takes into account the volume or value of past business generated or potential future business generated by the HCPs.

E. Sale of Practice

The OIG has stated that when a hospital or other entity purchases a physician's practice and thereafter there are no referrals from that physician to the hospital or entity, the anti-kickback statute does not appear to be implicated. In ordinary circumstances, a hospital would not violate the statute if it purchases the practice of a physician who retires or leaves the community after the purchase and thus no longer makes referrals to that hospital. [56 Fed. Reg. 35952 (July 29, 1991)] Because the statute would not be violated in such cases, compliance with a safe harbor is not required.

Nevertheless, a relatively restrictive safe harbor has been adopted that applies to certain sales of physician practices when occurring as the result of retirement or some other event that removes the selling physician from the practice of medicine or from the service area in which he or she was practicing [42 C.F.R. Section 1001.952(e)].

The safe harbor provides that for purposes of the AKS, remuneration does not include any payment made to a practitioner by a hospital or other entity where the practitioner is selling his or her practice to the hospital or other entity, so long as the following four standards are met:

1. The period from the date of the first agreement pertaining to the sale to the completion date of the sale is not more than three years.
2. The practitioner who is selling his or her practice will not be in a professional position after completion of the sale to make or influence referrals to, or otherwise

generate business for, the purchasing hospital or entity for which payment may be made by a federally-funded health care program.

3. The practice being acquired must be located in a Health Professional Shortage Area (HPSA) for the practitioner's specialty area.

4. Commencing at the time of the first agreement pertaining to the sale, the purchasing hospital or entity must diligently, and in good faith, engage in commercially reasonable recruitment activities that:

    a. May reasonably be expected to result in the recruitment of a new practitioner to take over the acquired practice within a one-year period; and

    b. Will satisfy the conditions of the practitioner recruitment safe harbor *(see N. "Practitioner Recruitment," page 7.32)*.

The safe harbor is of limited practical value because of the requirement that the purchased practice be located in a HPSA. Further, the safe harbor does not protect practice acquisitions where the selling physician continues to practice and is a member of the hospital's staff after the sale. In addition, the safe harbor appears to protect only the purchase of the practice of an individual practitioner, and not the practice of a medical group.

F. Referral Services

Hospitals, professional societies and consumer-oriented groups often operate a referral service and charge a fee to participants to recoup the cost of operating the service. Because such a fee could be construed as a payment in order to obtain referrals in violation of the AKS, a safe harbor has been established to protect this type of practice [42 C.F.R. Section 1001.952(f)]. To safeguard against abuse, the provision is available only when several standards are met.

Hospitals may operate a free referral service for members of their medical staff (i.e., the physicians pay no fees to participate in the service), which arguably would not implicate the anti-kickback statute. However, this practice raises a technical legal question as to whether a physician's payment of medical staff dues, or provision of services to the hospital by sitting on hospital committees, could be construed as a fee for participating in the referral service. It is advisable that hospitals operating referral services comply with the referral service safe harbor, if possible, even if no fee is charged to physicians to participate.

For purposes of the AKS, remuneration does not include any payment or exchange of anything of value between an individual or entity (participant) and another entity serving as a referral service, as long as all of the following four standards are met:

1. The referral service does not exclude any participant who meets the qualifications for participation.

2. Any payment the participant makes to the referral services is assessed equally against, and collected equally from, all participants, and is based only on the cost of operating the referral services, and not on the volume or value of any referrals to, or business otherwise generated by, either party for the other party.

3. The referral service imposes no requirements on the manner in which the participant provides services to a referred person, except that the referral service may require that the participant charge the person referred at the same rate it charges others

not referred by the referral service, or that the services be furnished free or at reduced rates.

4. The referral service makes and documents the following five specified disclosures to each person seeking a referral:
    a. How the participants are selected,
    b. Whether the participant has paid a fee to the referral service,
    c. How a particular participant from the group is selected,
    d. The nature of the relationship between the referral service and the group of participants, and
    e. The nature of any restrictions that would exclude a participant in the future.

It is permissible under the safe harbor for a hospital to require medical staff membership as one of the qualifications for participants. Note that the required disclosures do not only require disclosure regarding fees if participants pay a fee; disclosure is also required if no fee is paid.

A participant is typically selected for a particular patient based on medical specialty, whether the participant accepts the patient's insurance, office location relative to the patient's home, fluency in a particular foreign language, etc. If several participants meet the patient's needs and selection is then based on a rotation basis, this factor must also be disclosed to the patient. Often the disclosure regarding the nature of the relationship between the referral service and the participants will be medical staff membership. Examples of restrictions that might exclude a participant from participation are a judgment or an allegation of malpractice or refusal to treat a certain level of uncompensated care cases.

Documentation

The referral service must maintain a written record certifying that the required disclosures were made to each person seeking a referral. The documentation must be signed by either the person making the disclosure on behalf of the referral service, or by the patient seeking the referral. Given that many referral services operate by telephone, it is likely that the person making the disclosure will be in the best position to sign the required documentation. It is important to note that the disclosure requirement will not be met if the referral service merely maintains a blank copy of the disclosure form or policies and procedures regarding instructions to staff on how to make the disclosure. [56 Fed. Reg. 35952, 35976 (July 29, 1991)]

G. Warranties

The OIG has determined that it is in the public interest to have companies offer warranties as an inducement to purchase a product. Thus, a safe harbor was established stating that, for purposes of the AKS, "remuneration" does not include any payment or exchange of anything of value under a warranty provided by a manufacturer or supplier of one or more items and services to the buyer (such as a health care provider or beneficiary) of the items and services, as long as the buyer and the manufacturer or supplier comply with the standards listed below. [42 C.F.R. Section 1001.952(g)]

The buyer must comply with both of the following standards:

1. The buyer (unless the buyer is a federal health care program beneficiary) must fully and accurately report any price reduction of the item or service (including a free item or service), which was obtained as part of the warranty, in the applicable cost reporting mechanism or claim for payment filed with DHHS or a state agency.
2. The buyer must provide, upon request by the Secretary of DHHS or a state agency, information provided by the manufacturer or supplier as specified below.

The manufacturer or supplier must comply with all of the following requirements:

1. Either of the following two standards:
    a. The manufacturer or supplier must fully and accurately report the price reduction of the item or service (including a free item or service), which was obtained as part of the warranty, on the invoice or statement submitted to the buyer, and inform the buyer of its obligations listed above; or
    b. Where the amount of the price reduction is not known at the time of sale, the manufacturer or supplier must fully and accurately report the existence of a warranty on the invoice or statement, inform the buyer of its obligations listed above, and, when the price reduction becomes known, provide the buyer with documentation of the calculation of the price reduction resulting from the warranty.
2. The manufacturer or supplier must not pay any remuneration to any individual (other than a beneficiary) or entity for any medical, surgical, or hospital expense incurred by a beneficiary other than for the cost of the items and services subject to the warranty.
3. If a manufacturer or supplier offers a warranty for more than one item or one or more items and related services, the federally reimbursable items and services subject to the warranty must be reimbursed by the same federal health care program and in the same federal health care program payment.
4. The manufacturer or supplier must not condition a warranty on a buyer's exclusive use of, or a minimum purchase of, any of the manufacturer's or supplier's items or services.

For purposes of this safe harbor, **"warranty"** means either:

1. Any written affirmation of fact or written promise made in connection with the sale of an item or bundle of items, or services in combination with one or more related items, by a manufacturer or supplier to a buyer, which affirmation of fact or written promise relates to the nature of the quality of workmanship and affirms or promises that such quality or workmanship is defect free or will meet a specified level of performance over a specified period of time;
2. Any undertaking in writing in connection with the sale by a manufacturer or supplier of an item or bundle of items, or services in combination with one or more related items, to refund, repair, replace, or take other remedial action with respect to such item or bundle of items in the event that such item or bundle of items, or services in combination with one or more related items, fails to meet the specifications set forth in the undertaking which written affirmation, promise, or undertaking becomes

part of the basis of the bargain between a seller and a buyer for purposes other than resale of such item or bundle of items; or

3. A manufacturer's or supplier's agreement to replace another manufacturer's or supplier's defective item or bundle of items, on terms equal to the agreement that it replaces.

H. Discounts

For purposes of the AKS, remuneration does not include a discount on an item or service for which payment may be made in whole or in part under Medicare, Medicaid, or any other federally-funded health care program for a buyer as long as the buyer, seller and offeror (who is not a seller) comply with the applicable standards set forth below [42 C.F.R. Section 1001.952(h)].

An **"offeror"** may be any individual or entity that provides a discount on an item or service to a buyer, but that is not the seller of the item or service. For example, many pharmaceutical manufacturers sell some or all of their products through wholesalers, which, in turn, sell the products to hospitals, retail pharmacies, and others. A manufacturer may offer a discount in the form of a rebate to the ultimate purchaser that is in addition to any discount from the wholesaler to the retailer. For purposes of this safe harbor, the manufacturer would be the offeror, the wholesaler would be the seller, and the retailer would be the buyer. While typically the wholesaler would be the seller and its retail customer the buyer, if a wholesaler offers a discount to a retail purchaser that has purchased the discounted product from another party, the wholesaler could qualify as an offeror. [64 Fed. Reg. 63518, 63528 (Nov. 19, 1999)]

Buyer Requirements

If the buyer is a health maintenance organization (HMO) or competitive medical plan (CMP) acting in accordance with a risk contract under Section 1876(g) (concerning Medicare risk-sharing contractors) or 1903(m) (concerning Medicaid managed care organizations) of the Social Security Act, or under another state health care program, it need not report the discount except as otherwise may be required under the risk contract.

If the buyer is an entity that reports its costs on a cost report required by DHHS or a state health care program, which includes hospitals, it must comply with all of the following four standards:

1. The discount must be earned based on purchases of that same good or service bought within a single fiscal year of the buyer;
2. The buyer must claim the benefit of the discount in the fiscal year in which the discount is earned or the following year;
3. The buyer must fully and accurately report the discount in the applicable cost report; and
4. The buyer must provide, upon request by the Secretary of DHHS or a state agency, information provided by the seller or the offeror as specified below.

If the buyer is an individual or entity in whose name a claim or request for payment is submitted for the discounted item or service and payment may be made, in whole or in part, under Medicare, Medicaid or other federally-funded health care program (not including individuals or entities defined as buyers above), the buyer must comply with both of the following standards:

1. The discount must be made at the time of the sale of the good or service or the terms of the rebate must be fixed and disclosed in writing to the buyer at the time of the initial sale of the good or services; and
2. The buyer (if submitting the claim) must provide, upon request by the Secretary of DHHS or a state agency, information provided by the seller or the offeror as specified below.

Seller Requirements

The **"seller"** is an individual or entity that supplies an item or service for which payment may be made, in whole or in part, under Medicare, Medicaid or another federally-funded health care program to the buyer and who permits a discount to be taken off the buyer's purchase price. The seller must comply with all of the applicable standards within one of the following three categories:

1. If the buyer is an HMO or a CMP acting in accordance with a risk contract under Section 1876(g) or 1903(m) (described above), or under another state health care program, the seller need not report the discount to the buyer.
2. If the buyer is an entity that reports its costs on a cost report required by DHHS or a state agency, which includes hospitals, the seller must comply with one of the following two standards:
    a. Where a discount is required to be reported to Medicare or a state health care program by the buyer, the seller must fully and accurately report such discount on the invoice, coupon or statement submitted to the buyer; inform the buyer in a manner that is reasonably calculated to give notice to the buyer of its obligations to report such discount and to provide information upon request to the Secretary of DHHS or to a state agency; and refrain from doing anything that would impede the buyer from meeting its obligations under this safe harbor provision; or
    b. Where the value of the discount is not known at the time of sale, the seller must fully and accurately report the existence of a discount program on the invoice, coupon or statement submitted to the buyer and inform the buyer in a manner reasonably calculated to give notice to the buyer of its obligations to report such discount and to provide information upon request to the Secretary of DHHS or to a state agency. When the value of the discount becomes known, the seller must provide the buyer with documentation of the calculation of the discount identifying the specific goods or services purchases to which the discount will be applied. The seller must also refrain from doing anything that would impede the buyer from meeting its obligations under this safe harbor provision.
3. If the buyer is an individual or entity not included in the two paragraphs above, the seller must comply with either of the following two standards:
    a. Where the seller submits a claim or request for payment on behalf of the buyer and the item or service is separately claimed, the seller must provide, upon request by the Secretary of DHHS or a state agency, information provided by the offeror as specified below; or

b. Where the buyer submits a claim, the seller must fully and accurately report such discount on the invoice, coupon or statement submitted to the buyer; inform the buyer in a manner reasonably calculated to give notice to the buyer of its obligations to report such discount and to provide information upon request to the Secretary of DHHS or a state agency; and refrain from doing anything that would impede the buyer from meeting its obligations under this safe harbor provision.

Offeror Requirements

The **"offeror"** of a discount is an individual or entity that is not a seller as defined above, but promotes the purchase of an item or service by a buyer at a reduced price for which payment may be made, in whole or in part, under Medicare, Medicaid, or another federally-funded health care program. The offeror must comply with all of the applicable standards within the following three categories:

1. If the buyer is an HMO or a CMP acting in accordance with a risk contact under Section 1876(g) or 1903(m) (described above), or under another state health care program, the offeror need not report the discount to the buyer for purposes of this provision.

2. If the buyer is an entity that reports its costs on a cost report required by DHHS or a state agency, the offeror must comply with the following two standards:

   a. The offeror must inform the buyer in a manner reasonably calculated to give notice to the buyer of its obligations to report such a discount and to provide information upon request to the Secretary of DHHS or to a state agency; and

   b. The offeror of the discount must refrain from doing anything that would impede the buyer's ability to meet its obligations under this safe harbor provision.

3. If the buyer is an individual or entity in whose name a request for payment is submitted for the discounted item or service and payment may be made, in whole or in part, under Medicare, Medicaid or other federal the care programs (not including individuals or entities defined as buyers above), the offeror must comply with the following two standards:

   a. The offeror must inform the individual or entity submitting the claim or request for payment in a manner reasonably calculated to give notice to the individual or entity of its obligations to report such a discount and to provide information upon request to the Secretary of DHHS or a state agency; and

   b. The offeror of the discount must refrain from doing anything that would impede the buyer's or seller's ability to meet its obligations under this safe harbor provision.

Definitions

A **"rebate"** is any discount, the terms of which are fixed and disclosed in writing to the buyer at the time of the initial purchase to which the discount applies, but which is not given at the time of sale. Thus, the term discount includes rebates.

"Discount" means a reduction in the amount a buyer (who buys either directly or through a wholesaler or a group purchasing organization) is charged for an item or service based on an arm's-length transaction. The term discount does not include:

1. Cash payment or cash equivalents (except that rebates may be in the form of a check);
2. Supplying one good or service without charge or at a reduced charge to induce the purchase of a different good or service, unless the goods and services are reimbursed by the same federally-funded health care program using the same methodology and the reduced charge is fully disclosed to the federally-funded health care program and accurately reflected where appropriate, and as appropriate, to the reimbursement methodology;
3. A reduction in price applicable to one payer but not to Medicare, Medicaid or other federally-funded health care programs;
4. A routine reduction or waiver of any coinsurance or deductible amount owed by a program beneficiary;
5. Warranties;
6. Services provided in accordance with a personal or management services contract;
7. Other remuneration, in cash or in kind, not explicitly described in the definition of discount.
8. (Effective Jan. 1, 2023) Reductions in connection with the sale or purchase of a prescription pharmaceutical product from a manufacturer to a plan sponsor under Medicare Part D either directly to the plan sponsor under Medicare Part D, or indirectly through a pharmacy benefit manager acting under contract with a plan sponsor under Medicare Part D, unless is it as a price reduction or rebate that is required by law,

Because discounts include rebates (in addition to discounts given at the time of sale), rebates that are earned based upon reaching specified purchase levels may be protected under the discount safe harbor, as long as they are disclosed at the time of purchase and the applicable requirements discussed above are met.

However, free or discounted items given on one product or service for the purpose of inducing the purchase of another product or service that is paid by a federal health care program under a different payment methodology are not protected by the safe harbor. For example, discounts given on products or services covered under Medicare Part A to induce the purchase of products or services covered under Medicare Part B would not be protected.

I. Employees

The anti-kickback statute contains an exception for payments by employers to employees. In addition, the OIG has established a safe harbor regulation applicable to compensation to employees [42 C.F.R. Section 1001.952(i)]. The language of the exception and the regulation are virtually identical, and protect any amount paid by an employer to an employee who has a bona fide employment relationship with such employer for employment in the provision of any item or service for which payment may be made in whole or in part by a federally-funded health care program [42 U.S.C. Section 1320a-7b(b)(3)(B)].

The OIG has adopted the meaning of the term employee as defined in 26 U.S.C. Section 3121(d)(2), including the IRS's interpretation of that provision as codified in its regulations and other interpretive sources [56 Fed. Reg. 35952, 35981 (July 29, 1991)]. That code

section defines an **"employee"** to be any individual who, under the usual common law rules applicable in determining the employer-employee relationship, has the status of an employee.

The safe harbor is important in that it permits health care providers, such as hospitals, to compensate employees for marketing activities. Absent the safe harbor, payments to marketers could be prohibited by the anti-kickback statute if the marketers engage in recommending or arranging for referrals or purchases of federal health care program business. The safe harbor does not restrict the manner in which employees are paid, thus allowing commission-based payments to bona fide employees. In addition, the statutory and safe harbor exceptions to the anti-kickback statute do not require that the employee's compensation be at fair market value.

However, recent court decisions have held that the employment exception may not protect compensation to marketing employees where the employee is not engaged in supervised marketing and promotional activities on behalf of the employer, but instead has control over the referral of patients to the employer and is being compensated for making or arranging for those referrals [*U.S. v. Sunny Robinson*, No. 11-20645 (5th Cir. 2013) (unpublished); *U.S. v. Vernon*, 723 F.3d 1234 (11th Cir. 2013].

While most hospitals in California cannot employ physicians to provide medical services, because to do so would violate the state's corporate practice of medicine prohibition, hospitals may employ physicians to provide non-medical services, such as administrative and management services, and the employment exception and safe harbor can protect those arrangements.

J. Group Purchasing Arrangements

A safe harbor is available to protect fees paid to group purchasing organizations. **"Group purchasing organizations"** (GPOs) are purchasing agents for purchasers such as health care providers, who are often referred to as the GPO members. The GPO typically enters into agreements with suppliers or manufacturers, referred to in the safe harbor as vendors, through which supplies can be purchased by the GPO members at competitive (bulk) prices. GPOs are usually funded by fees received from the vendors. This safe harbor protects the administrative fees paid by vendors to the GPO, which could otherwise be viewed as payments for arranging for purchases in violation of the anti-kickback statute. Other safe harbors may protect the discounts or rebates that suppliers offer to GPO members *(see H. "Discounts," page 7.21)* and dividend or distribution payments to GPO members. *(See A. "Investment Interests," page 7.8. See also Q. "Cooperative Hospital Service Organizations," page 7.36.)* [42 C.F.R. Section 1001.952(j)]

The safe harbor provides that for purposes of the AKS, remuneration does not include any payment by a vendor to a GPO, as part of an agreement to furnish goods or services, as long as both of the following two standards are met:

1. The GPO has a written agreement with each GPO member that either:
    a. States that participating vendors will pay a fee to the GPO of 3 percent or less of the purchase price of the goods or services provided by that vendor, or
    b. If the fee is not fixed at 3 percent or less, the agreement specifies the amount (or if not known, the maximum amount) the GPO will be paid by each vendor (where such amount may be a fixed sum or a fixed percentage of the value of purchases made).

2. If the GPO member is a health care provider, the GPO must disclose in writing at least annually to the member, and to the Secretary of DHHS upon request, the amount received from each vendor with respect to purchases made by or on behalf of the member.

It should be noted that the GPO safe harbor applies only to payments made by a vendor of goods or services to a person authorized to act as a GPO. Payments, such as discounts, made by vendors of goods or services directly to health care providers must qualify under the discount safe harbor *(see H. "Discounts," page 7.21)*.

For purposes of this safe harbor, **"group purchasing organization"** means an entity authorized to act as a purchasing agent for a group of individuals or entities that furnish services for which payment may be made in whole or in part under Medicare, Medicaid or other federally-funded health care programs, and who are neither wholly-owned by the GPO, nor subsidiaries of a parent corporation that wholly owns the GPO (either directly or through another wholly-owned entity). Thus, a captive purchasing agent that is wholly-owned by a corporation that also owns the members for which purchases are made would not be protected under the GPO safe harbor.

K. Waiver of Beneficiary Copayment, Coinsurance and Deductible Amounts

Waivers of copayments, coinsurance or deductible amounts could be viewed as a form of remuneration to patients to induce them to purchase services from the waiving provider. However, a safe harbor states that for purposes of the AKS, remuneration does not include any reduction or waiver of a Medicare, Medicaid, or other federally-funded health care program beneficiary's obligation to pay copayment, coinsurance or deductible amounts (cost-sharing amounts) as long as all of the applicable standards are met. [42 C.F.R. Section 1001.952(k)] These standards are described below.

Hospital Standards

If the cost-sharing amounts are owed to a hospital for inpatient services for which a federal health care program pays under the prospective payment system, the hospital may reduce or waive the cost-sharing amounts if the following standards are met:

1. The hospital must not later claim the amount reduced or waived as bad debt for payment purposes under a federal health care program or otherwise shift the burden of the reduction or waiver onto a federal health care program, other payers, or individuals.
2. The hospital must offer to reduce or waive the cost-sharing amounts without regard to the reason for admission, the length of stay, or the DRG.
3. The hospital's offer to reduce or waive the cost-sharing amounts must not be made as part of a price reduction agreement between the hospital and a third-party payer, unless the agreement is part of a contract for the furnishing of items or services to a beneficiary of a Medicare supplemental policy.

Federally Qualified Health Center (FQHC) Standards

The safe harbor also protects the reduction or waiver of cost-sharing amounts for items or services for which payment may be made in whole or in part under Part B of Medicare or a state health care program, if the cost-sharing amounts are owed by a patient who qualifies for subsidized services under the Public Health Services (PHS) Act or under Title V (Maternal

and Child Health Services block grant program) or XIX (Medicaid) of the Social Security Act, to a FQHC or other facility under a PHS grant program or under Title V of the Social Security Act.

Pharmacy Standards

If the cost-sharing amounts are owed to a pharmacy for cost-sharing imposed under a federal health care program, the pharmacy may reduce or waive the cost-sharing amounts if:

1. The waiver or reduction is not offered as part of an advertisement or solicitation; and
2. Except for waivers or reductions offered to subsidy-eligible individuals, (i) the pharmacy does not routinely waive or reduce cost-sharing amounts; and (ii) the pharmacy waives the cost-sharing amounts only after determining in good faith that the individual is in financial need or after failing to collect the cost-sharing amounts after making reasonable collection efforts.

Ambulance Standards

If the cost-sharing amounts are owed to an ambulance provider for emergency ambulance services for which a federal health care program pays under a fee-for-service payment system, the ambulance provider may reduce or waive the cost-sharing amounts if all the following conditions are met:

1. The ambulance provider is owned and operated by a state, a political subdivision of a state, or a tribal health care program;
2. The ambulance provider engaged in an emergency response;
3. The ambulance provider offers the reduction or waiver on a uniform basis to all of its residents or (if applicable) tribal members, or to all individuals transported; and
4. The ambulance provider must not later claim the amount reduced or waived as a bad debt for payment purposes under a federal health care program or otherwise shift the burden of the reduction or waiver onto a federal health care program, other payers, or individuals.

Services Covered

This safe harbor was initially limited to inpatient services for which Medicare pays under the prospective payment system, and did not apply to cost-based fee-for-service providers, such as home health agencies or nursing homes [56 Fed. Reg. 35952 (July 29, 1991)]. The safe harbor also did not apply to waivers of a Medi-Cal share of cost, but was subsequently expanded to cover Medi-Cal share of cost, if applicable (81 Fed. Reg. 88368, 88371 (Dec. 7, 2016). However, the federal Medicaid regulations require that medical expenses incurred by an individual, the individual's family, or a financially-responsible relative, be deducted from income in determining Medi-Cal eligibility where a patient's income would exceed the income standard for eligibility, provided those expenses are not subject to payment by a third party [42 C.F.R. Section 435.831(d)]. Consistent with this regulation, California Welfare and Institutions Code Section 14005.9 provides that an individual with a share of cost is entitled to receive Medi-Cal benefits once he or she:

> has incurred expenses for Medicare and other health insurance deductibles or coinsurance charges and necessary medical and remedial services that are not subject to payment by a third party and which equal or exceed his or her share of cost ...

These provisions require a patient's share of cost obligation to be incurred before Medi-Cal benefits become available. Accordingly, if a hospital were to waive all or part of a patient's share of cost, the patient would not have incurred expenses adequate to satisfy the patient's share of cost obligation.

Special Fraud Alert

In May 1991, the OIG issued a Special Fraud Alert: Routine Waiver of Copayments or Deductibles Under Medicare Part B (available at https://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html). In this document, the OIG provided some examples of suspect practices, including:

1. Advertisements that state Medicare accepted as payment in full or no out-of-pocket expenses;
2. Advertisements promising discounts to Medicare beneficiaries;
3. Routine use of financial hardship forms that state that the beneficiary is unable to pay the copay or deductible, without a good faith attempt to determine the beneficiary's actual financial condition;
4. Charges made to Medicare beneficiaries are higher than those made to other patients for similar services and items (the higher charges offset the waiver of coinsurance);
5. Failure to collect copays or deductibles for a specific group of Medicare patients for reasons unrelated to indigency (e.g., a supplier waives coinsurance for all patients from a particular hospital, in order to get referrals);
6. Collection of copays and deductibles only where the beneficiary has Medicare supplemental insurance; and
7. Insurance programs that cover copays or deductibles only for items or services provided by the entity offering the insurance. The insurance premium paid by the beneficiary is insignificant and can be as low as $1 per month or per year. These premiums are not based upon actuarial risks, but are a sham used to disguise the routine waiver of copays and deductibles.

Policy Statement

On Oct. 30, 2015, the OIG issued an OIG Policy Statement Regarding Hospitals That Discount or Waive Amounts Owed by Medicare Beneficiaries for Self-Administered Drugs Dispensed in Outpatient Settings. The purpose of the policy statement was to assure hospitals that they will not be subject to OIG sanctions for discounting or waiving amounts Medicare beneficiaries may owe for self-administered drugs (SADs) they receive in outpatient settings when those drugs are not covered by Medicare Part B, even if the drugs may be covered by Medicare Part D. In order to discount or waive Medicare patient liability for SADs, hospitals:

1. Must uniformly apply their discount or waiver policies to all beneficiaries regardless of diagnosis or type of treatment;
2. May not market or advertise the discounts or waivers; and
3. Must not claim the discounted or waived amounts as bad debt or otherwise shift the costs to Medicare, Medicaid, or other payors or individuals.

Patient Financial Hardship

As a general rule, a hospital may not waive deductibles or coinsurance for outpatient services. However, the OIG has stated that one important exception to this prohibition is that providers may forgive the copayment in consideration of a particular patient's financial hardship. This hardship exception, however, must not be used routinely; it should be used occasionally to address the special financial needs of a particular patient. Except in such special cases, a good faith effort to collect deductibles and copayments must be made. [OIG Special Fraud Alert: Routine Waiver of Copayments or Deductibles Under Medicare Part B, issued May 1991 available at https://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html]

In a document called Hospital Discounts Offered to Patients Who Cannot Afford to Pay Their Hospital Bills dated Feb. 2, 2004 (available at www.oig.hhs.gov/fraud/docs/alertsandbulletins/2004/FA021904hospitaldiscounts.pdf), the OIG further explained its policies regarding waiver of copays and deductibles for Medicare patients with financial need, both inpatient and outpatient. The OIG stated that the financial need criterion is not limited to indigence; it can include any reasonable measures of financial hardship. Medicare copays and deductibles may be waived so long as:

1. The waiver is not offered as part of any advertisement or solicitation;
2. The party offering the waiver does not routinely waive coinsurance or deductible amounts; and
3. The party waives the coinsurance and deductible amounts after determining in good faith that the patient is in financial need, or reasonable collection efforts have failed.

The OIG stated that what constitutes a good faith determination of financial need may vary depending on the individual patient's circumstances, and that hospitals should have flexibility to take into account relevant variables, such as:

1. The local cost of living;
2. A patient's income, assets and expenses;
3. A patient's family size; and
4. The scope and extent of a patient's medical bills.

The OIG stated that hospitals should use a reasonable set of financial need guidelines that are based on objective criteria and appropriate for the applicable locality. The guidelines should be applied uniformly in all cases. Because the financial status of a patient may change over time, hospitals should recheck a patient's eligibility at reasonable intervals.

L. Increased Coverage, Reduced Cost-Sharing or Reduced Premiums Offered by Health Plans

A safe harbor exists permitting health plans to increase coverage, reduce cost-sharing amounts, or reduce premiums to enrollees [42 C.F.R. Section 1001.952(l)]. Because this provision does not apply to hospitals, a discussion of the requirements is beyond the scope of this manual.

M. Price Reductions Offered to Health Plans

For purposes of the AKS, remuneration does not include a price reduction a contract provider offers to a health plan in accordance with a written agreement for the sole purpose

of furnishing to enrollees items or services that are covered by the health plan, Medicare, or a state health care program, as long as both the plan and provider comply with all of the applicable standards within one of the following four categories of health plans [42 C.F.R. Section 1001.952(m)].

Risk-Based Plan with Government Contract

If the health plan is a risk-based HMO, CMP, or prepaid health plan under contract with CMS or a state agency and operating in accordance with Section 1876(g) (concerning Medicare risk-sharing contractors) or 1903(m) (concerning Medicaid managed care organizations) under a federal statutory demonstration authority or other federal authority, the provider must not claim payment in any form from DHHS or the state agency for items or services furnished in accordance with the agreement except as approved by CMS or the state health care program. In addition, the provider must not otherwise shift the burden of such an agreement to the extent that increased payments are claimed from Medicare or a state health care program.

Cost-Based Plan with Government Contract

If the health plan is an HMO, CMP, health care prepayment plan, prepaid health plan, or other health plan that has executed a contract or agreement with CMS or a state health care program to receive payment for enrollees on a reasonable cost or similar basis, the health plan and contract health care provider must comply with all of the following four standards:

1. The term of the agreement between the health plan and the contract health care provider must be for not less than one year;
2. The agreement between the health plan and the contract health care provider must specify in advance the covered items and services to be furnished to enrollees, and the methodology for computing the payment to the contract health care provider;
3. The health plan must fully and accurately report, on the applicable cost report or other claim form filed with DHHS or the state health care program, the amount it has paid the contract health care provider under the agreement; and
4. The contract health care provider must not claim payment in any form from DHHS or the state health care program for items or services furnished in accordance with the agreement except as approved by CMS or the state health care program, or otherwise shift the burden of such an agreement to the extent that increased payments are claimed from Medicare or a state health care program.

Non-Risk-Based Private Plan

If the health plan is not described in one of the two categories above, and the contract health care provider is not paid on an at-risk, capitated basis, both the health plan and contract health care provider must comply with all of the following six standards:

1. The term of the agreement between the health plan and the contract health care provider must be for not less than one year;
2. The agreement between the health plan and the contract health care provider must specify in advance the covered items and services to be furnished to enrollees, which party is to file claims or requests for payment with Medicare or the state health care program for such items and services, and the schedule of fees the contract health care provider will charge for furnishing such items and services to enrollees;

3. The fee schedule contained in the agreement between the health plan and the contract health care provider must remain in effect throughout the term of the agreement, unless a fee increase results directly from a payment update authorized by Medicare or the state health care program;
4. The party submitting claims or requests for payment from Medicare or the state health care program for items and services furnished in accordance with the agreement must not claim or request payment for amounts in excess of the fee schedule;
5. The contract health care provider and the health plan must fully and accurately report on any cost report filed with Medicare or a state health care program the fee schedule amounts charged in accordance with the agreement and, upon request, will report to the Medicare or a state health care program the amounts paid in accordance with the agreement; and
6. The party to the agreement that does not have the responsibility under the agreement for filing claims or requests for payment, must not claim or request payment in any form from DHHS or the state health care program for items or services furnished in accordance with the agreement, or otherwise shift the burden of such an agreement to the extent that increased payments are claimed from Medicare or a state health care program.

Risk-Based Private Plan

If the health plan is not described in one of the first two categories above, and the contract health care provider is paid on an at-risk, capitated basis, both the health plan and contract health care provider must comply with all of the following five standards:

1. The term of the agreement between the health plan and the contract health care provider must be for not less than one year;
2. The agreement between the health plan and the contract health care provider must specify in advance the covered items and services to be furnished to enrollees and the total amount per enrollee (which may be expressed in a per month or other time period basis) the contract health care provider will be paid by the health plan for furnishing such items and services to enrollees and must set forth any copayments, if any, to be paid by enrollees to the contract health care provider for covered services;
3. The payment amount contained in the agreement between the health plan and the contract health care provider must remain in effect throughout the term of the agreement;
4. The contract health care provider and the health plan must fully and accurately report to Medicare and a state health care program upon request, the terms of the agreement and the amounts paid in accordance with the agreement; and
5. The contract health care provider must not claim or request payment in any form from DHHS, a state health care program or an enrollee (other than copayment amounts specified in the agreement) and the health plan must not pay the contract health care provider in excess of the amounts specified in the agreement for items and services covered by the agreement.

This safe harbor protects direct contractors with health plans. The safe harbors described under T. "Price Reductions Offered to Eligible Managed Care Organizations," page 7.41, and U. "Price Reductions Offered by Contractors With Substantial Financial Risk to Managed Care Organizations," page 7.41, protect subcontractors as well.

Definitions

For purposes of this safe harbor provision, **"contract health care provider"** means an individual or entity under contract with a health plan to furnish items or services to enrollees who are covered by the health plan, Medicare, or a state health care program. **"Enrollee"** means an individual who has entered into a contractual relationship with a health plan (or on whose behalf an employer, or other private or governmental entity has entered into such a relationship) under which the individual is entitled to receive specified health care items and services, or insurance coverage for such items and services, in return for payment of a premium or a fee.

N. Practitioner Recruitment

A safe harbor regulation exists to protect so-called recruitment payments, which are payments by a hospital to a physician to relocate his or her practice to the hospital's service area [42 C.F.R. Section 1001.952(n)]. This regulation provides that, for purposes of the AKS, remuneration does not include any payment or exchange of anything of value by an entity in order to induce a practitioner who has been practicing within his or her current specialty for less than one year to locate, or to induce any other practitioner to relocate, his or her primary place of practice into a health professional shortage area (HPSA) for his or her specialty area, as defined in DHHS regulations, that is served by the entity, as long as all of the following nine standards are met:

1. The arrangement is set forth in a written agreement signed by the parties that specifies the benefits provided by the entity, the terms under which the benefits are to be provided, and the obligations of each party;
2. If a practitioner is leaving an established practice, at least 75 percent of the revenues of the new practice must be generated from new patients not previously seen by the practitioner at his or her former practice;
3. The benefits are provided by the entity for a period not in excess of three years, and the terms of the agreement are not renegotiated during this three-year period in any substantial aspect; provided, however, that if the HPSA to which the practitioner was recruited ceases to be a HPSA during the term of the written agreement, the payments made under the written agreement will continue to satisfy this paragraph for the duration of the written agreement (not to exceed three years);
4. There is no requirement that the practitioner make referrals to, be in a position to make or influence referrals to, or otherwise generate business for, the entity as a condition for receiving the benefits; provided, however, that for purposes of this paragraph, the entity may require as a condition for receiving benefits that the practitioner maintain staff privileges at the entity;
5. The practitioner is not restricted from establishing staff privileges at, referring any service to, or otherwise generating any business for, any other entity of his or her choosing;

6. The amount or value of the benefits provided by the entity may not vary (or be adjusted or renegotiated) in any manner based on the volume or value of any expected referrals to, or business otherwise generated for, the entity by the practitioner for which payment may be made in whole or in part under Medicare or a state health care program;
7. The practitioner agrees to treat patients receiving medical benefits or assistance under any federal health care program in a nondiscriminatory manner;
8. At least 75 percent of the revenues of the new practice must be generated from patients residing in a HPSA or a Medically Underserved Area (MUA) or who are part of a Medically Underserved Population (MUP); and
9. The payment or exchange of anything of value may not directly or indirectly benefit any person (other than the practitioner being recruited) or entity in a position to make or influence referrals to the entity providing the recruitment payments or benefits of items or services payable by a federal health care program.

Thus, the safe harbor applies only where a recruited practicing physician relocates his or her primary place of practice into a HPSA for his or her specialty area. HPSAs are currently designated only for the specialties of primary care, dentistry and mental health. [64 Fed. Reg. 63518, 63542 (Nov. 19, 1999)]

While the safe harbor for physician recruiting is quite narrow in scope, and protects only a limited number of recruiting arrangements, there has been considerable judicial interpretation of the application of the anti-kickback law to physician recruiting. For example, in *Polk County, Texas v. Peters*, the court held a recruiting agreement to be illegal at least in part because it contained the following requirement:

> Physician ... shall utilize Hospital for his patients who require hospitalization, unless, in the physician's professional judgment, the use of another medical facility is necessary or desirable in order to provide proper and appropriate treatment and care to such patient (or to comply with the desires of a patient or the patient's family). [Polk County, *Texas v. Peters*, 800 F.Supp. 1451 (E.D. Tex. 1992)]

Relying on cases in other circuits, the *Polk County* court found that a hospital's provision of an interest-free loan, free office space, utility subsidiaries and reimbursement for malpractice insurance to the recruited physician constituted illegal remuneration. [*U.S. v. Greber*, 760 F.2d 68 (3rd Cir.), cert. denied, 747 U.S. 988 (1985); *U.S. v. Kats*, 871 F.2d 105 (9th Cir. 1989); *U.S. v. Bay State Ambulance & Hosp. Rental Service, Inc.*, 874 F.2d 20 (1st Cir. 1989)] [59 Fed. Reg. 65372, 65375 (Dec. 19, 1994)] The court concluded that the recruitment benefits extended by the hospital were extended, in part, as an inducement to the recruited physician to refer patients to the hospital and thus violated the federal anti-kickback statute.

The court appears to have been heavily influenced by the fact that the physician was required to use the hospital which recruited him for his patients needing hospital services. However, the case does not specify that a referral commitment was required in order for a violation to result.

A federal court in *Feldstein v. Nash Community Health Services, Inc.* subsequently relied upon the physician self-referral law's recruiting exception to conclude that not all recruiting arrangements that are not protected by the recruitment safe harbor are prohibited by the

anti-kickback statute, and suggested that garden variety recruiting arrangements that do not involve an obligation on the part of the recruited physician to refer to the recruiting hospital ought to be permitted under the anti-kickback statute.[5] [*Feldstein v. Nash Community Health Services, Inc.*, 51 F.Supp.2d 673 (E.D.N.C. 1999)]

Like the earlier decision in *Polk County*, *Feldstein* analyzed a physician recruiting arrangement in the context of a civil dispute between the parties as to whether the agreement was enforceable. The court concluded that the question of the legality of the recruiting agreement should ultimately be sent to the jury as a question of fact. The case subsequently settled, so no further guidance developed in further proceedings. The court distinguished *Polk County* on the ground that the recruitment agreement found to be illegal there had contained an express referral obligation. The *Feldstein* court concluded that an agreement to refer such as was presented in *Polk* would, when coupled with remuneration, result in prohibited inducement.

In light of this case law, it is important that recruited physicians not be obligated to refer patients to the recruiting hospital.

Hospitals that recruit physicians must also be familiar with federal and state physician self-referral laws *(see chapter 6, "Physician Self-Referral Laws")* and, for tax-exempt hospitals, private benefit and inurement restrictions *(see chapter 9, "Issues for Tax-Exempt Hospitals").*

O. Obstetrical Malpractice Insurance Subsidies

A hospital may wish to subsidize the malpractice insurance premium of an obstetrician(s) needed in its community who is considering terminating his or her obstetrical practice due to the high cost of malpractice insurance. A very limited safe harbor is available to protect certain obstetrical malpractice insurance subsidies. The safe harbor provides that for purposes of the AKS, remuneration does not include any payment made by a hospital or other entity to another entity that is providing malpractice insurance (including a self-funded entity), where the payment is used to pay for some or all of the costs of malpractice insurance premiums for a practitioner (including a certified nurse-midwife as defined in Section 1861(gg) of the Social Security Act) who engages in obstetrical practice as a routine part of his or her medical practice in a primary care health professional shortage area (HPSA), as long as all of the following seven standards are met [42 C.F.R. Section 1001.952(o)]:

1. The payment is made in accordance with a written agreement between the entity paying the premiums and the practitioner, which sets out the payments to be made by the entity, and the terms under which the payments are to be provided.
2. The practitioner must certify that for the initial coverage period (not to exceed one year) the practitioner has a reasonable basis for believing that at least 75 percent of the practitioner's obstetrical patients treated under the coverage of the malpractice insurance will either:
    a. Reside in a HPSA or medically-underserved area (MUA), or
    b. Be part of a medically-underserved population (MUP).

    Thereafter, for each additional coverage period (not to exceed one year), at least 75 percent of the practitioner's obstetrical patients treated under the prior coverage period (not to exceed one year) must have either:

5 The OIG has also approved physician recruiting by hospitals in an advisory opinion (OIG Advisory Opinion No. 01-4) based upon a demonstration of community need.

a. Resided in a HPSA or MUA, or

b. Been part of an MUP.

3. There is no requirement that the practitioner make referrals to, or otherwise generate business for, the entity as a condition for receiving the obstetrical malpractice insurance subsidy.

4. The practitioner is not restricted from establishing staff privileges at, referring any service to, or otherwise generating any business for any other entity of his or her choosing.

5. The amount of payment may not vary based on the volume or value of any previous or expected referrals to, or business otherwise generated for, the entity by the practitioner for which payment may be made under any federally-funded health care program.

6. The practitioner must treat obstetrical patients who receive medical benefits or assistance under any federally-funded health care program in a non-discriminatory manner.

7. The insurance is a bona fide malpractice insurance policy or program, and the premium, if any, is calculated based on a bona fide assessment of the liability risk covered under the insurance.

Thus, the safe harbor is available only to protect subsidies to obstetricians who practice in HPSAs and whose patients primarily reside in a HPSA or an MUA, or are part of an MUP.

For purposes of this safe harbor, **"costs of malpractice insurance premiums"** means, for practitioners who engage in obstetrical practice full-time, any costs attributable to malpractice insurance. For practitioners who engage in obstetrical practice on a part-time or sporadic basis, **"costs of malpractice insurance premiums"** means the costs attributable exclusively to the obstetrical portion of the practitioner's malpractice insurance and related exclusively to obstetrical services provided in a primary care HPSA.

Hospitals should note that the subsidy must be paid directly to the insurer, and not to the practitioner. This safe harbor does not authorize payments by any federally-funded health care program to hospitals or other institutional providers for costs they incur in providing malpractice insurance. Any allowable costs for such insurance is governed strictly by Medicare and Medicaid rules.

Any malpractice insurance subsidies provided by a hospital that are not protected by the safe harbor can potentially create risk under the AKS, and should be carefully analyzed prior to implementation.

P. Investments in Group Practices

For purposes of the AKS, "remuneration" does not include any payment that is a return on an investment interest, such as a dividend or interest income, made to a solo or group practitioner investing in his or her own practice or group practice if the following four standards are met [42 C.F.R. Section 1001.952(p)]:

1. The equity interests in the practice or group must be held by licensed health care professionals who practice in the practice or group.

2. The equity interests must be in the practice or group itself, and not some subdivision of the practice or group.

3. In the case of group practices, the practice must:

    a. Meet the definition of "group practice" in the federal physician self-referral statute and implementing regulations *(see CHA Appendix HC 6-A, found at the end of chapter 6)*; and

    b. Be a unified business with centralized decision making, pooling of expenses and revenues, and a compensation/profit distribution system that is not based on satellite offices operating substantially as if they were separate enterprises or profit centers.

4. Revenues from ancillary services, if any, must be derived from "in-office ancillary services" that meet the definition of such term in the federal physician self-referral statute and implementing regulations *(see chapter 6, "Physician Self-Referral Laws").*

Q. Cooperative Hospital Service Organizations

Under Internal Revenue Service Code Section 501(e), a cooperative hospital service organization (CHSO) may be formed by one or more hospitals (known as "patron-hospitals") to provide specifically enumerated services, such as purchasing, billing, and clinical services solely for the benefit of its patron-hospitals. The CHSO is required to distribute "all net earnings to patrons on the basis of services performed" [26 U.S.C. Section 501(e)(2)].

For purposes of the AKS, "remuneration" does not include any payment made between a CHSO and its patron-hospital, both of which are described in Internal Revenue Code Section 501(e) and are tax-exempt under Internal Revenue Code Section 501(c)(3), where the CHSO is wholly owned by two or more patron-hospitals, as long as the following standards are met [42 C.F.R. Section 1001.952(q)]:

1. If the patron-hospital makes a payment to the CHSO, the payment must be for the purpose of paying for the bona fide operating expenses of the CHSO; or

2. If the CHSO makes a payment to the patron-hospital, the payment must be for the purpose of paying a distribution of net earnings required to be made under Internal Revenue Code Section 501(e)(2).

R. Ambulatory Surgical Center Investment

Safe harbors are available to protect investment by a hospital and by physicians in an ambulatory surgery center (ASC), as well as investment by physicians in ASCs. For purposes of the AKS, "remuneration" does not include any payment that is a return on an investment interest (such as a dividend or interest income) made to an investor, as long as the investment entity is a certified ASC under 42 C.F.R. Part 416. A hospital/physician ASC must have its operating and recovery room space dedicated exclusively to the ASC (so ASCs that are located on the premises of a hospital that share their operating or recovery room space with the hospital for treatment of the hospital's inpatients or outpatients are not protected by this safe harbor), patients referred to the ASC by an investor must be fully informed of the investor's investment interest, and all of the applicable standards are met within one of the following four categories [42 C.F.R. Section 1001.952(r)]:

Hospital/Physician ASCs

At least one investor must be a hospital. All remaining investors must be one of the following:

1. Physicians who meet the requirements listed under "Surgeon-Owned ASCs," page 7.38, "Single-Specialty ASCs," page 7.38, or "Multi-Specialty ASCs," page 7.39; or
2. Group practices (as defined below) composed of such physicians; or
3. Surgical group practices (as defined below); or
4. Investors who are not employed by the ASC or by any investor, are not in a position to provide items or services to the ASC or any of its investors, and are not in a position to refer patients directly or indirectly to the ASC or any of its investors.

In addition, all of the following eight standards must be met:

1. The terms on which an investment interest is offered to an investor must not be related to the previous or expected volume of referrals, services furnished, or the amount of business otherwise generated from that investor to the ASC.
2. The ASC or any investor (or other individual or entity acting on behalf of the ASC or any investor) must not loan funds to or guarantee a loan for an investor if the investor uses any part of such loan to obtain the investment interest.
3. The amount of payment to an investor in return for the investment must be directly proportional to the amount of the capital investment (including the fair market value of any preoperational services rendered) of that investor.
4. The ASC and any hospital or physician investor must treat patients receiving medical benefits or assistance under any federally-funded health care program in a nondiscriminatory manner.
5. The ASC may not use space, including, but not limited to, operating and recovery room space, located in, or owned by, any hospital investor, unless such space is leased from the hospital in accordance with a lease that complies with all the standards of the space rental safe harbor *(see B. "Space Rental," page 7.10)*; nor may it use equipment owned by, or services provided by, the hospital unless such equipment is leased in accordance with a lease that complies with the equipment rental safe harbor *(see C. "Equipment Rental," page 7.12)*, and such services are provided in accordance with a contract that complies with the personal services and management contracts safe harbor *(see D. "Personal Services and Management Contracts," page 7.13)*.
6. All ancillary services for federally-funded health care program beneficiaries performed at the ASC must be directly and integrally related to primary procedures performed at the ASC, and none may be separately billed to Medicare or other federally-funded health care programs.
7. The hospital may not include on its cost report, or any claim for payment from a federally-funded health care program, any costs associated with the ASC (unless such costs are required to be included by a federally-funded health care program).
8. The hospital may not be in a position to make or influence referrals directly or indirectly to any investor or the ASC.

Surgeon-Owned ASCs

If all of the investors in an ASC are either general surgeons or surgeons engaged in the same surgical specialty who are in a position to refer patients directly to the ASC and perform surgery on such referred patients; surgical group practices (as defined above) composed exclusively of such surgeons; or investors who are not employed by the ASC or any of its investors, and are not in a position to provide items or services to the entity or to make or influence referrals directly or indirectly to the entity or any of its investors, all of the following six standards must be met:

1. The terms on which an investment interest is offered to an investor must not be related to the previous or expected volume of referrals, services furnished, or the amount of business otherwise generated from that investor to the ASC.
2. At least one-third of each surgeon investor's medical practice income from all sources for the previous fiscal year or previous 12-month period must be derived from the surgeon's performance of procedures (as defined above).
3. The ASC or any investor (or other individual or entity acting on behalf of the ASC or any investor) must not loan funds to, or guarantee a loan for, an investor if the investor uses any part of such loan to obtain the investment interest.
4. The amount of payment to an investor in return for the investment must be directly proportional to the amount of the capital investment (including the fair market value of any preoperational services rendered) of that investor.
5. All ancillary services for federally-funded health care program beneficiaries performed at the ASC must be directly and integrally related to primary procedures performed at the ASC, and none may be separately billed to Medicare or other federally-funded health care programs.
6. The ASC and any surgeon investors must treat patients receiving medical benefits or assistance under any federally-funded health care program in a nondiscriminatory manner.

Single-Specialty ASCs

If all of the investors are physicians engaged in the same medical specialty who are in a position to refer patients directly to the ASC and perform procedures on such referred patients; group practices composed exclusively of such physicians; or investors who are not employed by the ASC or by any investor, are not in a position to provide items or services to the ASC or any of its investors, and are not in a position to make or influence referrals directly or indirectly to the ASC or any of its investors, all of the following six standards must be met:

1. The terms on which an investment interest is offered to an investor must not be related to the previous or expected volume of referrals, services furnished, or the amount of business otherwise generated from that investor to the ASC.
2. At least one-third of each physician investor's medical practice income from all sources for the previous fiscal year or previous 12-month period must be derived from the physician's performance of procedures.
3. The ASC or any investor (or other individual or entity acting on behalf of the ASC or any investor) must not loan funds to, or guarantee a loan for, an investor if the investor uses any part of such loan to obtain the investment interest.

4. The amount of payment to an investor in return for the investment must be directly proportional to the amount of the capital investment (including the fair market value of any preoperational services rendered) of that investor.
5. All ancillary services for federally-funded health care program beneficiaries performed at the ASC must be directly and integrally related to primary procedures performed at the ASC, and none may be separately billed to Medicare or other federally-funded health care programs.
6. The ASC and any physician investors must treat patients receiving medical benefits or assistance under any federally-funded health care program in a nondiscriminatory manner.

Multi-Specialty ASCs

If all of the investors are physicians who are in a position to refer patients directly to the ASC and perform procedures on such referred patients; group practices composed exclusively of such physicians; or investors who are not employed by the ASC or by any investor, are not in a position to provide items or services to the ASC or any of its investors, and are not in a position to make or influence referrals directly or indirectly to the ASC or any of its investors, all of the following seven standards must be met:

1. The terms on which an investment interest is offered to an investor must not be related to the previous or expected volume of referrals, services furnished, or the amount of business otherwise generated from that investor to the ASC.
2. At least one-third of each physician investor's medical practice income from all sources for the previous fiscal year or previous 12-month period must be derived from the physician's performance of procedures.
3. At least one-third of the procedures performed by each physician investor for the previous fiscal year or previous 12-month period must be performed at the ASC.
4. The ASC or any investor (or other individual or entity acting on behalf of the ASC or any investor) must not loan funds to, or guarantee a loan for, an investor if the investor uses any part of such loan to obtain the investment interest.
5. The amount of payment to an investor in return for the investment must be directly proportional to the amount of the capital investment (including the fair market value of any preoperational services rendered) of that investor.
6. All ancillary services for federally-funded health care program beneficiaries performed at the ASC must be directly and integrally related to primary procedures performed at the ASC, and none may be separately billed to Medicare or other federally-funded health care programs.
7. The ASC and any physician investors must treat patients receiving medical benefits or assistance under any federally-funded health care program in a nondiscriminatory manner.

Accordingly, for multi-specialty ASCs, whether or not hospital owned, physicians are required to perform at least one-third of their ambulatory surgery procedures at the ASC they own.

Definitions

For purposes of this safe harbor (as applied to all four categories of ASCs under the safe harbor), **"procedures"** means any procedure or procedures on the list of Medicare-covered procedures for ASCs in accordance with regulations issued by DHHS. **"Group practice"** means a group practice that meets all of the standards of the group practice safe harbor *(see P. "Investments in Group Practices," page 7.35)*. **"Surgical group practice"** means a group practice that meets all of the standards of the group practice safe harbor *(see P. "Investments in Group Practices," page 7.35)* and is composed exclusively of surgeons who meet the requirements listed under "Surgeon-Owned ASCs," page 7.38.

It is often the case that physician investment in ASCs, either with or without hospital investment, do not meet all of the above requirements for safe harbor protection. For example, if at least one surgeon-investor in an ASC does not derive at least one-third of his or her medical practice income from performance of ambulatory surgery procedures, then none of the investments in the ASC are protected by the safe harbors. Nevertheless, where ASCs do not meet all of the requirements of the safe harbors, but physician investments in the ASC are bona fide and are not linked to referrals to the ASC, there should be minimal risk under the AKS statute. However, the requirement that physicians perform at least one-third of their ambulatory surgery procedures at the ASC should not be imposed unless all requirements of the multi-specialty safe harbor are met.

S. Referral Arrangement for Specialty Services

A safe harbor protects referral of patients by a hospital to another hospital for services not available at the first hospital, with the understanding that the patient will be referred back to the first hospital at a specified point in the patient's treatment, for example, when the patient reaches a particular stage of recovery. Because giving a hospital an opportunity to earn money may constitute an "inducement" or "remuneration," the AKS is potentially implicated. However, the OIG has recognized that such referrals benefit patients by assuring proper continuity of care or convenient access to necessary services.

The safe harbor provides that for purposes of the AKS, "remuneration" does not include any exchange of value among individuals and entities where one party agrees to refer a patient to the other party for the provision of a specialty service payable in whole or in part by a federally-funded health care program in return for an agreement on the part of the other party to refer that patient back at a mutually agreed upon time or circumstance, as long as the following four standards are met [42 C.F.R. Section 1001.952(s)]:

1. The mutually agreed upon time or circumstance for referring the patient back to the originating individual or entity is clinically appropriate.
2. The service for which the referral is made is not within the medical expertise of the referring individual or entity, but is within the special expertise of the other party receiving the referral.
3. The parties receive no payment from each other for the referral and do not share or split a global fee from any federally-funded health care program in connection with the referred patient.
4. Unless both parties belong to the same group practice, the only exchange of value between the parties is the remuneration the parties receive directly from third-party payers or the patient compensating the parties for the services they each have furnished to the patient.

T. Price Reductions Offered to Eligible Managed Care Organizations

A safe harbor protects price reductions offered to eligible managed care organizations [42 C.F.R. Section 1001.952(t)]. The safe harbor protects reductions given by **"first tier contractors"** (who contract directly with managed-care organizations) as well as reductions given by **"downstream contractors"** (who contract with a first tier contractor, with certain additional limitations) to first tier contractors.

The requirements of the safe harbor are:

1. That there be a written agreement signed by the parties specifying:
    a. The items and services covered by the agreement;
    b. A term of at least one year; and
    c. That the party providing items or services cannot claim payment in any form, directly or indirectly, from a federal health care program for items or services covered by the agreement (with certain specified exceptions);
2. Neither party gives or receives remuneration in return for, or to induce the provision or acceptance of, business, other than the business covered by the agreement for which payment may be made on a fee-for-service or cost basis; and
3. Neither party shifts the financial burden of the agreement to the extent that increased payments are claimed from a federal health care program.

U. Price Reductions Offered by Contractors With Substantial Financial Risk to Managed Care Organizations

Another safe harbor protects reductions in price offered by contractors with substantial financial risk to managed care organizations [42 C.F.R. Section 1001.952(u)]. The safe harbor protects price reductions offered to managed care plans by first tier contractors as well as reductions offered by downstream contractors to the first tier contractors (or between downstream contractors). Key requirements of the safe harbor include the following (refer to safe harbor regulations for additional requirements):

1. There be an agreement in writing and signed by the parties specifying the items or services covered by the agreement and with a term of at least one year;
2. Participation in a quality assurance program that promotes the coordination of care, protects against underutilization and specifies patient goals, including measurable outcomes where appropriate; and
3. Specifying a methodology for determining payment that is commercially reasonable and consistent with fair market value established in an arm's-length transaction be specified that includes the intervals at which payment will be made and the formula for calculating incentives and penalties, if any.

The first tier contractor must have substantial risk for the cost or utilization of services and must be obligated to provide care through one of four specified payment methodologies. In establishing the arrangement, neither party may give or receive remuneration in return for, or to induce the provision or acceptance of, business (other than business covered by the arrangement) for which payment may be made in whole or in part on a fee-for-service or cost basis. Neither party to the arrangement may shift the financial burden of such arrangement to the extent that payments are claimed from a federal health care program. If the first tier

contractor has an investment interest in the managed care plan, that investment interest must satisfy the criteria in subsection (1) of the investment interests safe harbor [42 C.F.R. Section 1001.952(a)(1)].

V. Ambulance Replenishing

A safe harbor provides that for purposes of the AKS, "remuneration" does not include any gift or transfer of drugs or medical supplies (including linens) by a hospital or other receiving facility to an ambulance provider for the purpose of replenishing comparable drugs or medical supplies used by the ambulance provider (or a first responder) in connection with the transport of a patient by the ambulance to the hospital or other receiving facility [42 C.F.R. Section 1001.952(v)] if the following conditions are satisfied:

1. The ambulance that is replenished must be used to provide emergency ambulance services an average of three times per week, as measured over a reasonable period of time. Replenishing for non-emergency runs is permitted, so long as the ambulance is used for emergency runs an average of three times per week [66 Fed. Reg. 62979, 62983 (Dec. 4, 2001)].
2. Drugs and medical supplies initially used by a first responder and replenished at the scene of the illness or injury by the ambulance provider that transports the patient are deemed to have been used by the ambulance provider.

The ambulance replenishing arrangement must also satisfy all of the following conditions:

1. Under no circumstances may the ambulance provider (or first responder) and the receiving facility both bill for the same replenished drug or supply. Replenished drugs or supplies may only be billed (including claiming bad debt) to a federally-funded health care program by either the ambulance provider (or first responder) or the receiving facility.
2. All billing or claims submission by the receiving facility, ambulance provider or first responder for replenished drugs and medical supplies used in connection with the transport of a federally-funded health care program beneficiary must comply with all applicable payment and coverage rules and regulations. Compliance with this condition will be determined separately for the receiving facility and the ambulance provider (and first responder, if any), so long as the receiving facility and ambulance provider (or first responder) refrain from doing anything that would impede the other party or parties from meeting these obligations.
3. The receiving facility or ambulance provider, or both, must:
    a. Maintain records of the replenished drugs and medical supplies and the patient transport to which the replenished drugs and medical supplies are related;
    b. Provide a copy of such records to the other party within a reasonable time (unless the other party is separately maintaining records of the replenished drugs and medical supplies); and
    c. Make those records available to the Secretary of DHHS promptly upon request.

4. A pre-hospital case report, including, but not limited to, a trip sheet, patient care report or patient encounter report, prepared by the ambulance provider and filed with the receiving facility will meet this requirement, provided that it documents the specific type and amount of medical supplies and drugs used on the patient and subsequently replenished.
5. Documentation may be maintained and, if required, filed with the other party in hard copy or electronically. If a replenishing arrangement includes linens, documentation need not be maintained for their exchange. If documentation is not maintained for the exchange of linens, the receiving facility will be presumed to have provided an exchange of comparable clean linens for soiled linens for each ambulance transport of a patient to the receiving facility. These records must be maintained for five years.
6. The replenishing arrangement must not take into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under any federally-funded health care program (other than the referral of the particular patient to whom the replenished drugs and medical supplies were furnished).
7. The receiving facility and the ambulance provider otherwise comply with all federal, state, and local laws regulating ambulance services, including, but not limited to, emergency services, and the provision of drugs and medical supplies, including, but not limited to, laws relating to the handling of controlled substances.
8. In addition, the arrangement must satisfy all of the standards in one of the following three categories: general replenishing, fair market value replenishing, and government-mandated replenishing, each of which is described below.

General Replenishing

The receiving facility must replenish medical supplies or drugs on an equal basis for all ambulance providers that bring patients to the receiving facility in any one of the three categories described below. A receiving facility may offer replenishing to one or more of the categories and may offer different replenishing arrangements to different categories, so long as the replenishing is conducted uniformly within each category. For example, a receiving facility may offer to replenish a broader array of drugs or supplies for ambulance providers that do not charge for their services than for ambulance providers that charge for their services. Within each category, the receiving facility may limit its replenishing arrangements to the replenishing of emergency transports only. A receiving facility may offer replenishing to one or more of the categories.

The categories are:

1. All ambulance providers that do not bill any patient or insurer, including federally-funded health care programs, for ambulance services, regardless of the payer or the patient's ability to pay (i.e., ambulance providers, such as volunteer companies, that provide ambulance services without charge to any person or entity);
2. All not-for-profit and state or local government ambulance service providers, including, but not limited to, municipal and voluntary ambulance services providers; or
3. All ambulance service providers.

The replenishing arrangement must be conducted in an open and public manner. A replenishing arrangement will be considered to be conducted in an open and public manner if one of the following two conditions is satisfied:

1. A written disclosure of the replenishing program is posted conspicuously in the receiving facility's emergency room or other location where the ambulance providers deliver patients. A copy of the disclosure must be given upon request to ambulance providers, government representatives, and members of the public subject to reasonable photocopying charges. The written disclosure can take any reasonable form and should include the category of ambulance service providers that qualifies for replenishment, the drugs or medical supplies included in the replenishment program, and the procedures for documenting and replenishing. A sample disclosure form developed by DHHS is included as CHA Appendix HC 7-A, "Sample Disclosure Regarding Ambulance Replenishing" at the end of this chapter. No written contract between the parties is required for purposes of this paragraph.
2. The replenishment arrangement operates in accordance with a plan or protocol of general application promulgated by an Emergency Medical Services (EMS) Council or comparable entity, agency or organization. A copy of the plan or protocol must be given upon request to ambulance providers, government representatives and members of the public, subject to reasonable photocopying charges. While parties are encouraged to participate in collaborative, comprehensive, community-wide EMS systems to improve the delivery of EMS in their local communities, nothing in this paragraph shall be construed as requiring the involvement of such organizations or the development or implementation of ambulance replenishment plans or protocols by such organizations.

Nothing in this "General Replenishing" section shall be construed as requiring disclosure of confidential proprietary or financial information related to the replenishing arrangement (including, but not limited to, information about cost, pricing or the volume of replenished drugs or supplies) to ambulance providers or members of the general public.

Fair Market Value Replenishing

The ambulance provider must pay the receiving facility fair market value, based on an arm's-length transaction for replenished medical supplies. If payment is not made at the same time as the replenishing, the receiving facility and the ambulance provider must make commercially reasonable payment arrangements in advance.

Government-Mandated Replenishing

The replenishing arrangement is undertaken in accordance with a state or local statute, ordinance, regulation or binding protocol that requires hospitals or receiving facilities to replenish ambulances that deliver patients to the hospital with drugs or medical supplies (including linens) that are used during the transport of that patient.

Definitions

For purposes of this safe harbor, **"receiving facility"** means a hospital or other facility that provides emergency medical services. An **"ambulance provider"** is a provider or supplier of ambulance transport services that provides emergency ambulance services. The term does not include a provider of ambulance transport services that provides only non-emergency

transport services. A **"first responder"** includes, but is not limited to, a fire department, paramedic service, or search and rescue squad that responds to an emergency call (through 9-1-1 or other emergency access number) and treats the patient, but does not transport the patient to the hospital or other receiving facility. An **"emergency ambulance service"** is a transport by ambulance initiated as a result of a call through 9-1-1 or other emergency access number or a call from another acute care facility unable to provide the higher level care required by the patient and available at the receiving facility.

W. Donations to Federally Qualified Health Centers

Hospitals or other entities may wish to provide items or services to a federally qualified health center (FQHC) that contribute to the FQHC's ability to maintain or increase the availability of, or enhance the quality of, services available to a medically-underserved population. If the FQHC refers patients to the hospital or other donors, the anti-kickback statute may be implicated. A safe harbor exists to protect such donors under specified circumstances. [42 C.F.R. Section 1001.952(w)]

For purposes of the AKS, remuneration does not include the transfer of any goods, items, services, donations or loans (whether the donation or loan is in cash or in-kind), or combination thereof from an individual or entity to an FQHC as long as the following nine standards are met:

1. The transfer is made pursuant to a contract, lease, grant, loan, or other agreement that is set out in writing; signed by the parties; and covers, and specifies the amount of, all goods, items, services, donations, or loans to be provided by the individual or entity to the FQHC. The amount of goods, items, services, donations, or loans specified in the agreement may be a fixed sum, fixed percentage, or set forth by a fixed methodology. The amount may not be conditioned on the volume or value of federally-funded health care program business generated between the parties. The written agreement will be deemed to cover all goods, items, services, donation, or loans provided by the individual or entity to the FQHC if all separate agreements between the individual or entity and the FQHC incorporate each other by reference or if they cross-reference a master list of agreements that is maintained centrally, is kept up to date, and is available for review by the Secretary of DHHS upon request. The master list should be maintained in a manner that preserves the historical record of arrangements.
2. The goods, items, services, donations, or loans are medical or clinical in nature or relate directly to services provided by the FQHC as part of the scope of the FQHC's Section 330 (of the Public Health Services Act) grant, including, by way of example, billing services, administrative support services, technology support, and enabling services, such as case management, transportation, and translation services, that are within the scope of the grant.
3. The FQHC reasonably expects the arrangement to contribute meaningfully to its ability to maintain or increase the availability, or enhance the quality, of services provided to a medically-underserved population served by the FQHC, and the FQHC documents the basis for the reasonable expectation prior to entering the arrangement. The documentation must be made available to the Secretary of DHHS upon request.

4. At reasonable intervals, but at least annually, the FQHC must re-evaluate the arrangement to ensure that it is expected to continue to satisfy the standard set forth in the immediately preceding paragraph, and must document the re-evaluation contemporaneously. The documentation must be made available to the Secretary of DHHS upon request. Arrangements must not be renewed or renegotiated unless the FQHC reasonably expects the standard set forth in the immediately preceding paragraph to be satisfied in the next agreement term. Renewed or renegotiated agreements must comply with the requirements of the immediately preceding paragraph.
5. The individual or entity does not require the FQHC (or its affiliated health care professionals) to refer patients to a particular individual or entity, and does not restrict the FQHC (or its affiliated health care professionals) from referring patients to any individual or entity.
6. Individuals and entities that offer to furnish goods, items, or services without charge or at a reduced charge to the FQHC must furnish such goods, items, or services to all patients from the FQHC who clinically qualify for them, regardless of the patient's payor status or ability to pay. The individual or entity may impose reasonable limits on the aggregate volume or value of the goods, items, or services furnished under the arrangement with the FQHC, provided such limits do not take into account a patient's payer status or ability to pay.
7. The agreement must not restrict the FQHC's ability, if it chooses, to enter into agreements with other providers or suppliers of comparable goods, items, or services, or with other lenders or donors. Where a FQHC has multiple individuals or entities willing to offer comparable remuneration, it must employ a reasonable methodology to determine which individuals or entities to select and must document its determination. In making these determinations, FQHCs should look to the procurement standards for recipients of federal grants set forth in 45 C.F.R. Sections 75.326 through 75.340.
8. The FQHC must provide effective notification to patients of their freedom to choose any willing provider or supplier. In addition, the FQHC must disclose the existence and nature of the required written agreement to any patient who inquires. The FQHC must provide such notification or disclosure in a timely fashion and in a manner reasonably calculated to be effective and understood by the patient.
9. The FQHC may, at its option, elect to require that an individual or entity charge a referred FQHC patient the same rate it charges to other similarly situated patients not referred by the FQHC or that the individual or entity charge a referred FQHC patient a reduced rate (where the discount applies to the total charge and not just to the cost-sharing portion owed by an insured patient).

This safe harbor applies only to Section 330-funded FQHCs. It does not apply to look-alike facilities [72 Fed. Reg. 56632, 56636 (Oct. 4, 2007)].

X. Electronic Prescribing Items and Services

When Congress adopted the Medicare prescription drug benefit (Medicare Part D), it directed the Secretary of DHHS to create standards for electronic prescribing with the objective of

improving patient safety, quality of care, and efficiency in the delivery of care. In addition, Congress directed the Secretary to create a safe harbor to protect certain arrangements involving the provision of items and services used solely to receive and transmit electronic prescription information.

The safe harbor provides that for purposes of the AKS, remuneration does not include nonmonetary remuneration consisting of items and services in the form of hardware, software, or information technology and training services that are necessary and used solely to receive and transmit electronic prescription information, defined as information about prescriptions for drugs or for any other item or service normally accomplished through a written prescription, if all of the following conditions are met [42 C.F.R. Section 1001.952(x)]:

1. The items and services are provided by a hospital to a physician who is a member of its medical staff; group practice to a prescribing health care professional who is a member of the group practice; and a prescription drug plan (PDP) sponsor or Medicare Advantage (MA) organization to pharmacists and pharmacies participating in the network of such sponsor or organization and to prescribing health care professionals.
2. The items and services are provided as part of, or are used to access, an electronic prescription drug program that meets the applicable standards under Medicare Part D at the time the items and services are provided.
3. The donor, or any person on the donor's behalf, does not take any action to limit or restrict the use or compatibility of the items or services with other electronic prescribing or EHR systems.
4. For items or services that can be used for any patient without regard to payor status, the donor does not restrict, or take any action to limit, the recipient's right or ability to use the items or services for any patient.
5. Neither the recipient nor the recipient's practice (or any affiliated individual or entity) makes the receipt of items or services, or the amount or nature of the items or services, a condition of doing business with the donor.
6. Neither the eligibility of a recipient for the items or services, nor the amount or nature of the items or services, is determined in a manner that takes into account the volume or value of referrals or other business generated between the parties.
7. The arrangement is set forth in a written agreement that:
    a. Is signed by the parties.
    b. Specifies the items and services being provided and the donor's cost of the items and services.
    c. Covers all of the electronic prescribing items and services to be provided by the donor (or affiliated parties). This requirement will be met if all separate agreements between the donor (and affiliated parties) and the recipient incorporate each other by reference or if they cross-reference a master list of agreements that is maintained and updated centrally and is available for review by the Secretary of DHHS upon request. The master list should be maintained in a manner that preserves the historical record of agreements.

d. The donor does not have actual knowledge of, and does not act in reckless disregard or deliberate ignorance of, the fact that the recipient possesses or has obtained items or services equivalent to those provided by the donor.

If the hardware, software, or information technology and training services are not used solely to receive and transmit electronic prescription information, the requirements of this safe harbor are not fulfilled. However, the safe harbor regarding EHRs may apply. *(See Y. "Electronic Health Records Items and Services," page 7.48.)*

The OIG has stated that licenses, rights of use, intellectual property, upgrades, and educational support services (including, for example, help desk and maintenance services) are items and services that can potentially fit in this safe harbor, if all safe harbor conditions are met, while billing, scheduling, administrative, and other general office software cannot. Operating software that is necessary for the hardware to operate can qualify for safe harbor protection, as can patches designed to link the donor's existing electronic prescribing system to the recipient's existing electronic prescribing system. The provision of technology for personal, non-medical purposes is not protected, nor is the provision of office staff. [71 Fed. Reg. 45110, 45117 (Aug. 8, 2006)]

Selection of Recipients

The OIG has also stated that, for purposes of this safe harbor, donors may select recipients of electronic prescribing technology based upon the total number of prescriptions written by the recipient, but cannot select them based upon the number or value of prescriptions written by the recipient that are dispensed or paid by the donor (or on any other criteria based on any other business generated between the parties). Donors also may not select recipients based on the overall value of prescriptions written by the recipient or on the volume or value of prescriptions written by the recipient that are reimbursable by any federally-funded health care program. [71 Fed. Reg. 45110, 45118 (Aug. 8, 2006)]

Y. Electronic Health Records Items and Services

A safe harbor for electronic health record (EHR) items and services provides that for purposes of the AKS, "remuneration" does not include nonmonetary remuneration consisting of items and services in the form of software or information technology and training services (including cybersecurity software and services) necessary and used predominantly to create, maintain, transmit, or receive, or protect **"electronic health records,"** defined as repositories of consumer health status information in computer processable form used for clinical diagnosis and treatment for a broad array of clinic conditions, if all of the following conditions are met [42 C.F.R. Section 1001.952(y)]:

1. The items and services are provided to an individual or entity engaged in the delivery of health care by:
    a. An individual or entity, other than a laboratory company, that provides services covered by a federally-funded health care program and submits claims or requests for payment, either directly or through reassignment, to the program; or is comprised of such types of individuals or entities, or
    b. A health plan.
2. The software is interoperable at the time it is provided to the recipient. For purposes of this subparagraph, software is deemed to be interoperable if, on the date it is

provided to the recipient, it has been certified by a certifying body authorized by the National Coordinator for Health Information Technology certification criteria identified in the then-applicable version of 45 C.F.R. Part 170.

3. Neither the recipient nor the recipient's practice (or any affiliated individual or entity) makes the receipt of items or services, or the amount or nature of the items or services, a condition of doing business with the donor.

4. Neither the eligibility of a recipient for the items or services, nor the amount or nature of the items or services, is determined in a manner that directly takes into account the volume or value of referrals or other business generated between the parties. For the purposes of this paragraph, the determination is deemed not to directly take into account the volume or value of referrals or other business generated between the parties if any one of the following conditions is met:

    a. The determination is based on the total number of prescriptions written by the recipient (but not the volume or value of prescriptions dispensed or paid by the donor or billed to a federally-funded health care program);

    b. The determination is based on the size of the recipient's medical practice (for example, total patients, total patient encounters, or total relative value units);

    c. The determination is based on the total number of hours that the recipient practices medicine;

    d. The determination is based on the recipient's overall use of automated technology in his or her medical practice (without specific reference to the use of technology in connection with referrals made to the donor);

    e. The determination is based on whether the recipient is a member of the donor's medical staff, if the donor has a formal medical staff;

    f. The determination is based on the level of uncompensated care provided by the recipient; or

    g. The determination is made in any reasonable and verifiable manner that does not directly take into account the volume or value of referrals or other business generated between the parties.

5. The arrangement is set forth in a written agreement that:

    a. Is signed by the parties;

    b. Specifies the items and services being provided, the donor's cost of those items and services, and the amount of the recipient's contribution; and

    c. Covers all of the EHR items and services to be provided by the donor (or any affiliate). This requirement will be met if all separate agreements between the donor (and affiliated parties) and the recipient incorporate each other by reference or if they cross-reference a master list of agreements that is maintained and updated centrally and is available for review by the Secretary of DHHS upon request. The master list should be maintained in a manner that preserves the historical record of agreements.

6. For items or services that are of the type that can be used for any patient without regard to payor status, the donor does not restrict, or take any action to limit, the recipient's right or ability to use the items or services for any patient.
7. The items and services do not include staffing of the recipient's office and are not used primarily to conduct personal business or business unrelated to the recipient's clinical practice or clinical operations.
8. The recipient pays 15 percent of the donor's cost for the items and services, subject to these conditions:
    a. If the donation is the initial donation of EHR items and services, or the replacement of part or all of an existing system of EHR items and services, the recipient must pay 15 percent of the donor's cost before receiving the items and services. The contribution for updates to previously donated EHR items and services need not be paid in advance of receiving the update; and
    b. The donor (or any affiliated individual or entity) does not finance the recipient's payment or loan funds to be used by the recipient to pay for the items and services.
9. The donor does not shift the costs of the items or services to any federally-funded health care program.

NOTE: In the 2020 Final Rule, the OIG eliminated the Dec. 31, 2021 sunset date for this safe harbor and expanded the protection to allow the 15% cost-sharing collected from recipients to be collected at a "reasonable interval," rather than requiring it to be paid in advance. In addition, the OIG eliminated the "information blocking" element of the safe harbor as a result of the passage of the 21st Century Cures Act and the Office of the National Coordinator for Health Information Technology's related regulations.

Definitions

"Cybersecurity" means the process of protecting information by preventing, detecting, and responding to cyberattacks.

"Interoperability" means able to securely exchange data with and use data from other health information technology; and allow for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable state or federal law.

The OIG interprets the scope of covered EHR technology to exclude:

1. Hardware (and operating software that makes the hardware function);
2. Storage devices;
3. Software with core functionality other than EHR (e.g., human resources or payroll software or software packages focused primarily on practice management or billing);
4. Items or services used by a recipient primarily to conduct personal business or business unrelated to the recipient's clinical practice or clinical operations; or
5. The provision of staff to recipients or their offices. (For example, the provision of staff to transfer paper records to the electronic format would not be protected.)

The OIG interprets **"hardware"** to include routers and modems.

The safe harbor protects software, information technology and training services necessary and used predominantly for EHR purposes to include the following:

1. Interface and translation software;
2. Rights, licenses, and intellectual property related to EHR software;
3. Connectivity services, including broadband and wireless internet services;
4. Clinical support and information services related to patient care (but not separate research or marketing support services);
5. Maintenance services;
6. Secure messaging (e.g., permitting physicians to communicate with patients through electronic messaging); and
7. Training and support services (such as access to help desk services).

There are no limits on the value of technology that may be donated.

The OIG notes that this safe harbor does not require that the protected technology be used solely for EHR purposes. Instead, the EHR purposes must be predominant. Thus, depending on the circumstances, some software that relates to patient administration, scheduling functions, and billing and clinical support can be included. However, technology used primarily to conduct personal business or business unrelated to the recipient's clinical practice or clinical operations, or the provision of staff to the recipient or the recipient's office, are not protected.

All donated software and health information technology and training services are subject to the recipient's 15 percent cost sharing obligation. If updates and upgrades are included in the initial purchase price, they do not trigger additional cost sharing responsibility on the part of the recipient at the time the update or upgrade is provided. Any updates, upgrades, or modifications that are not covered under the initial purchase prices, are subject to separate cost sharing obligations by the recipient (to the extent that the donor incurs additional costs).

With respect to calculation of the costs for internally-developed (homegrown) software (that is, software that is not purchased from an outside vendor) and internally-developed add-on modules and components (that is, software purchased from an outside vendor and internally customized to ensure operational functionality), parties should use a reasonable and verifiable method for allocating costs and are strongly encouraged to maintain contemporaneous and accurate documentation. Methods of cost allocation will be scrutinized by the OIG to ensure that they do not inappropriately shift costs in a manner that provides an excess benefit to the recipient or results in the recipient effectively paying less than 15 percent of the donor's true cost of the technology. [71 Fed. Reg. 45110, 45121-45133 (Aug. 8, 2006)]

Z. Federally-Qualified Health Centers and Medicare Advantage Organizations

A safe harbor protects remuneration between a federally-qualified health center (FQHC), or an entity controlled by an FQHC, and a Medicare Advantage (MA) organization that is paid pursuant to a written agreement to provide services to the MA organization's enrollees [42 C.F.R. Section 1001.952(z)].

AA. Drug Discounts Under the Medicare Coverage Gap Discount Program

A safe harbor protects drug discounts to beneficiaries under the Medicare Coverage Gap Discount Program under which drug manufacturers agree with CMS to provide certain beneficiaries access to discounts on drugs [42 C.F.R. Section 1001.952 (aa)]. The safe harbor applies to certain drugs (applicable drugs) and certain beneficiaries (applicable beneficiaries), as defined under the program, and requires that the manufacturer participate in, and be in compliance with all requirements of, the program.

AB. Local Transportation

A safe harbor protects free or discounted local transportation provided by eligible entities, which includes hospitals [42 C.F.R. Section 1001.952 (bb)]. The following are the conditions that must be met under the safe harbor:

1. The availability of the free or discounted transportation services:
    a. Is set forth in a policy, which the eligible entity applies uniformly and consistently; and
    b. Is not determined in a manner related to the past or anticipated volume or value of federal health care program business;
2. The free or discounted transportation services are not air, luxury, or ambulance-level transportation;
3. The eligible entity does not publicly market or advertise the free or discounted local transportation services, no marketing of health care items and services occurs during the course of the transportation or at any time by drivers who provide the transportation, and drivers or others arranging for the transportation are not paid on a per-beneficiary-transported basis;
4. The eligible entity makes the free or discounted transportation available only:
    a. To an individual who is an established patient of the eligible entity that is providing the free or discounted transportation, if the eligible entity is a provider or supplier of health care services; and an established patient of the provider or supplier to or from which the individual is being transported;
    b. Within 25 miles of the health care provider or supplier to or from which the patient would be transported, or within 75 miles if the patient resides in a rural area, except that, if the patient is discharged from an inpatient facility following inpatient admission or released from a hospital after being placed in observation status for at least 24 hours and transported to the patient's residence, or another residence of the patient's choice, the mileage limits do not apply; and
    c. For the purpose of obtaining medically necessary items and services.
5. The eligible entity that makes the transportation available bears the costs of the free or discounted transportation services and does not shift the burden of these costs onto any federal health care program, other payers, or individuals.

The safe harbor also protects a shuttle service made available to federal health care program beneficiaries if the following requirements are met:

1. The shuttle service is not air, luxury, or ambulance-level transportation;

2. The shuttle service is not marketed or advertised (other than posting necessary route and schedule details), no marketing of health care items and services occurs during the course of the transportation or at any time by drivers who provide the transportation, and drivers or others arranging for the transportation are not paid on a per-beneficiary-transported basis;

3. The eligible entity makes the shuttle service available only within the eligible entity's local area, meaning there are no more than 25 miles from any stop on the route to any stop at a location where health care items or services are provided, except that if a stop on the route is in a rural area, the distance may be up to 75 miles between that stop and any providers or suppliers on the route; and

4. The eligible entity that makes the shuttle service available bears the costs of the free or discounted shuttle services and does not shift the burden of these costs onto any federal health care program, other payers, or individuals.

The OIG interprets this safe harbor to be available for transportation provided through rideshare arrangements. [85 Fed. Reg. 77684, 77707 (Dec. 2, 2020)]

Definitions

An **"eligible entity"** is any individual or entity, except for individuals or entities (or family members or others acting on their behalf) that primarily supply health care items.

"Established patient" is a person who has selected and initiated contact to schedule an appointment with a provider or supplier, or who previously has attended an appointment with the provider or supplier.

"Shuttle service" is a vehicle that runs on a set route, on a set schedule.

"Rural area" is an area that is not an urban area, as defined in this rule.

"Urban area" is a Metropolitan Statistical Area (MSA) as defined by the Executive Office of Management and Budget.

AC. Point-of-Sale Reductions in Price for Prescription Pharmaceutical Products

NOTE: This safe harbor has a delayed effective date of Jan. 1, 2023.

A safe harbor for price reductions for prescription pharmaceutical products provides that for purposes of the AKS, "remuneration" does not include a reduction in price from a manufacturer to a plan sponsor under Medicare Part D or a Medicaid Managed Care Organization (MCO) for a prescription pharmaceutical product that is payable, in whole or in part, by a plan sponsor under Medicare Part D or a Medicaid MCO, provided the following conditions are met with regard to that price reduction [42 C.F.R. Section 1001.952(cc)]:

1. The manufacturer and the plan sponsor under Medicare Part D, a Medicaid MCO, or the pharmacy benefit manager (PBM) acting under contract with either, set the price reduction in advance, in writing, by the time of the first purchase of the product at that reduced price by the plan sponsor or Medicaid MCO on behalf of an enrollee;

2. The reduction in price does not involve a rebate unless the full value of the price reduction is provided to the dispensing pharmacy by the manufacturer, directly or indirectly, through a point-of-sale chargeback or series of point-of-sale chargebacks, or is required by law; and

3. The price reduction must be completely reflected in the price of the prescription pharmaceutical product at the time the pharmacy dispenses it to the beneficiary.

Definition

A **"point-of-sale chargeback"** is a payment by a manufacturer made directly or indirectly (through a PBM or other entity) to a dispensing pharmacy equal to the price reduction agreed upon in writing between the Plan Sponsor under Part D, the Medicaid MCO, or a PBM acting under contract with either, and the manufacturer of the prescription pharmaceutical product.

AD. Pharmacy Benefit Manager Service Fees

NOTE: This safe harbor has a delayed effective date of Jan. 1, 2023.

A safe harbor for PBM service fees provides that for purposes of the AKS, "remuneration" does not include any payment by a pharmaceutical manufacturer to a PBM for services the PBM provides to the pharmaceutical manufacturer related to the pharmacy benefit management services that the PBM furnishes to one or more health plans as long as the following conditions are met [42 C.F.R. Section 1001.952(dd)]:

1. The PBM has a written agreement with the pharmaceutical manufacturer, signed by the parties, that covers all of the services the PBM provides to the manufacturer in connection with the PBM's arrangements with health plans for the term of the agreement and specifies each of the services to be provided by the PBM and the compensation associated with such services.
2. The services performed under the agreement do not involve the counseling or promotion of a business arrangement or other activity that violates any state or federal law.
3. The compensation paid to the PBM is:
    a. Consistent with fair market value in an arm's-length transaction;
    b. A fixed payment, not based on a percentage of sales; and
    c. Not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties, or between the manufacturer and the PBM's health plans, for which payment may be made in whole or in part under Medicare, Medicaid, or other federal health care program.
4. The PBM discloses the following in writing:
    a. To each health plan with which it contracts, at least annually, the services rendered to each pharmaceutical manufacturer related to the PBM's arrangements to furnish pharmacy benefit management services to the health plan, and
    b. To the Secretary upon request, the services rendered to each pharmaceutical manufacturer related to the PBM's arrangements to furnish pharmacy benefit management services to the health plan and the fees paid for such services.

AE. Care Coordination Arrangements to Improve Quality, Health Outcomes, and Efficiency

OIG finalized a new safe harbor in its 2020 Final Rule as part of three new safe harbors intended to remove regulatory obstacles to value-based payment arrangements. These safe harbors focus on risk assumed at the value-based enterprise (VBE) level. One of those safe harbors is for in-kind remuneration used for care coordination and care management activities, where the physician is not at financial risk [42 C.F.R. Section 1001.952(ee)]. These care coordination arrangements are protected if all of the following 13 standards are met:

1. The remuneration exchanged is in-kind, used predominantly to engage in value-based activities that are directly connected to the coordination and management of care for the target patient population and does not result in more than incidental benefits to persons outside of the target patient population, and the in-kind remuneration is not exchanged or used more than incidentally for the recipient's billing or financial management services, or for the purpose of marketing items or services furnished by the VBE or a VBE participant to patients or for patient recruitment activities.
2. The value-based arrangement is commercially reasonable, considering both the arrangement itself and all value-based arrangements within the VBE.
3. The terms of the value-based arrangement are set forth in writing and signed by the parties in advance of, or contemporaneously with, the commencement of the value-based arrangement and any material change to the value-based arrangement. The writing must state at a minimum:
    a. The value-based purpose(s) of the value-based activities provided for in the value-based arrangement;
    b. The value-based activities to be undertaken by the parties to the value-based arrangement;
    c. The term of the value-based arrangement;
    d. The target patient population;
    e. A description of the remuneration;
    f. Either the offeror's cost for the remuneration and the reasonable accounting methodology used by the offeror to determine its cost, or the fair market value of the remuneration;
    g. The percentage and amount contributed by the recipient;
    h. If applicable, the frequency of the recipient's contribution payments for ongoing costs; and
    i. The outcome or process measure(s) against which the recipient will be measured.
4. The parties to the value-based arrangement establish one or more legitimate outcome or process measures that:
    a. The parties reasonably anticipate will advance the coordination and management of care for the target patient population based on clinical evidence or credible medical or health sciences support;

b. Include one or more benchmarks that are related to improving or maintaining improvements in the coordination and management of care for the target patient population;

c. Are monitored, periodically assessed, and prospectively revised as necessary to ensure that the measure and its benchmark continue to advance the coordination and management of care of the target patient population;

d. Relate to the remuneration exchanged under the value-based arrangement; and

e. Are not based solely on patient satisfaction or patient convenience.

5. The offeror of the remuneration does not take into account the volume or value of, or condition the remuneration on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement.

6. The recipient pays at least 15 percent of the offeror's cost for the remuneration, using any reasonable accounting methodology, or the fair market value of the in-kind remuneration. If it is a one-time cost, the recipient makes such contribution in advance of receiving the in-kind remuneration. If it is an ongoing cost, the recipient makes such contribution at reasonable, regular intervals.

7. The value-based arrangement does not limit the VBE participant's ability to make decisions in the best interests of its patients, induce parties to furnish medically unnecessary items or services, or reduce or limit medically necessary items or services furnished to any patient, or direct or restrict referrals to a particular provider, practitioner, or supplier if:

a. A patient expresses a preference for a different practitioner, provider, or supplier;

b. The patient's payor determines the provider, practitioner, or supplier; or

c. Such direction or restriction is contrary to applicable law under Medicare and Medicaid.

8. The exchange of remuneration by a limited technology participant and another VBE participant or the VBE must not be conditioned on any recipient's exclusive use or minimum purchase of any item or service manufactured, distributed, or sold by the limited technology participant.

9. The VBE, a VBE participant in the value-based arrangement acting on the VBE's behalf, or the VBE's accountable body or responsible person reasonably monitors and assesses the following and reports the monitoring and assessment of the following to the VBE's accountable body or responsible person, as applicable, no less frequently than annually or at least once during the term of the value-based arrangement for arrangements with terms of less than one year:

a. The coordination and management of care for the target patient population in the value-based arrangement;

b. Any deficiencies in the delivery of quality care under the value-based arrangement; and

c. Progress toward achieving the legitimate outcome or process measure(s) in the value-based arrangement.

10. If the VBE's accountable body or responsible person determines that the value-based arrangement has resulted in material deficiencies in quality of care or is unlikely to further the coordination and management of care for the target patient population, the parties must within 60 days either: terminate the arrangement or develop and implement a corrective action plan designed to remedy the deficiencies within 120 days. If the corrective action plan fails to remedy the deficiencies within 120 days, the value-based arrangement must be terminated.

11. The offeror does not and should not know that the remuneration is likely to be diverted, resold, or used by the recipient for an unlawful purpose.

12. For a period of at least six years, the VBE or VBE participant makes available upon request, all materials and records sufficient to establish compliance.

13. The remuneration is not exchanged by a pharmaceutical manufacturer, distributor, or wholesaler, a pharmacy benefit manager, a laboratory company, or a pharmacy that primarily compounds drugs or primarily dispenses compounded drugs, except to the extent the entity is a limited technology participant, a manufacturer of a device or medical supply, an entity or individual that sells or rents durable medical equipment, prosthetics, orthotics, or supplies covered by a federal health care program (other than a pharmacy or a physician, provider, or other entity that primarily furnishes services), or a medical device distributor or wholesaler that is not otherwise a manufacturer of a device or medical supplies.

Definitions

"Coordination and management of care" (or coordinating and managing care) means the deliberate organization of patient care activities and sharing of information between two or more VBE participants, one or more VBE participants and the VBE, or one or more VBE participants and patients, that is designed to achieve safer, more effective, or more efficient care to improve the health outcomes of the target patient population.

"Digital health technology" means hardware, software, or services that electronically capture, transmit, aggregate, or analyze data and that are used for the purpose of coordinating and managing care. This term includes any internet or other connectivity service that is necessary and used to enable the operation of the item or service for that purpose.

"Limited technology participant" means a VBE participant that exchanges digital health technology with another VBE participant or a VBE and that is:

1. A manufacturer of a device or medical supply, but not including a manufacturer of a device or medical supply that was obligated under 42 C.F.R. Section 403.906 to report one or more ownership or investment interests held by a physician or an immediate family member during the preceding calendar year, or that reasonably anticipates that it will be obligated to report one or more ownership or investment interests held by a physician or an immediate family member during the present calendar year (for purposes of this paragraph, the terms "ownership or investment interest," "physician," and "immediate family member" have the same meaning as set forth in 42 C.F.R. Section 403.902); or

2. An entity or individual that sells or rents durable medical equipment, prosthetics, orthotics, or supplies covered by a federal health care program (other than a pharmacy or a physician, provider, or other entity that primarily furnishes services).

"Manufacturer of a device or medical supply" means an entity that meets the definition of applicable manufacturer in 42 C.F.R. Section 403.902 because it is engaged in the production, preparation, propagation, compounding, or conversion of a device or medical supply that meets the definition of covered drug, device, biological, or medical supply in 42 C.F.R. Section 403.902, but not including entities under common ownership with such entity.

"Target patient population" means an identified patient population selected by the VBE or its VBE participants using legitimate and verifiable criteria that:

1. Are set out in writing in advance of the commencement of the value-based arrangement and
2. Further the VBE's value-based purpose(s).

"Value-based activity" means any of the following activities, provided that the activity is reasonably designed to achieve at least one value-based purpose of the value-based enterprise:

1. The provision of an item or service,
2. The taking of an action, or
3. The refraining from taking an action

Making a referral is not a value-based activity.

"Value-based arrangement" means an arrangement for the provision of at least one value-based activity for a target patient population to which the only parties are the value-based enterprise and one or more of its VBE participants or VBE participants in the same value-based enterprise.

"Value-based enterprise" (VBE) means two or more VBE participants:

1. Collaborating to achieve at least one value-based purpose;
2. Each of which is a party to a value-based arrangement with the other or at least one other VBE participant in the VBE;
3. That have an accountable body or person responsible for financial and operational oversight of the VBE; and
4. That have a governing document that describes the VBE and how the VBE participants intend to achieve its value-based purpose(s).

"Value-based enterprise participant" or VBE participant means an individual or entity that engages in at least one value-based activity as part of a VBE, other than a patient acting in their capacity as a patient.

"Value-based purpose" means:

1. Coordinating and managing the care of a target patient population;
2. Improving the quality of care for a target patient population;
3. Appropriately reducing the costs to or growth in expenditures of payors without reducing the quality of care for a target patient population; or

4. Transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population.

AF. Value-Based Arrangements With Substantial Downside Financial Risk

OIG finalized a new safe harbor in its 2020 Final Rule as part of three new safe harbors intended to remove regulatory obstacles to value-based payment arrangements. These safe harbors focus on risk assumed at the value-based enterprise level. One of those safe harbors is for value-based arrangements with substantial downside financial risk [42 C.F.R. Section 1001.952(ff)]. This safe harbor requires the following eight standards are met:

1. The remuneration is not exchanged by:
    a. A pharmaceutical manufacturer, distributor, or wholesaler;
    b. A pharmacy benefit manager;
    c. A laboratory company;
    d. A pharmacy that primarily compounds drugs or primarily dispenses compounded drugs;
    e. A manufacturer of a device or medical supply;
    f. An entity or individual that sells or rents durable medical equipment, prosthetics, orthotics, or supplies covered by a federal health care program (other than a pharmacy or a physician, provider, or other entity that primarily furnishes services); or
    g. A medical device distributor or wholesaler that is not otherwise a manufacturer of a device or medical supplies.
2. The VBE (directly or through a VBE participant, other than a payor, acting on the VBE's behalf) has assumed through a written contract or a value-based arrangement (or has entered into a written contract or a value-based arrangement to assume in the next six months) substantial downside financial risk from a payor for a period of at least one year.
3. The VBE participant (unless the VBE participant is the payor from which the VBE is assuming risk) is at risk for a meaningful share of the VBE's substantial downside financial risk for providing or arranging for the provision of items and services for the target patient population.
4. The remuneration provided by, or shared among, the VBE and VBE participant:
    a. Is directly connected to one or more of the VBE's value-based purposes, at least one of which must be a value-based purpose;
    b. Unless exchanged pursuant to risk methodologies defined in this section, is used predominantly to engage in value-based activities that are directly connected to the items and services for which the VBE has assumed (or has entered into a written contract or value-based arrangement to assume in the next six months) substantial downside financial risk;
    c. Does not include the offer or receipt of an ownership or investment interest in an entity or any distributions related to such ownership or investment interest; and

d. Is not exchanged or used for the purpose of marketing items or services furnished by the VBE or a VBE participant to patients or for patient recruitment activities.

5. The value-based arrangement is set forth in writing, is signed by the parties in advance of, or contemporaneously with, the commencement of the value-based arrangement and any material change to the value-based arrangement, and specifies all material terms including:

   a. Terms evidencing that the VBE is at substantial downside financial risk or will assume such risk in the next six months for the target patient population;

   b. A description of the manner in which the VBE participant (unless the VBE participant is the payor from which the VBE is assuming risk) has a meaningful share of the VBE's substantial downside financial risk; and

   c. The value-based activities, the target patient population, and the type of remuneration exchanged.

6. The VBE or VBE participant offering the remuneration does not take into account the volume or value of, or condition the remuneration on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement.

7. The value-based arrangement does not:

   a. Limit the VBE participant's ability to make decisions in the best interests of its patients;

   b. Direct or restrict referrals to a particular provider, practitioner, or supplier if a patient expresses a preference for a different practitioner, provider, or supplier; the patient's payor determines the provider, practitioner, or supplier, or such direction or restriction is contrary to applicable law under Medicare or Medicaid, or

   c. Induce parties to reduce or limit medically necessary items or services furnished to any patient.

8. For a period of at least six years, the VBE or VBE participant makes available to the secretary, upon request, all materials and records sufficient to establish compliance.

Definitions

"Substantial downside financial risk" means:

1. Financial risk equal to at least 30 percent of any loss, where losses and savings are calculated by comparing current expenditures for all items and services that are covered by the applicable payor and furnished to the target patient population to a bona fide benchmark designed to approximate the expected total cost of such care;

2. Financial risk equal to at least 20 percent of any loss, where:

   a. Losses and savings are calculated by comparing current expenditures for all items and services furnished to the target patient population pursuant to a defined clinical episode of care that are covered by the applicable payor to a

bona fide benchmark designed to approximate the expected total cost of the care for the defined clinical episode of care; and

b. The parties design the clinical episode of care to cover items and services collectively furnished in more than one care setting; or

3. The VBE receives from the payor a prospective, per-patient payment that is designed to produce material savings and paid on a monthly, quarterly, or annual basis for a predefined set of items and services furnished to the target patient population, designed to approximate the expected total cost of expenditures for the predefined set of items and services.

"Meaningful share" means the VBE participant:

1. Assumes two-sided risk for at least five percent of the losses and savings, as applicable, realized by the VBE pursuant to its assumption of substantial downside financial risk; or
2. Receives from the VBE a prospective, per-patient payment on a monthly, quarterly, or annual basis for a predefined set of items and services furnished to the target patient population, designed to approximate the expected total cost of expenditures for the predefined set of items and services, and does not claim payment in any form from the payor for the predefined items and services.

AG. Value-Based Arrangements with Full Financial Risk

OIG finalized a new safe harbor in its 2020 Final Rule as part of three new safe harbors intended to remove regulatory obstacles to value-based payment arrangements. These safe harbors focus on risk assumed at the value-based enterprise level. One of those safe harbors is for value-based arrangements with full financial risk [42 C.F.R. Section 1001.952(gg)]. This safe harbor requires the following nine standards are met:

1. The remuneration is not exchanged by:
   a. A pharmaceutical manufacturer, distributor, or wholesaler;
   b. A pharmacy benefit manager;
   c. A laboratory company;
   d. A pharmacy that primarily compounds drugs or primarily dispenses compounded drugs;
   e. A manufacturer of a device or medical supply;
   f. An entity or individual that sells or rents durable medical equipment, prosthetics, orthotics, or supplies covered by a federal health care program (other than a pharmacy or a physician, provider, or other entity that primarily furnishes services); or
   g. A medical device distributor or wholesaler that is not otherwise a manufacturer of a device or medical supplies.
2. The VBE (directly or through a VBE participant, other than a payor, acting on behalf of the VBE) has assumed through a written contract or a value-based arrangement (or has entered into a written contract or a value-based arrangement to assume in the next one year) full financial risk from a payor.

3. The value-based arrangement is set forth in writing, is signed by the parties, and specifies all material terms, including the value-based activities and the term.
4. The VBE participant (unless the VBE participant is a payor) does not claim payment in any form from the payor for items or services covered under the contract or value-based arrangement between the VBE and the payor.
5. The remuneration provided by, or shared among, the VBE and VBE participant:
    a. Is directly connected to one or more of the VBE's value-based purposes;
    b. Does not include the offer or receipt of an ownership or investment interest in an entity or any distributions related to such ownership or investment interest; and
    c. Is not exchanged or used for the purpose of marketing items or services furnished by the VBE or a VBE participant to patients or for patient recruitment activities.
6. The value-based arrangement does not induce parties to reduce or limit medically necessary items or services furnished to any patient.
7. The VBE or VBE participant offering the remuneration does not take into account the volume or value of, or condition the remuneration on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement.
8. The VBE provides or arranges for a quality assurance program for services furnished to the target patient population that protects against underutilization and assesses the quality of care furnished to the target patient population.
9. For a period of at least six years, the VBE or VBE participant makes available to the secretary, upon request, all materials and records sufficient to establish compliance.

Definitions

"Full financial risk" means the VBE is financially responsible on a prospective basis for the cost of all items and services covered by the applicable payor for each patient in the target patient population for a term of at least one year.

"Prospective basis" means that the VBE has assumed financial responsibility for the cost of all items and services covered by the applicable payor prior to the provision of items and services to patients in the target patient population.

"Items and services" means health care items, devices, supplies, and services.

AH. Arrangements for Patient Engagement and Support to Improve Quality Health Outcomes, and Efficiency

OIG finalized a new safe harbor in its 2020 Final Rule for providing patient engagement tools and support to improve quality, healthy outcomes, and efficiency, but the safe harbor is available only to "value-based enterprise" participants in a target patient population [42 C.F.R. Section 1001.952(hh)]. This safe harbor protects arrangements for patient engagement if all of the following nine standards are met:

1. The VBE participant is not:
    a. A pharmaceutical manufacturer, distributor, or wholesaler;

b. A pharmacy benefit manager;

c. A laboratory company;

d. A pharmacy that primarily compounds drugs or primarily dispenses compounded drugs;

e. A manufacturer of a device or medical supply, unless the patient engagement tool or support is digital health technology;

f. An entity or individual that sells or rents durable medical equipment, prosthetics, orthotics, or supplies covered by a federal health care program (other than a pharmacy, a manufacturer of a device or medical supply, or a physician, provider, or other entity that primarily furnishes services);

g. A medical device distributor or wholesaler that is not otherwise a manufacturer of a device or medical supply; or

h. A manufacturer of a device or medical supply that was obligated under 42 C.F.R. Section 403.906 to report one or more ownership or investment interests held by a physician or an immediate family member during the preceding calendar year, or that reasonably anticipates that it will be obligated to report one or more ownership or investment interests held by a physician or an immediate family member during the present calendar year, even if the patient engagement tool or support is digital health technology (for purposes of this paragraph, the terms "ownership" or "investment interest," "physician," and "immediate family member" have the same meaning as set forth in 42 C.F.R. Section 403.902).

2. The patient engagement tool or support is furnished directly to the patient (or the patient's caregiver, family member, or other individual acting on the patient's behalf) by a VBE participant that is a party to the value-based arrangement or its eligible agent.

3. The patient engagement tool or support:

   a. Is an in-kind item, good, or service;

   b. That has a direct connection to the coordination and management of care of the target patient population;

   c. Does not include any cash or cash equivalent;

   d. Does not result in medically unnecessary or inappropriate items or services reimbursed in whole or in part by a federal health care program;

   e. Is recommended by the patient's licensed health care professional; and

   f. Advances one or more of the following goals:

      - Adherence to a treatment regimen determined by the patient's licensed health care professional.

      - Adherence to a drug regimen determined by the patient's licensed health care professional.

      - Adherence to a follow up care plan established by the patient's licensed health care professional.

- Prevention or management of a disease or condition as directed by the patient's licensed health care professional.
- Ensures patient safety.

4. The patient engagement tool or support is not funded or contributed by a VBE participant that is not a party to the applicable value-based arrangement or an entity.
5. The aggregate retail value of patient engagement tools and supports furnished to a patient by a VBE participant on an annual basis does not exceed $527 (effective Jan. 1, 2022). This monetary cap was initially $500 per year, but the cap is adjusted each calendar year to the nearest whole dollar by the increase in the Consumer Price Index — Urban All Items (CPI-U) for the 12-month period ending the preceding September 30. OIG will publish guidance after September 30 of each year announcing the increase.
6. The VBE participant or any eligible agent does not exchange or use the patient engagement tools or supports to market other reimbursable items or services or for patient recruitment purposes.
7. For a period of at least six years, the VBE participant makes available to the Secretary, upon request, all materials and records sufficient to establish that the patient engagement tool or support was distributed in a manner that meets the conditions listed above.
8. The availability of a tool or support is not determined in a manner that takes into account the type of insurance coverage of the patient.

Definitions

"Eligible agent" means any person or entity that is not identified in paragraph 1. above as ineligible to furnish protected tools and supports under this paragraph.

AI. CMS-Sponsored Model Arrangements and CMS-Sponsored Model Patient Incentives

OIG finalized a new safe harbor in its 2020 Final Rule for delivery and payment arrangements, and patient incentives, provided in connection with models under either the CMS Innovation Center or the Medicare Shared Savings Program [42 C.F.R. Section 1001.952(ii)]. The safe harbor does not replace the existing fraud and abuse waivers (which remain in effect), but instead should reduce the future need for model-specific waivers.

This safe harbor provides that remuneration does not include an exchange of anything of value between or among CMS-sponsored model parties under a CMS-sponsored model arrangement for which CMS has determined that this safe harbor is available if all of the following conditions are met:

1. The CMS-sponsored model parties reasonably determine that the CMS-sponsored model arrangement will advance one or more goals of the CMS-sponsored model;
2. The exchange of value does not induce CMS-sponsored model parties or other providers or suppliers to furnish medically unnecessary items or services, or reduce or limit medically necessary items or services furnished to any patient;

3. The CMS-sponsored model parties do not offer, pay, solicit, or receive remuneration in return for, or to induce or reward, any federal health care program referrals or other federal health care program business generated outside of the CMS-sponsored model;
4. The CMS-sponsored model parties in advance of or contemporaneously with the commencement of the CMS-sponsored model arrangement set forth the terms of the CMS-sponsored model arrangement in a signed writing. The writing must specify at a minimum the activities to be undertaken by the CMS-sponsored model parties and the nature of the remuneration to be exchanged under the CMS-sponsored model arrangement;
5. The parties to the CMS-sponsored model arrangement make available to the Secretary, upon request, all materials and records sufficient to establish whether the remuneration was exchanged in a manner that meets the conditions of this safe harbor; and
6. The CMS-sponsored model parties satisfy such programmatic requirements as may be imposed by CMS in connection with the use of this safe harbor.

Additionally, remuneration does not include a CMS-sponsored model patient incentive for which CMS has determined that this safe harbor is available if all of the following conditions are met:

1. The CMS-sponsored model participant reasonably determines that the CMS-sponsored model patient incentive will advance one or more goals of the CMS-sponsored model;
2. The CMS-sponsored model patient incentive has a direct connection to the patient's health care unless the participation documentation expressly specifies a different standard;
3. The CMS-sponsored model patient incentive is furnished by a CMS-sponsored model participant (or by an agent of the CMS-sponsored model participant under the CMS-sponsored model participant's direction and control), unless otherwise specified by the participation documentation;
4. The CMS-sponsored model participant makes available to the Secretary, upon request, all materials and records sufficient to establish whether the CMS-sponsored model patient incentive was distributed in a manner that meets the conditions of this safe harbor; and
5. The CMS-sponsored model patient incentive is furnished consistent with the CMS-sponsored model and satisfies such programmatic requirements as may be imposed by CMS in connection with the use of this safe harbor.

Definitions

"CMS-sponsored model" means a model being tested under section 1115A(b) of the Social Security Act or a model expanded under section 1115A(c) of the Social Security Act or the Medicare shared savings program under section 1899 of the Social Security Act.

"CMS-sponsored model arrangement" means a financial arrangement between or among CMS-sponsored model parties to engage in activities under the CMS-sponsored model

that is consistent with, and is not a type of arrangement prohibited by, the participation documentation.

"CMS-sponsored model participant" means an individual or entity that is subject to and is operating under participation documentation with CMS to participate in a CMS-sponsored model.

"CMS-sponsored model party" means a CMS-sponsored model participant or another individual or entity whom the participation documentation specifies may enter into a CMS-sponsored model arrangement.

"CMS-sponsored model patient incentive" means remuneration not of a type prohibited by the participation documentation that is furnished to a patient under the terms of a CMS-sponsored model.

"Participation documentation" means the participation agreement, legal instrument setting forth the terms and conditions of a grant or cooperative agreement, regulations, or model-specific addendum to an existing contract with CMS that specifies the terms of a CMS-sponsored model.

This safe harbor protects:

1. For a CMS-sponsored model governed by participation documentation other than the legal instrument setting forth the terms and conditions of a grant or a cooperative agreement, the exchange of remuneration between CMS-sponsored model parties that occurs on or after the first day on which services under the CMS-sponsored model begin and no later than 6 months after the final payment determination made by CMS under the model;
2. For a CMS-sponsored model governed by the legal instrument setting forth the terms and conditions of a grant or cooperative agreement, the exchange of remuneration between CMS-sponsored model parties that occurs on or after the first day of the period of performance (as defined at 45 C.F.R. Section 75.2) or such other date specified in the participation documentation and no later than 6 months after closeout occurs pursuant to 45 C.F.R. Section 75.381; and
3. For a CMS-sponsored model patient incentive, an incentive given on or after the first day on which patient care services may be furnished under the CMS-sponsored model as specified by CMS in the participation documentation and no later than the last day on which patient care services may be furnished under the CMS-sponsored model, unless a different timeframe is established in the participation documentation. A patient may retain any incentives furnished in compliance with this provision.

AJ. Cybersecurity Technology and Related Services

OIG finalized a new safe harbor in its 2020 Final Rule for donations of cybersecurity technology and related services, as long as four conditions are met:

1. The donor does not:
    a. Directly take into account the volume or value of referrals or other business generated between the parties when determining the eligibility of a potential recipient for the technology or services, or the amount or nature of the technology or services to be donated; or

b. Condition the donation of technology or services, or the amount or nature of the technology or services to be donated, on future referrals.

2. Neither the recipient nor the recipient's practice (or any affiliated individual or entity) makes the receipt of technology or services, or the amount or nature of the technology or services, a condition of doing business with the donor.

3. A general description of the technology and services being provided and the amount of the recipient's contribution, if any, are set forth in writing and signed by the parties.

4. The donor does not shift the costs of the technology or services to any federal health care program.

[42 C.F.R. Section 1001.952(jj)]

Definitions

"Cybersecurity" means the process of protecting information by preventing, detecting, and responding to cyberattacks.

"Technology" means any software or other types of information technology.

AK. ACO Beneficiary Incentive Program

OIG finalized a new safe harbor in its 2020 Final Rule protecting incentive payments made by an ACO to an assigned beneficiary under a beneficiary incentive program established under section 1899(m) of the Social Security Act. By statute, ACOs participating in certain CMS-approved, two-sided risk models may provide incentive payments to beneficiaries who receive qualifying primary care services. The anti-kickback statute safe harbor follows the statutory exception, and protects incentive payments for beneficiaries assigned to the ACO by CMS. [42 C.F.R. Section 1001.952(kk)]

V. HHS WAIVERS OF THE AKS

Section 1115A(d)(1) of the Social Security Act (the Act) authorizes the Secretary of Health and Human Services to waive certain fraud and abuse laws as necessary solely for purposes of testing payment and service delivery models developed by the Center for Medicare and Medicaid Innovation (the Innovation Center). The OIG has issued waivers for the following HHS innovative health care programs:[6]

1. Pioneer Accountable Care Organization (ACO) Model — On Dec. 8, 2011, the Department's Office of Inspector General (OIG) and CMS jointly issued waivers for specified arrangements involving accountable care organizations (ACOs) participating in the Pioneer ACO Model. This model began in 2012 and the final performance year concluded on Dec. 31, 2016.

2. Bundled Payment for Care Improvement (BPCI) Models — The OIG and CMS have jointly issued waivers for specified arrangements involving BPCI Model participants. BPCI Model 1 waivers were issued on Sept. 13, 2012, and waivers for models 2, 3 and 4 were issued on July 26, 2013. The final performance year concluded on Sept. 30, 2018.

6 This list excludes waivers which are specific to Maryland and Vermont.

3. Health Care Innovation Awards (HCIA) Round Two — On Jan. 20, 2015, the OIG issued waivers for patient engagement arrangements in the Health Care Innovation Awards (HCIA) Round Two project. (There are currently no HCIA Round Two projects continuing).

4. Comprehensive ESRD Care (CEC) Model — On July 15, 2015, the OIG and CMS jointly issued waivers for specified arrangements involving large dialysis organizations (LDOs) and small dialysis organizations (non-LDOs) participating in the CEC Model.

5. Comprehensive Care for Joint Replacement (CJR) Model — The model began on April 1, 2016. On Dec. 05, 2017, the OIG and CMS jointly issued new waivers, effective Jan. 1, 2018, for specified arrangements permitted under the Comprehensive Care for Joint Replacement Model (more fully described below). These new waivers were the result of certain programmatic changes being made by the CMS to the CJR Model and on their effective date superseded the original waiver notice, which was jointly issued by OIG and CMS on Nov. 16, 2015.

6. Next Generation ACO Model — The Next Generation ACO Model began in 2016 and, though was previously scheduled to run through 2020, was extended due to the COVID-19 pandemic to run until Dec. 31, 2021. The OIG and CMS jointly issued five waivers applicable to the Next Generation ACO Models, which were finalized on Dec. 12, 2018.

7. Oncology Care Model (OCM) — On July 1, 2016, the OIG and CMS jointly issued waivers for specified arrangements permitted under a 5-year Oncology Care Model which began in January 2017, pursuant to which certain participating physician practices have entered into payment arrangements that include financial and performance accountability for episodes of care surrounding chemotherapy administration to cancer patients.

8. Part D Enhanced Medication Therapy Management (MTM) Model — On June 2, 2016, the OIG issued a waiver for certain beneficiary incentives provided by PDP Sponsors in the MTM Model 5-year performance period which began Jan. 1, 2017.

9. Part D Payment Modernization Model — On Nov. 15, 2019, the OIG issued a waiver for certain beneficiary incentives provided by Part D Sponsors in the Part D Payment Modernization Model. CMS announced that the model will conclude on Dec. 31, 2021, and will not be tested in CY 2022- CY 2024.

10. Medicare Advantage Value-Based Insurance Design (VBID) Model — On Aug. 18, 2020 the OIG issued an amended notice of waivers, effective Jan. 1, 2021, for certain beneficiary incentives provided by Medicare Advantage Organizations in the VBID Model (the result of certain programmatic changes made by CMS to the model and which amends and restates the original waiver notice issued by the OIG on Nov. 15, 2019.

11. Medicare Diabetes Prevention Program (MDPP) Expanded Model — On March 1, 2018, the OIG issued a waiver for certain beneficiary engagement incentive arrangements that are part of the MDPP expanded model.

12. Bundled Payments for Care Improvement Advanced (BPCI Advanced) Model — On Dec. 13, 2019, the OIG and CMS jointly issued an amended notice of waivers for specified arrangements entered into pursuant to the BPCI Advanced Model. The amended notice of waivers was issued as a result of certain programmatic changes being made by the CMS to the model. The Dec. 13, 2019, amended notice supersedes the original waiver notice jointly issued by OIG and CMS on May 25, 2018.
13. Medicare Shared Savings Program — On Oct. 29, 2015, the OIG and CMS jointly published the Medicare Program; Final Waivers in Connection with the Shared Saving Program Final Rule, which waivers are more fully described below.
14. Part D Senior Savings Model — On Aug. 11, 2020, the OIG issued a waiver for certain beneficiary incentives provided by Part D Sponsors in the Part D Senior Savings Model. Through this Part D Senior Savings Model, CMS is testing the impact of offering beneficiaries an increased choice of enhanced alternative Part D plan options that offer lower out-of-pocket costs for insulin. The voluntary model began on Jan. 1, 2021, and is scheduled to continue for five years, through Dec. 31, 2025.
15. Comprehensive Kidney Care Contracting (CKCC) Options of the Kidney Care Choices Model — On Sept. 11, 2020, the OIG and CMS jointly issued a waiver for specified start-up arrangements entered into by certain individuals and entities participating in the implementation period of the CKCC Options of the Kidney Care Choices Model. The first performance year for this model will commence Jan. 1, 2022, and is designed to operate for five performance years.
16. Global and Professional Options of the Direct Contracting Model — On Sept. 18, 2020, the OIG and CMS jointly issued a waiver for specified start-up arrangements entered into by certain individuals and entities participating in the implementation period of the Global and Professional Options of the Direct Contracting Model.

Additional information about the AKS waivers for ACOs and for participants in the Comprehensive Care for Joint Replacement model is included below. More detailed information about these and the other AKS waivers can be found at www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Fraud-and-Abuse-Waivers.html. Not all model-specific waivers are necessarily available to all participants in a given model. Those seeking waiver protection should keep in mind that a waiver will apply to their arrangement(s) only if they are eligible to use the waiver and all conditions of the waiver are met, so consultation with legal counsel is encouraged to ensure that waivers are available to them and that arrangements for which they seek waiver protection meet all required conditions.

A. AKS Waivers for Accountable Care Organizations

The development and operation of accountable care organizations (ACOs), which were established as part of the 2011 health care reform's shared savings program for Medicare fee-for-service beneficiaries, clearly can implicate the AKS and its prohibitions [42 U.S.C. Section 1395jjj]. It is critical that a potential ACO and its participants carefully consider the application of the AKS with respect to both the ACO's development and its operation.

An **"ACO"** is a group of providers and suppliers of services (e.g., hospitals, physicians and others involved in patient care) who work together to coordinate care for the Medicare beneficiaries they serve, agree to be accountable for the quality and cost of care for a defined group of Medicare fee-for-service beneficiaries and share in savings (and potentially losses) associated with the care for those assigned beneficiaries. There are ACOs continuing under the Medicare Shared Savings Program (the final performance year for Pioneer Model ACOs was Dec. 31, 2016, and the Next General Model ACOs concluded Dec. 31, 2021). The formation and operation of an ACO likely requires the ACO and its various providers and participants (including hospitals and physicians) to enter into arrangements that could implicate the AKS, such as arrangements and/or agreements that relate to the ACO's:

1. Creation and infrastructure,
2. Network development,
3. Clinical management,
4. Information technology, and
5. Provider and supplier participation agreements.

All of these arrangements could involve the creation of incentives and distribution of savings and losses generated by the activities of the ACO, which could also potentially implicate the AKS.

As part of the final ACO Shared Savings Program regulation process, CMS and the OIG issued an interim final rule, effective Nov. 2, 2011, that included five separate fraud and abuse waivers that protect a broad range of ACO activities from the reach of the federal physician self-referral law, certain civil monetary penalties law provisions and the AKS [76 Fed. Reg. 67992 (Nov. 2, 2011)]. Subsequently CMS and OIG issued a final rule finalizing the waivers effective Oct. 29, 2015 [80 Fed. Reg. 66726 (Oct. 29, 2015)].

If the particular requirements of the waiver are met, the waivers generally protect the ACO's activities from the reach of the AKS with respect to its:

1. Pre-participation or start-up activities;
2. ACO-related arrangements;
3. Distributions of shared savings;
4. ACO arrangements that implicate the Stark law; and
5. Certain incentives offered to patients.

B. AKS Waiver for Joint Replacement Model

Effective April 1, 2016, CMS established the Comprehensive Care for Joint Replacement Model (CJR Model), which is intended to enhance the quality and efficiency of hip and knee replacement surgeries for Medicare patients. Under the CJR Model, hospitals, physicians and other providers are held jointly accountable for the quality and cost of a joint replacement episode of care, which begins with the hospital admission and ends 90 days after discharge.

Recognizing that the CJR Model calls for distributions of Medicare payments among hospitals, physicians and other health care providers that could create risk under the AKS, on Nov. 16, 2015, DHHS issued a Notice of Waivers of Certain Fraud and Abuse Laws in Connection with the Comprehensive Care for Joint Replacement Model.

The 2015 CMS notice included three waivers to protect the following arrangements among providers under the CJR Model from violation of the AKS law (subject to satisfaction of numerous requirements):

1. Gainsharing and alignment payments under sharing arrangements between hospitals and other providers;
2. Distribution payments from physician groups (now referred to as CJR collaborators) to other providers (referred to as collaboration agents); and
3. Patient engagement incentive items or services provided by hospitals to Medicare beneficiaries in an episode of care.

On Dec. 05, 2017, the OIG and CMS jointly issued an updated notice of waivers (which may be found at https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/2017-CJR-Model-Waivers.pdf), effective Jan. 1, 2018, which revised the requirements of the three waivers initially provided for in the 2015 CMS waiver notice, and added a fourth waiver for downstream distribution payments from a collaboration agent to a downstream collaboration agent (subject to satisfaction of numerous requirements). The updated waivers were the result of certain programmatic changes made by the CMS to the CJR Model and on their effective date superseded the original 2015 CMS waiver notice.

The performance period was scheduled to end on Sept. 30, 2021, but on April 29, 2021, CMS issued a final rule extending the CJR Model through Dec. 31, 2024. In addition, that final rule revised certain aspects of the CJR Model including the episode of care definition, the target price calculation, the reconciliation process, the beneficiary notice requirements and the appeals process. In addition, for performance years six through eight, the final rule eliminated the 50 percent cap on gainsharing payments for certain recipients, and extended additional flexibilities provided to hospitals related to certain Medicare program rules consistent with the revised episode of care definition.

VI. FEDERAL ENFORCEMENT AND PENALTIES

The federal anti-kickback statute contains both criminal and civil sanctions and is enforced by the OIG and the U.S. Department of Justice.

A. Criminal Penalties

The criminal sanctions for a conviction under the federal anti-kickback statute may include imprisonment for not more than ten years, a fine of not more than $100,000 for each offense, or both [42 U.S.C. Section 1320a-7b(b)]. If a provider is convicted of a criminal offense related to participation in Medicare, Medi-Cal, or any other federally-funded health care program, or is convicted of a felony relating to health care fraud, the Secretary of DHHS is required to bar the provider from participation in federal health care programs and to notify the appropriate state agencies to bar the provider from participation in state health care programs [Section 1128(a)(1) and (3) of the Social Security Act].

B. Civil Penalties

In addition to the imposition of criminal sanctions, violators of the anti-kickback statute are subject to civil money penalties of up to $100,000 for each prohibited act and up to three

times the total amount of remuneration offered, paid, solicited, or received (regardless of whether a portion of the remuneration was for a lawful purpose) [42 U.S.C. Section 1320a-7a(a)(7)]. A lower standard of proof applies when these civil remedies are sought than applies when a criminal prosecution is brought.

DHHS may also exclude any person or entity that commits an act described in the anti-kickback statute from participation in the Medicare program and direct states to exclude that person or entity from participation in state health care programs [42 U.S.C. Section 1320a-7(a)(7)]. DHHS can exercise this authority based on an administrative determination, without obtaining a criminal conviction.

VII. RELATIONSHIP TO FALSE CLAIMS ACT

In addition to civil and criminal sanctions under AKS, it has been successfully argued that seeking reimbursement for services that were induced by illegal kickbacks can give rise to liability under the federal False Claims Act, which carries substantial civil and criminal penalties *(see chapter 3, "Federal and State False Claims Acts")*. [31 U.S.C. Sections 3729-3731; *United States ex. rel. Thompson v. Columbia*, 20 F.Supp.2d 1017 (Aug. 18, 1998); *United States ex. rel Sharp v. Consolidated Medical Transport, Inc.*, 2001 U.S. Dist. LEXIS 13923 (N.D. Ill. Sept. 4, 2001)]

The anti-kickback statute was revised by the ACA to specifically provide that a claim that includes items and services resulting from a violation of the statute constitutes a false claim [42 U.S.C. Section 1320a-7b(g)]. However, the impact of this change is unclear, as it is arguable whether particular services actually result from the payment of kickbacks, as opposed to resulting, for example, from the need for those services.

VIII. RELATIONSHIP TO PHYSICIAN SELF-REFERRAL (STARK) LAWS

As a general rule, compliance with an anti-kickback safe harbor provision does not ensure compliance with federal or state physician self-referral laws (also referred to as Stark and PORA laws). *(See chapter 6, "Physician Self-Referral Laws.")* Hospitals should review their business and payment arrangements under both the anti-kickback and physician self-referral laws in consultation with experienced legal counsel to assure compliance with these laws.

The physician self-referral law and the anti-kickback statute are two very different laws. Although both laws are directed at the problem of inappropriate financial incentives influencing medical decisions, the laws differ in scope and structural approach. Some of the major differences are:

1. The Stark law pertains only to physician referrals under Medicare (**"physician"** also includes a dentist, podiatrist, optometrist and chiropractor). The anti-kickback statute affects anyone who engages in business with a federal health care program, including providers, plans, vendors and suppliers.
2. The Stark law is not a criminal law. It is a civil law and does not require a wrongful intent for an entity to violate the law. Billing for designated health services (DHS) rendered pursuant to a prohibited referral is punishable by the return of all Medicare payments made for services provided to patients referred by the physician. In

addition, civil monetary penalties may be imposed for billing for DHS that the provider knew or should have known were rendered pursuant to a prohibited referral.

3. The anti-kickback statute is a felony criminal law that prohibits the knowing and willful payment or receipt of remuneration to compensate or induce referrals. Thus, an entity must have some wrongful intent to be in violation of the law. A violation is punishable by exclusion from federal health care programs, criminal fines, a prison sentence, or civil money penalties.
4. The Stark law contains many exceptions to the general referral prohibition. Compliance with an exception is required if a physician makes referrals to a DHS entity with which the physician has a financial relationship.
5. The anti-kickback law contains many safe harbors. Compliance with a safe harbor is voluntary. Transactions that don't meet a safe harbor don't necessarily violate the statute.

In each situation where the anti-kickback law applies, the Stark statute may apply also. A hospital contemplating a proposed business arrangement with physicians should first determine whether it meets a Stark exception. If it does not, then physicians participating in the arrangement will be prohibited from referring Medicare patients to the hospital. If the proposed business arrangement meets a Stark exception, then it should be analyzed under the anti-kickback statute. *(See chapter 6, "Physician Self-Referral Laws.")*

IX. CONSEQUENCES FOR TAX-EXEMPT STATUS

The IRS has ruled that violation of the anti-kickback statute constitutes a failure to comply with the requirements of a charitable organization described in Internal Revenue Code Section 501(c)(3). In Revenue Ruling 97-21, a hospital lost its exemption after it was found in criminal violation of knowingly and willfully violating the federal anti-kickback statute by providing recruitment incentives that constituted illegal payment for referrals. This ruling can be found at https://www.irs.gov/pub/irs-tege/rr1997-21.pdf.

X. STEPS TO TAKE UPON DISCOVERING A POSSIBLE ANTI-KICKBACK VIOLATION

Upon discovering a possible anti-kickback law violation, the matter should immediately be reported to the hospital's compliance officer or legal counsel. All pertinent documents should be preserved intact. In no case should documents be destroyed or altered in any manner. Anti-kickback violations can result in required disclosure under certain circumstances, as claims submitted on behalf of physicians who were parties to arrangements violating the statute may be considered false claims. This determination is complex, and should be made only with the advice of your organization's legal counsel. *(See chapter 15, "Repayment and Self-Disclosure.")*

XI. ADVISORY OPINIONS, FRAUD ALERTS AND OTHER RESOURCES

Health care providers and other entities that are uncertain as to whether their arrangements violate the AKS or qualify for safe harbor protection may request an advisory opinion from

the OIG in accordance with the regulations found at 42 C.F.R. Part 1008. The advisory opinion process provides advice on the application of the anti-kickback statute and other OIG sanction statutes regarding a specific factual situation. An OIG opinion may be helpful in deciding whether to move forward with an arrangement.

An OIG opinion applies only to the requestor's specific factual situation and documentation submitted, and may not be relied upon by anyone other than the requestor. However, all advisory opinions are posted on the OIG's website (with identifying and proprietary information redacted) and provide valuable information as to the OIG's thinking regarding various arrangements. For instructions on how to request an advisory opinion and to read advisory opinions, go to https://oig.hhs.gov/compliance/advisory-opinions/index.asp.

The OIG also issues fraud alerts, special bulletins, guidances, and open letters. For the most part, these documents address national trends in health care fraud, including what the OIG views as potential violations of the federal anti-kickback statute. They are based on information the OIG obtains concerning particular fraudulent and abusive practices within the health care industry. Fraud alerts are means for the OIG to notify the health care industry that it has become aware of practices that it plans to pursue and prosecute, or bring civil or administrative action against, as appropriate. Bulletins, guidance and open letters provide information and guidance to the health care industry for structuring various business and payment arrangements and avoiding OIG scrutiny. The alerts, bulletins, guidance and open letters also serve as a tool to encourage industry compliance by informing providers of the OIG's thinking on a particular practice. These documents, together with compliance toolkits, videos and other resources, may be viewed through the OIG's Compliance Resource Portal at https://oig.hhs.gov/compliance/index.asp.

XII. REMUNERATION TO BENEFICIARIES

In addition to the federal anti-kickback law, there is a similar restriction under the Civil Monetary Penalties Law (CMP) on providing certain benefits directly to Medicare or Medi-Cal beneficiaries that may induce them to self-refer to a particular provider. Civil monetary penalties (CMPs) may be imposed on any person who offers or provides remuneration to a Medicare or Medi-Cal beneficiary that the person knows, or should know, is likely to influence the beneficiary to order or receive covered items or services from a particular provider [42 U.S.C. Section 1320a-7a(a)(5)]. This prohibition restricts the ability of hospitals to provide free or discounted items or services to Medicare or Medi-Cal patients where those benefits are likely to influence the patient to receive services from the hospital.

Certain benefits are not considered remuneration for purposes of the CMP law. Any benefit protected by an anti-kickback safe harbor is not considered remuneration for purposes of this law. [42 C.F.R. Section 1003.110 (previously Section 1003.101), Definition of Remuneration]

NOTE: In the 2020 Final Rule, the OIG created a new patient engagement and support safe harbor which protects the provision of certain patient engagement tools and support to beneficiaries to improve quality, healthy outcomes, and efficiency. The value of these items or services was capped at $500 per patient, per year (currently $527 based on annual CPI increase) and is only to value based enterprise participants in a target patient population.

Also, waivers of copayments and deductibles that are not protected by the anti-kickback safe harbor, such as waivers for hospital outpatients, are protected if:

1. The waiver is not offered as part of an advertisement or solicitation;
2. Waivers are not routinely made; and
3. Either a prior determination is made that the patient is in financial need, or the coinsurance and deductibles are not collected after reasonable collection efforts.

[42 U.S.C. Section 1320a-7a(i)(6)(A); 42 C.F.R. Section 1003.110, Definition of Remuneration]

Also protected are incentives given to promote the delivery of preventive care where the delivery of such services is not tied (directly or indirectly) to the delivery of other services covered by Medicare or Medicaid [42 U.S.C. Section 1320a-7a(i)(6)(D); 42 C.F.R. Section 1003.110, Definition of Remuneration].

In addition, ACA added two more exceptions to the CMP law to protect free or discounted items or services under certain circumstances. The first exception protects the offer or provision of items or services to beneficiaries for free, or at less than fair market value, if:

1. The items or services consist of coupons, rebates, or other rewards from a retailer;
2. The items or services are offered or transferred on equal terms available to the general public, regardless of health insurance status; and
3. The offer or transfer of the items or services is not tied to the provision of other items or services reimbursed in whole or in part by Medicare or a state health care program.

[42 U.S.C. Section 1320a-7a(i)(6)(G); 42 C.F.R. Section 1003.110, Definition of Remuneration]

The second similar exception protects free or less than fair market value items or services if:

1. The items or services are not offered as part of any advertisement or solicitation;
2. The items or services are not tied to the provision of other services reimbursed in whole or in part by Medicare or a state health care program;
3. There is a reasonable connection between the items or services and the medical care of the patient; and
4. The person provides the items or services after determining in good faith that the patient is in financial need.

[42 U.S.C. Section 1320a-7a(i)(6)(H); 42 C.F.R. Section 1003.110, Definition of Remuneration]

Another exception protects items or services that improve a beneficiary's ability to obtain items and services payable by Medicare or Medicaid, and pose a low risk of harm to Medicare and Medicaid beneficiaries and the Medicare and Medicaid programs by:

1. Being unlikely to interfere with, or skew, clinical decision making;
2. Being unlikely to increase costs to federal health care programs or beneficiaries through overutilization or inappropriate utilization; and
3. Not raising patient safety or quality-of-care concerns

[42 U.S.C. Section 1320a-7a(i)(6)(F); 42 C.F.R. Section 1003.110, Definition of Remuneration]

Hospitals may elect to reduce copayment amounts for Medicare patients before the beginning of a year for some or all covered outpatient department services to an amount

established by the Secretary from time to time (that is not less than 20 percent of the Medicare fee schedule amount). [42. U.S.C. Section 1395l(t)(8)(B); 42 C.F.R. Section 1003.110, Definition of Remuneration]

In the 2020 Final Rule, the OIG created an additional exception to protect the provision of telehealth technologies by a provider of services, physician, or a renal dialysis facility to a patient with end-stage renal disease who is receiving home dialysis for which payment is being made under Medicare part B if:

1. The telehealth technologies are furnished by the provider of services, physician, or the renal dialysis facility that is currently providing the in-home dialysis, telehealth services, or other end-stage renal disease care to the patient, or has been selected or contacted by the patient to schedule an appointment or provide services;
2. The telehealth technologies are not offered as part of any advertisement or solicitation; and
3. The telehealth technologies are provided for the purpose of furnishing telehealth services related to the patient's end-stage renal disease.

[42 C.F.R. Section 1003.110, Definition of Remuneration]

XIII. FEDERAL ELIMINATING KICKBACKS IN RECOVERY ACT OF 2018 (EKRA)

The federal Eliminating Kickbacks in Recovery Act of 2018 (EKRA) was signed into law on Oct. 24, 2018, and is a new public-private intent-based criminal anti-kickback law that prohibits any form of remuneration for referrals to recovery homes, treatment facilities and laboratories (including laboratories unrelated to substance abuse testing or treatment). The primary difference between EKRA and the federal anti-kickback statute described above is that EKRA applies to remuneration for or to induce referrals to both public and private payors, while the federal anti-kickback statute is limited to federal health care programs. There are eight exceptions to EKRA, including arrangements that comply with the requirements of certain (but not all) of the safe harbors under the federal anti-kickback statute. However, one exception for payments to employees prohibits payments that vary with referrals made by the employee, which prohibition is not included in the employee safe harbor under the federal anti-kickback statute. EKRA has preemption provisions that expressly exclude from EKRA's reach, conduct that is prohibited under Section 1128B of the Social Security Act (including the federal anti-kickback statute), as well as state laws on the same subject matter. The definition of clinical treatment facility expressly excludes hospitals. [18 U.S.C. Section 220]. Given the preemption provisions and the limited applicability to hospitals, further discussion is beyond the scope of this manual.

XIV. CALIFORNIA ANTI-KICKBACK LAWS

A. General Rule

Similar to the federal anti-kickback statute, California's primary anti-kickback law, Business and Professions Code Section 650, prohibits remuneration of any kind in exchange for the referral of patients. However, Section 650 prohibits such arrangements with regard to any patient, not just government program-sponsored patients, and in this regard is broader than the federal statute.

Business and Professions Code Section 650 provides as follows:

> [T]he offer, delivery, receipt, or acceptance by any person licensed under this division or the Chiropractic Initiative Act of any rebate, refund, commission, preference, patronage dividend, discount, or other consideration, whether in the form of money or otherwise, as compensation or inducement for referring patients, clients, or customers to any person, irrespective of any membership, proprietary interest or co-ownership in or with any person to whom these patients, clients, or customers are referred is unlawful.

It is important to note that the statute prohibits payments to or from a person licensed under the Healing Arts Division of the Business and Professions Code. A **"person"** includes legal entities, such as corporations, in addition to individuals [Business and Professions Code Section 653]. The persons subject to Section 650 include laboratories, pharmacies, physicians, pharmacists, podiatrists, psychologists, dentists, dental hygienists, chiropractors, nurses, midwives, physician assistants, speech-language pathologists and audiologists, optometrists, occupational therapists, physical therapists, respiratory therapists, clinical laboratory technologists, acupuncturists, psychiatric technicians, marriage and family therapists, licensed clinical social workers, etc. If there is no such licensed person involved in a compensation arrangement, that arrangement is not prohibited by Section 650.

Payments to and from hospitals are almost always subject to Section 650, because hospitals generally have clinical laboratory and pharmacy licenses, and are therefore persons licensed under the Healing Arts Division of the Business and Professions Code. Additionally, a person or entity that is not licensed under the Healing Arts Division but enters into an arrangement that violates Section 650 with a person who is so licensed is also liable under Section 650. [Business and Professions Code Section 652.5]

Section 650 prohibits payments for referrals of clients and customers in addition to patients. Thus, the California court in *Mason v. Hosta* held that a payment by an emergency physician to a hospital administrator to refer hospital clients to the physician violated Section 650 and was unenforceable [*Mason v. Hosta*, 152 CalApp.3d 980 (1984)].

The scienter, or knowledge, standard under Section 650 requires only a showing of general intent, as opposed to the higher knowing and willful standard under the federal anti-kickback law. This means that Section 650 can be violated by a party who had no knowledge that the conduct in question violated the law. A California court has considered whether, in a prosecution under Section 650 involving federal health care program patients, federal preemption principles require that the federal knowing and willful standard should apply, and determined that preemption principles do not require that the heightened federal knowledge standard be satisfied [*People v. Guiamelon*, 205 Cal.App.4th 383 (2012)].

B. Exceptions

Payments for Services

There is an exception under Section 650 for "the payment or receipt of consideration for services other than the referral of patients which is based on a percentage of gross revenue or similar type of contractual arrangement," where the consideration is commensurate with the value of services furnished or with the fair rental value of any premises or equipment leased or provided. This exception arguably can protect a large variety of arrangements between hospitals and physicians, such as personal services arrangements and leases, where the compensation paid or the lease amount is consistent with fair market value and

there is no requirement to make referrals. The exception can also protect compensation paid by hospitals to marketers, whether employees or independent contractors, as long as they do not market directly to patients (although, as noted above, only marketing payments to employees are protected under the relevant federal anti-kickback safe harbor). *(See* People v. Duz-Mor Diagnostic Laboratory, Inc*., 68 Cal.App.4th 654 (1998), in which the court held that the payments by a laboratory to independent contractor marketers did not violate Section 650 where the payments were consistent with the fair market value of the marketers' services because the marketer referred only clients or customers to the laboratory, such as physicians, and did not refer patients.)*

In a similar vein, the courts have tacitly recognized that a fair allocation between a hospital and physicians of a combined bill does not violate Section 650 *(see, e.g.,* Blank v. Palo Alto-Stanford Hospital Center*, 234 Cal.App.2d 377 (1965), in which the court upheld an arrangement between a hospital and a radiology group under which the hospital submitted a single combined bill for radiology services, retained two-thirds of the gross income from radiology services, and paid the radiology group one-third of the gross income)*. This concept may be useful to hospitals that are increasingly entering into combined billing arrangements with physicians; for example, in hospital outpatient clinics and medical foundations.

On the other hand, payments over fair market value to a hospital by a recipient of referrals from the hospital raise concerns under Section 650. The California Attorney General has opined that Section 650 was violated where a pharmacy paid rent to a hospital and a clinic based on a percentage of sales to patients referred to the pharmacy and the rental payments exceeded the fair market rent [53 Ops.Cal.Atty.Gen. 117 (April 1, 1970)].

Ownership Interest/Investments

Section 650 also includes an exemption which specifically protects ownership relationships, as follows:

> [I]t shall not be unlawful for any person licensed under this division to refer a person to any laboratory, pharmacy, clinic (including entities exempt from licensure pursuant to Section 1206 of the Health & Safety Code), or health care facility solely because the licensee has a proprietary interest or co-ownership interest in the laboratory, pharmacy, clinic or health care facility; provided, however, that the licensee's return on investment for that proprietary interest or co-ownership shall be based upon the amount of the capital investment or proportional ownership of the licensee, which ownership interest is not based on the number or value of any patients referred. Any referral excepted under this section shall be unlawful if the prosecutor proves that there was no valid medical need for the referral.

This exception protects, for example, referrals by physicians to a hospital in which they have ownership interests, provided that their return on investment is based on their proportional ownership interest and their ownership interest is not related in any manner on the number or value of their referrals to the hospital. The exception can also protect investment by physicians in joint ventures with hospitals.

Hardware, Software and Information Technology

Another exception under Section 650 permits hospitals to provide to members of their medical staffs nonmonetary remuneration in the form of hardware, software, or information technology and training services where the items and services are necessary and used solely to receive and transmit electronic prescription information. Legislation passed in 2008, AB

55, revised this exception to conform to similar federal anti-kickback safe harbors, which more broadly protect nonmonetary remuneration for items and services used to receive and transmit both electronic prescription information and EHR [Business and Professions Code Section 650(e)]. AB 55 also added a similar exception to the Medi-Cal anti-kickback statute [Welfare and Institutions Code Section 14107.2].

Payments for Advertising; Internet-Based Service Providers

Another exception provides that the payment or receipt of consideration for advertising, where the licensee offers or sells services through a third party advertiser, does not constitute a referral of patients when the advertiser does not itself recommend, endorse, or otherwise select the licensee. The fee paid to the advertiser must be commensurate with the service provided. Also, the licensee must disclose in the advertisement that a consultation is required and that the purchaser will receive a refund if not eligible to receive the service. The advertiser must make available to prospective purchasers advertisements for services of all licensees advertising through the advertiser in the applicable geographic area. Advertisers offering a discounted price for a service must also disclose the regular, undiscounted price. It appears that the purpose of this exception is to clarify that payments to advertisers may be protected by the exception for consideration at fair market value other than for the referrals of patients.

With the growth in telehealth, and the California Governor's Oct. 1, 2021, approval of AB 457's Protection of Patient Choice in Telehealth Provider Act, Section 650 was further amended to provide certain protections to internet based providers in order to support telehealth. Effective Jan. 1, 2022, to the extent consistent with federal law, regulations, or guidance, the payment or receipt of consideration for internet-based advertising, appointment booking, or any service that provides information and resources to prospective patients of licensees will not be deemed to constitute a referral of a patient, provided the internet-based service provider does not recommend or endorse a specific licensee to a prospective patient.

C. Relationship to Federal Anti-Kickback Statute and Safe Harbors

The interplay between the federal anti-kickback statute and state anti-kickback laws such as those in California is somewhat unclear. For example, if an arrangement fits within a federal safe harbor, but there is no comparable safe harbor under California law (which is often the case), could the arrangement be prosecuted under California law? In 2006, the California Attorney General addressed this relationship to some extent in an opinion regarding whether a physician may prescribe a medical device distributed by a company in which the physician has an ownership interest without violating the California Medicaid anti-kickback statute (addressed below), which is similar to the federal anti-kickback statute but applies only with respect to California Medi-Cal patients [89 Ops.Cal.Atty.Gen. 25 (Feb. 27, 2006)]. The Attorney General looked to the federal anti-kickback statute for guidance in interpreting California's law, and concluded that if the investment interest in question is lawful under the federal anti-kickback statute, then it should also be permissible under California's Medi-Cal statute.

The issue was also addressed in a Florida Supreme Court case involving a challenge to Florida's anti-kickback statute with respect to Medicaid patients [*State v. Harden*, 938 So.2d 480 (Fla. 2006)]. The arrangement at issue was payments to employees for marketing services for which there is a federal safe harbor but no comparable safe harbor under Florida anti-kickback law. The court in essence held that the Florida anti-kickback statute was void

because it would criminalize activity that Congress had intended to permit. Because the state law was an obstacle to the execution and accomplishment of congressional objectives and purposes, it was preempted by federal law. It is unclear whether other courts, including courts in California, will follow the *Harden* case. It would also appear that the analysis would apply only with respect to federally-sponsored patients, such as Medicare or Medi-Cal patients, who are within the scope of the federal anti-kickback statute, and would likely not apply with respect to arrangements involving non-government sponsored patients. Accordingly, it is best to attempt to structure arrangements to comply with both federal anti-kickback law safe harbors and, if possible, the exceptions under California's anti-kickback law described above.

D. Penalties

A violation of Business and Professions Code Section 650 is punishable by imprisonment in the county jail for up to one year, a fine of up to $50,000, or both. A second or subsequent conviction is punishable by imprisonment in state prison and a fine of $50,000.

E. Other Applicable State Laws

Welfare and Institutions Code Section 14107.2 contains anti-kickback prohibitions that are very similar to those of the federal anti-kickback statute, which are applicable to remuneration for, or to induce referrals of, Medi-Cal patients. The principal differences between the federal statute and California's Medi-Cal analog are that the California statute does not require knowing and willful conduct, and no safe harbor regulations exist under the California statute.

Labor Code Section 3215 prohibits kickbacks in connection with referrals of workers' compensation patients. However, Labor Code Section 3217(d) specifically provides that Section 3215 does not prohibit practices that are permitted under Business and Professions Code Section 650.

Health and Safety Code Section 445 provides that no person shall profit from a referral of a person to a hospital, physician, health care facility, or dispensary for any form of medical care or treatment.

APPENDIX HC 7-A

Sample Disclosure Regarding Ambulance Replenishing

The following is a sample written disclosure for purposes of satisfying the requirements of the ambulance replenishing safe harbor. This form is for illustrative purposes only; hospitals may, but are not required to, adapt this sample form.

Notice of Ambulance Restocking Program

Hospital X offers the following ambulance restocking program:

1. We will restock all ambulance providers (other than ambulance providers that do not provide emergency services) that bring patients to Hospital X *[or to a subpart of Hospital X, such as the emergency room]* in the following category or categories: *[insert description of category of ambulances to be restocked, i.e., all ambulance providers, all ambulance providers that do not charge patients or insurers for their services, or all nonprofit and government ambulance providers]*. *[Optional: We only offer restocking of emergency transports.]*
2. The restocking will include the following drugs and medical supplies, and linens, used for a patient prior to delivery of the patient to Hospital X: *[insert description of drugs and medical supplies, and linens to be restocked]*.
3. The ambulance providers *[will/will not]* be required to pay for the restocked drugs and medical supplies, and linens.
4. The restocked drugs and medical supplies, and linens, must be documented as follows: *[insert description consistent with the documentation requirements described in 42 C.F.R. Section 1001.952(v). By way of example only, documentation may be by a patient care report filed with the receiving facility within 24 hours of delivery of the patient that records the name of the patient, the date of the transport, and the relevant drugs and medical supplies.]*
5. This restocking program does not apply to the restocking of ambulances that provide only non-emergency services or to the general stocking of an ambulance provider's inventory.
6. To ensure that Hospital X does not bill any federal health care program for restocked drugs or supplies for which a participating ambulance provider bills or is eligible to bill, all participating ambulance providers must notify Hospital X if they intend to submit claims for restocked drugs or supplies to any federal health care program. Participating ambulance providers must agree to work with Hospital X to ensure that only one party bills for a particular restocked drug or supply.
7. All participants in this ambulance restocking arrangement that bill federal health care programs for restocked drugs or supplies must comply with all applicable federal program billing and claims filing rules and regulations.
8. For further information about our restocking program or to obtain a copy of this notice, please contact *[insert name]* at *[insert telephone number]*.

Dated: _____

8 Financial Assistance Policies

I. Introduction 8.1

II. Overview of the HFPP Law 8.2

A. Basic Provisions 8.2

B. Effective Date 8.2

C. Hospitals Affected by the Law 8.2

D. Emergency Physician Fair Pricing Policies Law 8.3

III. Definitions 8.3

IV. Requirements of the HFPP Law 8.5

A. Differences Between Discount and Charity Policies 8.5

B. Determining Patient Eligibility 8.6

Types of Eligible Patients 8.6

Rural Hospitals 8.8

Tests for Eligibility for Charity Care or Discount Payment 8.8

Documentation of Patient Eligibility 8.10

Timing of Eligibility Determinations 8.12

Handling Disputes and Denials of Eligibility 8.12

C. Maximum Expected Payments Allowed Under the HFPP Law 8.12

Limitations on Patient Liability 8.12

May Services Be Excluded? 8.15

D. Limiting Debt Collection 8.16

Notice Prior to Commencing Collection Activities 8.16

Collection Practices 8.17

E. Providing Notices 8.23

Written Notice to Patients 8.23

Posted Notices 8.25

Providing Applications for Medi-Cal and Other Programs 8.26

Information to Accompany Bills to Patients Without Third-Party Coverage 8.26

F. Reimbursing Overcharges to Patients 8.27

Return of Principal 8.27

Payment of Interest 8.28

G. OSHPD Reporting 8.28

H. Effect on Customary Charges 8.28
I. Penalties 8.28
Other Factors Influencing the Penalty Amount 8.30
V. Federal Laws Regarding Financial Assistance Policies 8.31
A. Effective Date 8.32
B. Financial Assistance Policies (FAPs) — Section 1.501(r)–4 ..... 8.32
Method for Applying for Financial Assistance 8.33
Provider List 8.34
Publicizing the FAP 8.35
C. Limitations on Patient Charges — Section 1.501(r)–5 ..... 8.37
Look-Back Method 8.37
Prospective Medicare or Medicaid Method 8.39
Gross Charges 8.39
Safe Harbor for Charging More than AGB 8.39
D. Billing and Collections Policies — Section 1.501(r)–6 ..... 8.39
What is an ECA? 8.39
Reasonable Efforts 8.41
No Waiver 8.45
E. Relationship to Related State Laws 8.45
F. Hospital Reporting Requirements 8.46
G. Reports to Congress 8.46
H. Enforcement 8.46
VI. Comparison of State and Federal Requirements for Financial Assistance Policies 8.47

FORMS & APPENDICES

FAP 3 Comparison of California and IRS Requirements Regarding Financial Assistance Policies

8 Financial Assistance Policies

I. INTRODUCTION

This chapter describes the requirements of the Hospital Fair Pricing Policies (HFPP) law; the Emergency Physician Fair Pricing Policies (EPFPP) law; and the financial assistance requirements for tax-exempt hospitals of Internal Revenue Code Section 501(r), added by the Patient Protection and Affordable Care Act (ACA) of 2010.

The HFPP law was enacted to assist low-income patients who are uninsured or underinsured in obtaining hospital services at discounted prices by mandating that California hospitals develop and implement policies for charity care and discounted payment. Among other requirements, the HFPP law mandates that hospitals limit the liability of eligible patients within prescribed guidelines, and return, with interest, collections from such patients if they have been overcharged. The law also limits debt collection activities, and requires that hospitals provide clear, written discount and charity care policies to patients and to the Office of Statewide Health Planning and Development (OSHPD), now known as the California Department of Health Care Access and Information (HCAI)[1]. The EPFPP law extends the discount and charity care requirement to emergency room physicians and obligates hospitals to provide notice to patients regarding the obligations of emergency physicians.

Section 501(r) of the Internal Revenue Code establishes separate federal requirements that serve many of the same purposes as the HFPP law; however, the federal law applies only to nonprofit and certain governmental hospitals. Thus, hospitals subject to Section 501(r) must comply with both the HFPP and Section 501(r). The federal requirements also include community health needs assessment requirements that are addressed in detail in chapter 9.

Key Chapter Compliance Tips:

1. Develop a written policy for determination of eligibility for charity care and discount payment.
2. Develop a process for documenting patient eligibility for charity care and discount payment.
3. Provide written notice regarding the hospital's charity care and discount payment policies to patients as part of the admission or registration process.
4. Develop a written debt collection policy.

1 In 2021, OSHPD changed its name to the California Department of Health Care Access and Information ("HCAI"). Since the laws and regulations referenced in this chapter have not yet been updated to refer to the agency by its new name, this chapter continues to refer to the agency as OSHPD.

II. OVERVIEW OF THE HFPP LAW

A. Basic Provisions

Hospitals subject to California's HFPP law must "maintain an understandable written policy regarding discount payments for financially-qualified patients as well as an understandable written charity care policy." Both policies must state the hospital's process for determining whether a patient is eligible for charity care or discounted payment, and the discount payment policy must also state eligibility criteria based upon income consistent with the application of the Federal Poverty Level (FPL). [Health and Safety Code Section 127405(a) and (b)]

More specifically, the HFPP requires that hospitals must:

1. Determine patient eligibility for charity care or discounted payment based on the patient's income and assets, following prescribed guidelines. *(See B. "Determining Patient Eligibility," page 8.6.)*
2. Limit payment liability for financially-qualified patients to the highest of various government payment rates for comparable health services. *(See C. "Maximum Expected Payments Allowed Under the HFPP Law," page 8.12.)*
3. Limit debt collection activities for such patients and provide interest-free, extended-payment plans for repaying the hospital and any entity with which it contracts for debt collection or account assignment. *(See D. "Limiting Debt Collection," page 8.16.)*
4. Provide notices, clearly and in writing, of discount payment and charity care policies, to patients and to OSHPD. *(See E. "Providing Notices," page 8.23.)*
5. Reimburse overcharges, plus interest, that should not have been collected under the law. *(See F. "Reimbursing Overcharges to Patients," page 8.27.)*

B. Effective Date

California's HFPP law regulating hospital pricing for low-income individuals, AB 774 (Chapter 755, Statutes of 2006), became effective on Jan. 1, 2007, and is currently codified at Health and Safety Code Sections 127400-127446. It was amended in 2021 by AB 1020 (Chapter 473, Statutes of 2021) and AB 532 (Chapter 465, Statutes of 2021).

The HFPP law requires hospitals to submit specific documents relating to their charity care and discount payment policies to OSHPD. OSHPD issued regulations, effective Jan. 1, 2008, specifying how such documents should be submitted [Title 22, California Code of Regulations, Sections 96040-96050]. *(See G. "OSHPD Reporting," page 8.28, for more information.)* OSHPD will review a hospital's policy for compliance with the 2021 amendments upon submission of the hospital's new policy, which is due on or before Jan. 1, 2023.

C. Hospitals Affected by the Law

The HFPP law applies to all California-licensed general acute care hospitals, acute psychiatric hospitals and special hospitals, with the exception of facilities operated by the State Department of State Hospitals or the State Department of Corrections and Rehabilitation [Health and Safety Code Section 127400(d)]. The California Department of Public Health (CDPH) is responsible for enforcement of the HFPP law for violations occurring prior to Jan. 1,

2024; OSHPD is responsible for enforcement of the HFPP law for violations occurring on or after Jan. 1, 2024. [Health and Safety Code Section 127401]. The HFPP law does not apply to distinct part nursing facilities.

D. Emergency Physician Fair Pricing Policies Law

The Emergency Physician Fair Pricing Policies (EPFPP) law is substantially similar to the HFPP. Most of the requirements and prohibitions that apply to hospitals pursuant to the HFPP also apply to emergency physicians under the EPFPP. The main differences are:

1. Emergency physicians are not required to have both a charity care policy and a discount payment policy. Emergency physicians may have a discount payment policy only.
2. Emergency physicians may (but are not required to) rely on the hospital's determination of eligibility for discount payment, rather than independently requesting and evaluating information regarding the patient's income and assets.
3. Emergency physicians are not required to offer an extended payment plan. However, if they do, the plan must be interest-free and must meet certain specific statutory requirements. Emergency physicians may rely on the hospital's determination of family income and essential living expenses for purposes of establishing a reasonable payment plan.
4. The maximum payment from eligible patients for physician services differs from the maximum payment for hospital services. *(See "Determining Maximum Payment," page 8.13, for details.)*
5. Emergency physicians are not required to provide all patients written notice regarding the availability of discount payment at the time care is rendered, and do not need to provide patients with applications for Medi-Cal or other programs. However, emergency physicians are required to provide a specific notice when billing patients who have not provided proof of third-party coverage. *(See "Information to Accompany Bills to Patients Without Third-Party Coverage," page 8.26, for details.)*
6. Emergency physicians are not required to provide a copy of their discount payment policy to OSHPD or any other state agency.

Hospitals that bill for emergency physician services should ensure that their policies and procedures comply with the EPFPP. [Health and Safety Code Sections 127450-127462]

III. DEFINITIONS

Key terms with special definitions used in the HFPP law include the following:

"Charity care" is not defined in the law. However, the manner in which it is used in the law describes full charity care or free care, where the patient is not expected to pay anything at all or a very nominal amount.

"Discount payment": A situation where the hospital has determined that the patient does not qualify for free care, but is eligible for a discount and is expected to pay only a part of the bill [Title 22, California Code of Regulations, Section 96040(c)].

"Emergency physician": A physician who is credentialed by a hospital and either employed

or contracted by the hospital to provide emergency medical services in the emergency department of the hospital. "Emergency physician" does not include a physician specialist who is called into the emergency department of a hospital or who is on staff or has privileges at the hospital outside of the emergency department. [Health and Safety Code Section 127450(c)]

"Federal Poverty Level" (FPL): The poverty guidelines updated periodically in the *Federal Register* by the U.S. Department of Health and Human Services [Health and Safety Code Section 127400(b)]. The federal government prefers the term "Federal Poverty Guidelines." The actual dollar amounts may be found at http://aspe.hhs.gov/poverty.

"Financially qualified patient": A patient who is both of the following:

1. A patient who is a self-pay patient or a patient with high medical costs; and
2. A patient who has a family income that does not exceed 400 percent of the federal poverty level.

[Health and Safety Code Section 127400(c)]

"Patient's family":

1. For patients 18 years of age and older, the family includes the patient's spouse, registered domestic partner, and dependent children under 21 years of age, whether living at home or not.
2. For patients under 18 years of age, the family includes the patient's parent, caretaker relatives, and other children (under 21 years of age) of the parent or caretaker relative.

[Health and Safety Code Section 127400(h)]

"Patient with high medical costs": A patient whose family income does not exceed 400 percent of the federal poverty level. **"High medical costs"** means any of the following:

1. Annual out-of-pocket costs incurred by the individual at the hospital that exceed the lesser of 10 percent of the patient's current family income or family income in the prior 12 months.
2. Annual out-of-pocket medical expenses that exceed 10 percent of the patient's family income, if the patient provides documentation of the patient's medical expenses paid by the patient or the patient's family in the prior 12 months.
3. A lower level determined by the hospital in accordance with the hospital's charity care policy.

[Health and Safety Code Section 127400(g)]

"Self-pay patient": A patient who does not have third-party coverage from a health insurer, health care service plan, Medicare, or Medicaid, and whose injury is not a compensable injury for purposes of workers' compensation, automobile insurance, or other insurance as determined and documented by the hospital. Self-pay patients may include charity care patients. [Health and Safety Code Section 127400(f)]

"Uninsured patient": This term is not defined in the law. The terms "uninsured" and "self-pay" appear to be synonymous as used in the HFPP law.

IV. REQUIREMENTS OF THE HFPP LAW

This section of the manual covers in detail each of the five major requirements of an HFPP-compliant policy regarding charity and discounted care, including:

1. Determining patient eligibility,
2. Limiting expected reimbursement,
3. Limiting debt collection activities,
4. Providing written notices, and
5. Reimbursing any overcharges.

Hospitals' obligations to report their policies and procedures to OSHPD can be found in G. "OSHPD Reporting," page 8.28.

When developing policies and reviewing hospital practices, it is important to know that CDPH may cite a hospital for failing to comply with its policy, even if the policy contains requirements that would not otherwise legally be required. In other words, even if a hospital's policies specify procedures or actions that are not required by law, the hospital may be cited by CDPH for failure to follow them. Hospitals should be careful to tailor their policies to the requirements of the law.

A. Differences Between Discount and Charity Policies

Uninsured patients or patients with high medical costs who are at or below 400 percent of FPL must be eligible to apply for charity care or discounted payment [Health and Safety Code Section 127405(a)(1)].

Thus, the HFPP law requires hospitals to have both a written charity care policy and a written discount payment policy. Although "charity care" is not defined in the law, the manner in which the term is used in the law describes full charity care or free care, where the patient is not expected to pay anything at all or a very nominal amount. The term **"discount payment"** describes a situation where the hospital has determined that the patient does not qualify for free care, but is eligible for a discount and is expected to pay only a part of the bill. The portion that the patient is not expected to pay is called partial charity care. [Title 22, California Code of Regulations, Section 96040(c)] *(See OSHPD's Frequently Asked Questions at https://hcai.ca.gov/data-and-reports/cost-transparency/hospital-fair-pricing-policies/.)*

It makes sense that the mandatory 400 percent FPL eligibility criteria applies only to the discount payment policy, and that the charity care policy has more stringent eligibility criteria and a more generous discount. This understanding is supported by the language of Health and Safety Code Section 127405(d) (which discusses maximum rates based on Medicare and Medi-Cal rates only in the context of discount payment, not the separately addressed charity care policies) and Health and Safety Code Section 127425(g) (which prohibits a hospital from sending an account to a collection agency, debt buyer, or other assignee under a hospital's charity care policy or discount payment policy when the patient is attempting in good faith to settle a bill by negotiating a payment plan). This is further supported by the EPFPP, which imposes on emergency physicians only a discount policy requirement that must apply to the same patients eligible under the HFPP discount payment policy. Additionally, each hospital's written discount policy must state that an emergency physician providing emergency services in the hospital is required to provide discounts to uninsured

and high medical cost patients whose incomes are at or below 400 percent of FPL [Health and Safety Code Section 127405(a)(1)(B)]. Taken together, this implies that a hospital may impose a charge on a patient who is eligible for charity care, but it appears that any such charge may be only nominal in amount.

A reduction in charges based on a patient's ability to pay, which appears to be covered by the notion of a discount payment policy rather than a charity care policy under HFPP, is recorded as charity care under OSHPD accounting and reporting guidelines. Hospital discount payment policies should explain that the discounted charge is partial charity care. *(See OSHPD's Frequently Asked Questions at* https://hcai.ca.gov/data-and-reports/cost-transparency/hospital-fair-pricing-policies/*.)*

Compliance Tip: Hospitals may confine the use of the 400 percent of FPL guideline to their discount payment policy; stricter criteria are acceptable for the charity care policy. Hospital policies must provide notice of emergency physician obligations to provide discounted care.

B. Determining Patient Eligibility

Several types of patients may be eligible to benefit under HFPP, including both uninsured and insured patients, and the law establishes several specific tests of eligibility. The EPFPP law allows emergency physicians to rely on a hospital's determination of patient eligibility for discount and charity care [Health and Safety Code Section 127452(d)(1)]. This section of the manual describes:

1. The patient criteria for eligibility for a hospital's charity care or discount payment policy;
2. The ways in which hospitals may test for or determine eligibility in specific cases;
3. Patient obligations to provide documentation establishing eligibility;
4. The timing of eligibility determinations; and
5. How to handle disputes.

Types of Eligible Patients

Self-Pay Patients

A patient who is uninsured and who is at or below 400 percent of FPL is eligible to apply for the hospital's charity care policy or discount payment policy [Health and Safety Code Section 127405(a)(1)]. HFPP does not define "uninsured." It does, however, define the term **"self-pay patient"** as:

> a patient who does not have third-party coverage from a health insurer, health care service plan, Medicare, or Medicaid, and whose injury is not a compensable injury for purposes of workers' compensation, automobile insurance, or other insurance ... [Health and Safety Code Section 127400(f)]

The terms "uninsured" and "self-pay" appear to be synonymous as used in the HFPP law.

Insured Patients with Non-Covered Charges

The law is not clear on whether a patient who has health care coverage that covers some but not all of the services provided is eligible for charity care or discounted payment for the services not covered (such as out-of-network services or non-formulary drugs). In the absence of a clarification from the state, hospitals should choose a policy option and consistently follow that option for otherwise financially-eligible patients. (**NOTE:** Insured patients must be allowed to apply for charity care or discount payment if they have high medical costs, as discussed immediately below under "Insured Patients With High Medical Costs")

Insured Patients With High Medical Costs

A patient who is insured but has "high medical costs" and family income at or below 400 percent of FPL is eligible to apply for the hospital's charity care policy or discount payment policy [Health and Safety Code Section 127405(a)(1)].

The charity or discount applies to the portion of the bill that is the patient's responsibility, including copayments and deductibles. This provision applies to services covered by Medicare, but probably does not apply to services covered by Medi-Cal, as federal and state regulations require that Medicaid copayment obligations cannot be waived.

A **"patient with high medical costs"** is defined as "a person whose family income does not exceed 400 percent of the federal poverty level." [Health and Safety Code Section 127400(g)]

For these purposes, **"high medical costs"** means any of the following:

1. Annual out-of-pocket costs incurred by the individual at the hospital that exceed the lesser of 10 percent of the patient's current family income or family income in the prior 12 months. This test involves a comparison of the specific patient's out-of-pocket costs to the patient's family income. This test does not include any medical expenses other than the expenses incurred at the hospital, and it can be interpreted to include amounts billed to the patient by the hospital, net of any discounts or write-offs, for the preceding 12 months. **NOTE:** It is unclear whether to apply this standard according to date of billing or date of service, but if consistently applied, either interpretation should be permissible.
2. Annual out-of-pocket expenses that exceed 10 percent of the patient's family income, if the patient provides documentation of the patient's medical expenses paid by the patient or the patient's family in the prior 12 months. This test compares the total medical expenses paid by the patient or the patient's family for the patient within the past 12 months, to the patient's family income. This test appears to include expenses actually paid during the 12-month period, rather than expenses incurred. It includes all medical expenses of the patient, including expenses for physician services, hospital services (including services furnished by the hospital in question), drugs and all other medical services.
3. A lower level determined by the hospital in accordance with the hospital's charity care policy.

As initially implemented, HFPP excluded individuals from this definition if they were receiving a discounted rate from the hospital because of their third-party coverage. The definition

of "patient with high medical costs" has since been revised to include patients who receive a discounted rate from the hospital because of their third-party coverage. Thus, even if a patient receives a discount from the hospital because of his or her third party coverage, the patient may fall within the definition and the hospital must consider the patient for charity or discount care eligibility.

Compliance Tip: Insured low-income patients must be allowed to apply for charity care or discount payment if they have high medical costs.

Patients with Higher Incomes

The law provides for optional expanded eligibility. In other words, a hospital may choose to allow patients with income greater than 400 percent of FPL to be eligible for charity care or discount payment [Health and Safety Code Section 127405(a)(1)].

Compliance Tip: HFPP has prompted the question of whether a hospital may exclude a category of individuals, such as non-citizens, from eligibility for charity care or discount payment even if the individual satisfies the income and asset criteria. Under the law, a hospital must make its charity care and discount payment policy available to any financially-qualified "patients" [Health and Safety Code Section 127405(a)(1)]. A **"patient"** is a person who has been formally admitted to the hospital or registered or accepted as an outpatient [Title 22, California Code of Regulations, Section 70053(a)]. The language of HFPP thus does not appear to permit California hospitals to exclude non-citizens or other classes of patients from receiving free or discounted services.

Rural Hospitals

Rural hospitals, as defined in Health and Safety Code Section 124840, may establish eligibility levels for financial assistance and charity care at less than 400 percent of FPL as appropriate to maintain their financial and operational integrity [Health and Safety Code Section 127405(a)(2)]. Although HFPP does not define **"financial assistance,"** it may be inferred that this means the hospital's discount payment policy. Thus, a rural hospital may establish more stringent eligibility standards for its charity care and discount payment policies. A rural hospital that chooses to establish eligibility levels at less than 400 percent of FPL should document why the lower level is required to maintain the facility's financial and operational integrity.

Tests for Eligibility for Charity Care or Discount Payment

Testing for Income and Assets

The tests for eligibility differ depending on whether the hospital is testing for eligibility for charity care or for discounted payment.

For purposes of determining eligibility for charity care, hospitals may consider both income and the patient's monetary assets. For purposes of determining eligibility for discounted

payment, hospitals may consider only income, and not assets. This poses a problem under Medicare if the hospital intends to claim the discount as allowable Medicare bad debt. Although Medicare does allow discounts of copayments to medically- or financially-indigent beneficiaries to be claimed as allowable bad debt, Medicare policy requires more testing and documentation than is contemplated by the HFPP. Under the relevant Medicare policy guidelines *(see* Provider Reimbursement Manual-I*, Section 312)* a hospital:

1. Cannot rely on a declaration of indigency by the patient,
2. Must test ability to pay by taking into account income and resources,
3. Must assess the availability of other payer resources, and
4. Must carefully document all of the above in the patient financial file.

As a practical matter, the vast majority of Medicare beneficiaries will not qualify under a plan that complies with only the minimum requirements of the HFPP law. Medicare beneficiaries are insured patients, and their copayment liability is unlikely to qualify under the high medical costs provision. *(See D. "Medicare Bad Debt Payments," page 5.28, for more information about Medicare bad debt.)*

Assets. "Monetary assets" include assets that are readily convertible to cash, such as bank accounts and publicly traded stock, but not illiquid assets such as real property. Monetary assets do not include retirement or deferred compensation plans qualified under the Internal Revenue Code, or nonqualified deferred compensation plans. Furthermore, the first $10,000 of a patient's monetary assets may not be counted in determining eligibility, nor may 50 percent of a patient's monetary assets over the first $10,000. [Health and Safety Code Section 127405(c) and (e)(2)]

A hospital may require waivers or releases from the patient or the patient's family authorizing the hospital to obtain account information from financial or commercial institutions, or other entities that hold the monetary assets, to verify their value. [Health and Safety Code Section 127405(e)(2)]

Compliance Tip: While HFPP permits a patient's assets to be considered in determining eligibility for charity care, it does not require assets to be considered. Given the restrictions on the assets that may be considered and the complexity the application of the asset provisions entails, hospitals may prefer not to consider assets at all.

Income. For income testing for charity care or discount payment, the law provides that income tests consider the income of the patient's family. Health and Safety Code Section 127400(c)(2) states that a self-pay patient or a patient with high medical costs who has a family income that does not exceed 400 percent of the FPL is eligible. Similarly, Health and Safety Code Section 127400(g), in defining a patient with high medical costs, states that the tests compare the patient's out-of-pocket expenses at the hospital to the patient's family income, or compare medical expenses "paid by the patient or the patient's family" to the patient's family income.

Documentation of Patient Eligibility

A patient (or patient's legal representative) who requests a discounted payment, charity care, or other assistance in meeting his or her financial obligation to the hospital must "make every reasonable effort" to provide the hospital with documentation of income and health benefits coverage. The hospital may consider a failure to provide reasonable and necessary documentation when making its determination under its charity care or discount payment policy. [Health and Safety Code Section 127405(e)]

A hospital should act reasonably where a patient fails to provide requested documentation. If the documentation is essential to the determination of charity or discount care eligibility or benefits, charity care or discount care may be denied. If a hospital can reasonably make this determination without the requested documentation, the hospital should make the determination, although this may mean that the patient's benefits are lower than they might have been if the patient had furnished complete documentation.

A hospital should also consider the circumstances surrounding a patient's failure to provide requested documentation. If the patient makes a reasonable effort to obtain documentation, but is unable to do so through no fault of the patient, the hospital should attempt to make this determination without the documentation.

Compliance Tip: HFPP does not directly state that a hospital may deny charity care or discount care to a patient who fails to provide reasonable and necessary documentation, only that the failure to provide documentation may be considered by the hospital.

Documentation of Income

Documentation of income for purposes of determining eligibility for discount payment is limited to recent pay stubs or income tax returns [Health and Safety Code Section 127405(e)(1)]. Although the law does not state that documentation of income for purposes of determining eligibility for charity care is limited to pay stubs or tax returns, hospitals should require the same documentation of income for charity care as for discount payment. Any other approach would be difficult to implement, could lead to a violation of the law if a patient who applies for charity care is determined to be eligible only for discount payment, and appears inconsistent with the spirit, if not the literal language, of the law.

A question arises as to whether a hospital may request both pay stubs and tax returns. The better reading of the law is that a hospital may require only one of the two forms of documentation. Pay stubs and tax returns may accomplish different things as the pay stub reflects current income, while a tax return reflects previous income for an entire year. Nevertheless, the language of the statute does not appear to allow a hospital to require both forms of documentation.

However, it is likely permissible for a hospital to request one form of documentation, but to accept the other form of documentation if the patient can demonstrate the requested documentation does not exist or is unavailable. For example, a hospital may request tax returns, but accept pay stubs if tax returns are not available.

Compliance Tip: If a patient is unable to provide either a pay stub or an income tax return, HFPP does not prohibit a hospital from accepting another form of documentation, such as a patient statement that he or she does not have any income, and therefore does not have a pay stub or a tax return. However, the failure to obtain adequate documentation before affording a patient charity care or discount payment may have an impact on OSHPD reporting and thereby affect Medi-Cal Disproportionate Share Hospitals (DSH) payments. It may also affect the ability of a hospital to treat a Medicare account as a Medicare bad debt.

Use of Income and Asset Information

A hospital may not use income or asset information obtained during the eligibility process for purposes of collection activities. However, the use of information obtained by the hospital, collection agency or assignee independently of the eligibility process is not prohibited. [Health and Safety Code Section 127405(e)(3)] In light of this limitation, a hospital may wish to adopt the following policies:

1. Hospital personnel who are responsible for gathering or reviewing information used to make eligibility determinations should be different from the personnel who are responsible for collections. If this approach is not practical for smaller hospitals, extra care should be taken to ensure that information obtained in the eligibility process is not used to collect the debt.
2. Information concerning income or assets obtained as part of the eligibility process should be maintained in a file that is separate from the file used to collect the debt. The file containing the information used to determine eligibility should not be available to the personnel involved in debt collection, or at least should not be reviewed in the debt collection process.
3. To the extent the asset information is stored electronically, it should be stored in a file to which debt collection personnel do not have access.

Documentation of Coverage

HFPP requires that patients make every reasonable effort to provide documentation of health benefits coverage [Health and Safety Code Section 127405(e)]. The law does not limit the types of documentation of coverage a hospital may request. Hospitals should act reasonably in requesting such documentation.

Compliance Tip: A hospital must "make all reasonable efforts to obtain from the patient or his or her representative information about whether a private or public health insurance or sponsorship may fully or partially cover the charges for care rendered by the hospital ..." This includes, but is not limited to, private health insurance, including coverage offered through the California Health Benefit Exchange (Covered California), Medicare, Medi-Cal, California Children's Services (CCS), and "other state-funded programs designed to provide health coverage." [Health and Safety Code Section 127420(a)].

Timing of Eligibility Determinations

The HFPP law provides that eligibility for charity care or discount payment may be determined any time the hospital is in receipt of documentation of income and, if applicable, assets [Health and Safety Code Section 127405(e)(4)]. Presumably, the hospital may also wait until there is adequate documentation of the presence or absence of health coverage, although this is not expressly stated.

This provision raises a question of whether there is an unlimited amount of time for a patient to provide documentation, with a hospital required to make the charity care or discount payment decision whenever complete documentation is provided. This provision does not prohibit a hospital from placing a reasonable time limit on the submission of documentation, as the language of the statute is permissive rather than mandatory: the hospital "may" consider, not the hospital "shall" consider. Because certain debt collection referrals cannot occur until 150 days after initial patient billing *(see "Credit Reporting and Civil Actions," page 8.19)*, 150 days seems to constitute the minimum amount of time a patient should be given to comply with documentation requirements before the hospital determines the patient is ineligible for charity care or discount payment.

Handling Disputes and Denials of Eligibility

Eligibility Disputes

Hospitals may deny a patient's eligibility for charity care or discount payment either because the patient is not financially eligible or because the patient did not provide the documentation allowed by the law. However, a hospital's charity care and discount payment policies should designate an appropriate manager to review disputes concerning eligibility. This individual may be the business manager, chief financial officer, or "other appropriate manager as designated in the charity care policy and the discount payment policy." [Health and Safety Code Section 127405(a)(1)]

C. Maximum Expected Payments Allowed Under the HFPP Law

The HFPP law specifies limitations on billing patients who are eligible for charity care and discount care. This section provides a detailed discussion of the basic limits, the maximum allowable payments for both self-pay and insured patients, and whether any services may be excluded from these policies. *(See C. "Limitations on Patient Charges — Section 1.501(r)–5," page 8.37, for more information about the federal maximum rate.)*

Limitations on Patient Liability

Under the HFPP law, hospitals are limited to collecting from eligible patients the amount they would "expect, in good faith, to receive" for the same services from Medicare or Medi-Cal. If the hospital provides a service for which there is no established payment by Medicare or Medi-Cal, the hospital must establish an appropriate discounted payment, but patients who are eligible for financial assistance under the HFPP law cannot be required to undergo an independent dispute resolution process to establish the payment amount. [Health and Safety Code Section 127405(d)]

Similarly, hospitals are limited to collecting from eligible patients with high medical costs the difference between the amount of payment available from any third-party payer and the maximum rate established under HFPP.

For example, in the case of an eligible patient with high medical costs, when the third-party payment is $25,000 and the highest payment rate from a government payer is $24,000, no payment should be sought from the patient. If the total government payment in the example were $30,000, however, the patient could be billed the $5,000 difference. When determining the total maximum payment that would have been received for services if billed to one of the applicable government payers, it appears appropriate to include all pass-through payments and add-on payments such as outlier and disproportionate share adjustments. It is unclear whether any patient copayment obligation should be factored into that calculation.

The expected payment from the health programs listed above is service-specific rather than the average discount the hospital provides the program. This may be difficult for facilities to put into operation. In determining the maximum expected payment, a hospital may choose the government program rate that affords the highest reimbursement, and a hospital may apply rates from one program to some services, and rates from another program to other services.

Compliance Tip: Hospitals may make a good-faith estimate of the amount of patient liability for the specific service rather than an exact calculation of payment by a third-party payer.

Determining Maximum Payment

A hospital may include all aspects of payment for a service in determining the maximum expected payment. For example, if Medicare rates are used for inpatient hospital services, a hospital may take into account the Diagnosis-Related Group (DRG) payment amount, any disproportionate share adjustment, any direct or indirect medical education adjustment, and outlier payments.

A difficult question is whether hospitals may include Medi-Cal disproportionate share payments if Medi-Cal rates are used for inpatient hospital services. A reasonable argument can be made that such payments (converted to an amount per patient day) can be used, since Medi-Cal disproportionate share payments are made, at least theoretically, in return for providing specific Medi-Cal services, even though they are paid on an aggregate basis. The same argument could be made with regard to payments a hospital receives from the Department of Health Care Services under the Quality Assurance Fee (QAF) program. However, absent any direct guidance on this issue, hospitals could also reasonably conclude that only anticipated payments for specific services should be considered, in which case QAF payments would not be included.

A hospital is free to charge an amount that is lower than the amount that would be paid by a government program. A hospital may also charge patients eligible for discount payments who have different income levels a different amount for the same services, so long as the expected payment does not exceed the maximum allowed. Thus, a hospital may use a sliding scale approach, where a percentage of the maximum is charged depending on the patient's income.

Further, if it is too difficult operationally to include all payment add-ons, a hospital may exclude them from the patient's expected payment. For example, a hospital may decide it is

too difficult to include a medical education or disproportionate share adjustment if Medicare rates are used, and may simply omit them. A hospital may balance the administrative expense of including the add-ons and the possibility of computing a payment in excess of the maximum allowed, on the one hand, with the additional payment the hospital would likely realize for performing a complete calculation.

Hospitals may consider performing an estimated computation of the maximum payment amount at admission or upon discharge, and then reconciling this amount later. This is probably permissible; however the hospital would be required to pay interest on any payments received in excess of the maximum *(see "Payment of Interest," page 8.28)*. Again, this may be more difficult to accomplish correctly from an operational perspective than it is worth.

A slightly complicating factor in this calculus is the different definition of maximum payment amount described in Internal Revenue Code Section 501(r) for tax-exempt (IRS Section 501(c)(3)) hospitals. Under that provision, a patient eligible under a hospital's financial assistance policy (likely the same as a charity care and discount policy) cannot be liable for more than the rate "generally billed" to insured patients. In cases where the hospital has a sliding scale discount and/or charity policy, hospitals will need to ensure that such federal maximum rate is the maximum rate for which patients at the top end of that scale will be liable. *(See C. "Limitations on Patient Charges — Section 1.501(r)–5," page 8.37, for more information about the federal maximum rate.)*

Finally, under the EPFPP, emergency physicians must limit the expected payment from eligible patients to an amount specified in the law. When the law was written, it stated that expected payment may be no greater than 50 percent of the median of billed charges based on a nationally-recognized database of physician charges until the nonprofit FAIR Health, Inc. creates a database that makes available the rate of payment received by physicians from commercial insurers for the same services in the same or similar geographic region. When FAIR Health, Inc. makes available this database, the amount of payment may be no greater than the median or average of rates paid by commercial insurers for the same or similar services in the same or similar geographic region [Health and Safety Code Section 127452(b)]. FAIR Health, Inc., now publishes reimbursement information on its website at https://www.fairhealth.org.

If an emergency physician seeks reimbursement from the Maddy Fund pursuant to Health and Safety Code Section 1797.98c, the physician must cease any further billing or collection activity for that patient. If the emergency physician attempts to obtain reimbursement from the Maddy Fund but does not receive any, or does not seek reimbursement from the Maddy Fund, the provisions of EPFPP apply. [Health and Safety Code Section 127452(c)]

Insured Patients

Significantly, the expected payment limitation applies to patients with health care coverage who have incomes less than 400 percent of FPL, in addition to self-pay patients [Health and Safety Code Section 127405(a)(1)]. The appropriate way to apply the limitation for patients with insurance coverage is to limit an insured patient's financial responsibility (e.g., copayments and deductibles) to the amount by which the maximum government program rate for the services exceeds the payment received from the third party payer. For example, if the maximum rate is $10,000, an insurance company pays $9,000, and the patient's

copayment amount is $2,000, the maximum that may be collected from the patient would be $1,000. If the insurance company's payment exceeds the payment limitation, no amount may be collected from the patient.

Under the original version of the law, private third-party payers argued that:

1. A hospital's failure to charge patients the full amount of any copayment or deductible violated the terms of the contract between the hospital and the payer; and
2. The payer's reimbursement to the hospital should be reduced, or the payer has no liability to the hospital, because a prerequisite to coverage — namely, the assessment of the full deductible amount — never occurred.

However, the law now directly addresses this issue, stating that:

> No health care service plan, insurer, or any other person shall reduce the amount it would otherwise reimburse a claim for hospital services because a hospital has waived, or will waive, collection of all or a portion of a patient's bill for hospital services in accordance with the hospital's charity care or discount payment policy, notwithstanding any contractual provision. [Health and Safety Code Section 127444]

May Services Be Excluded?

A common question arising from the HFPP law is whether a hospital may exclude certain types of services from its charity care or discount payment policy. For example, may a hospital exclude medically unnecessary procedures such as cosmetic surgery?

A reasonable reading of HFPP is that once a hospital accepts a patient, all services furnished to the patient are subject to the discount payment policies. HFPP does not exclude any category of services. Rather, Health and Safety Code Section 127405(d) requires that a hospital must limit expected payment for services it provides to patients at or below 400 percent of FPL, without qualifying the services to which the statute applies.

Thus, the mandated upper payment limit should be available to patients through the discount payment policy regardless of the type of service. The statute does not specifically address the question of whether they should also be available through the charity care policy, but medically-unnecessary services, those of a purely cosmetic nature, probably can be excluded from a hospital's charity care policy.

A hospital that adopts a more generous financial standard than required by HFPP probably could exclude services furnished to patients who do not satisfy the mandated criteria in the law but would satisfy the more generous criteria.

The federal requirements under Internal Revenue Code Section 501(r) do not appear as inclusive as those of the HFPP. Federal law applies only to emergency and medically-necessary services. [26 U.S.C. Section 501(r)(5)(A)]

Compliance Tip: If a hospital wishes to restrict covered services for patients to whom it is providing discounts, but whose income exceeds 400 percent of FPL, the hospital should adopt a separate policy to address such patients.

D. Limiting Debt Collection

HFPP's restrictions on debt collection efforts have two main components: first, the law requires hospitals to give notice to patients prior to beginning collection activities, and second, the law outlines detailed requirements for collection practices. Importantly, the HFPP's debt collection requirements likely apply to all patient accounts, and not just to the accounts of those patients eligible for charity care or discount payment. This section begins with a brief discussion of the notice requirement and then discusses the requirements applicable to specific collection practices.

Federal law applicable to nonprofit hospitals subject to Internal Revenue Code Section 501(r) prohibits such hospitals from engaging in extraordinary collection efforts until reasonable efforts have been made to determine whether a patient is eligible for financial assistance. The Secretary of the Treasury issued interpretive regulations on this topic, including, in particular, what constitutes reasonable efforts by an organization to determine whether a patient is eligible for financial assistance *(see V. "Federal Laws Regarding Financial Assistance Policies," page 8.31)*.

Notice Prior to Commencing Collection Activities

A hospital, any assignee of a hospital, or the owner of patient debt, including a collection agency, must provide a patient with a clear and conspicuous notice of the following prior to commencing collection activities against him or her [Health and Safety Code Section 127430]:

1. A plainly worded summary of the patient's rights pursuant to HFPP, the Rosenthal Fair Debt Collection Practices Act, and the federal Fair Debt Collection Practices Act. The summary must include a statement that the Federal Trade Commission (FTC) enforces the federal act. A specific form of acceptable notice is contained in Health and Safety Code Section 127430(a)(1), as follows:

> State and federal law require debt collectors to treat you fairly and prohibit debt collectors from making false statements or threats of violence, using obscene or profane language, and making improper communications with third parties, including your employer. Except under unusual circumstances, debt collectors may not contact you before 8:00 a.m. or after 9:00 p.m. In general, a debt collector may not give information about your debt to another person, other than your attorney or spouse. A debt collector may contact another person to confirm your location or to enforce a judgment. For more information about debt collection activities, you may contact the FTC by telephone at 877-FTC-HELP (382-4357) or online at www.ftc.gov.

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2. A statement that nonprofit credit counseling services may be available in the area.

"Commencement of collection activities" is not defined in the law. California Department of Public Health (CDPH) audits of hospital compliance with HFPP requirements indicate CDPH's view that commencement of collection activities occurs when accounts are sent by a hospital to an outside collection agency. Based on that view, the hospital's notice should be sent prior

to transfer of the accounts to the outside collection agency. However, the 2021 amendments to the HFPP law contain a separate notice requirement that applies before a hospital can "assign[] a bill to collections" [Health and Safety Code Section 127425(e)]. This suggests that "assigning a bill to collections" is a precursor to the "commencement of collection activities" by an outside agency, such that a hospital would not be required to comply with all requirements that apply upon the "commencement of collection activities" when it has only "assign[ed] a bill to collections" without also "commenc[ing] collection activities." Practically speaking, however, hospital practices vary and commencement may occur because of correspondence or other communication with the patient immediately after the initial bill is sent to the patient. Thus, to be compliant with this notice requirement, hospitals may choose to include the notice described above with the initial bill.

The notice must also be given in any document indicating that the commencement of collection activities may occur [Health and Safety Code Section 127430(b)].

It is possible that the obligation to provide notice may exist with respect to the first collection activity taken by any entity. Thus, a hospital would be required to give notice before beginning collection activities, and any assignee of the debt, such as a collection agency, would also have to give notice before it begins any collection activity — even though the hospital already gave notice. The law is unclear on this point.

Collection Practices

The HFPP law contains detailed requirements concerning collection practices. These requirements are described in this section.

Extended Payment Plan

A hospital's discount payment policy must "include an extended payment plan to allow payment of the discounted price over time." Further, the statute mandates that a hospital's discount payment policy require the hospital and the patient to "negotiate the terms of the payment plan and take into consideration the patient's family income and essential living expenses." [Health and Safety Code Section 127405(b)] If the hospital and the patient cannot agree on the payment plan, the hospital must use the statutory formula to create a reasonable payment plan. HFPP defines a **"reasonable payment plan"** as "monthly payments that are not more than 10 percent of a patient's family income for a month, excluding deductions for essential living expenses." The statute defines **"essential living expenses"** as "expenses for any of the following: rent or house payment and maintenance, food and household supplies, utilities and telephone, clothing, medical and dental payments, insurance, school or child care, child or spousal support, transportation and auto expenses, including insurance, gas, and repairs, installment payments, laundry and cleaning, and other extraordinary expenses." [Health and Safety Code Section 127400(i)] Notably, this definition does not include any limits to the term "essential living expenses," nor does it appear to allow the hospital to establish its own limits.

HFPP provides that a hospital may not charge interest on an extended payment plan offered to assist a patient eligible under the hospital's charity care policy, discount payment policy, "or any other policy adopted by the hospital for assisting low-income patients with no insurance or high medical costs in settling outstanding past due hospital bills" [Health and Safety Code Section 127425(i)].

HFPP provides no other guidance concerning the terms under which a hospital must allow extended repayment. The law could be read as requiring specific and objective criteria for extended payment plans. Such criteria would set forth a mechanism for determining the term of a plan, and might include such factors as the size of the payment obligation and the patient's resources and expenses. Placing such criteria in a written policy would strengthen a hospital's position that it is in compliance with the law and help to avoid arbitrary and inconsistent decisions by the hospital's personnel.

HFPP allows hospitals to declare an extended payment plan inoperative if the patient fails to make all consecutive payments due during a 90-day period. Prior to declaring an extended payment plan inoperative, a hospital, collection agency, debt buyer, or assignee must:

1. Attempt to contact the patient by telephone;
2. Give notice in writing that the plan may become inoperative; and
3. Inform the patient of the opportunity to renegotiate the payment plan, and attempt to do so if requested by the patient. Until the plan is declared inoperative, no report may be made to a consumer credit reporting agency and no civil action may commence. The notice and phone call may be made to the last known phone number and address of the patient.

[Health and Safety Code Section 127425(i)]

Compliance Tip: At a minimum, a hospital's discount payment policy should state that patients may pay any amount due to the hospital over time, and that the hospital will negotiate the terms of the payment plan with the patient. The hospital should then negotiate in good faith. If the hospital and the patient cannot reach an agreement, the hospital must accept the "reasonable payment plan" defined by law.

Advancing Debt for Collection

A hospital must maintain a written policy about:

1. When, and under whose authority, patient debt is advanced for collection; and
2. Whether the collection activity is conducted by the hospital, an affiliate or subsidiary of the hospital, or by an external collection agency, or debt buyer.

[Health and Safety Code Section 127425(b)]

The statute does not define what it means to "advance a debt for collection." It is unclear whether this encompasses any communication to a patient regarding an outstanding bill, or whether it refers to more aggressive activities. To be cautious, a hospital's policy concerning collection should encompass all communications with a patient after the initial bill is sent, consistent with the notice requirement described above.

Further, the HFPP law was amended in 2021 to make clear that it "does not prohibit a hospital, debt collector, or debt buyer from selling or otherwise transferring patient debt to an organization that is exempt from taxation under Section 501(c)(3) of the Internal Revenue Code for the explicit purpose of the tax-exempt organization abolishing the patient debt by cancellation of the indebtedness, or otherwise prohibit payment of the patient's debt by a third party" [Health and Safety Code Section 127444(b)].

The requirement that the policy indicate under whose authority the debt is being advanced for collection suggests there must be a human intervention when a hospital first commences collection activities. Hospitals frequently use automated systems for debt collection, at least until the debt is sent to an outside collection agency or an internal office that acts like a collection agency. A reasonable interpretation of HFPP is that it probably requires an individual to make a patient-specific decision before any collection activities begin, including sending letters after the initial billing requesting payment.

The requirement that the hospital's policy state when a patient debt is advanced for collection indicates that the policy should include a timing component of some kind, as well as circumstances under which the bill will be advanced to collections.

Compliance Tip: Hospitals should include in their policy a clear statement of the timing and circumstances under which a bill will be advanced for collection, such as specifying that a bill will be advanced for collection if not paid within 30 days of the initial bill, and a consideration of such factors as lack of payment, failure to apply for available programs, or failure to contact the hospital in response to a bill.

Standards and Practice

Every hospital is required to establish a written policy defining the standards and practices for the collection of a debt. A hospital must also obtain a written agreement from each collection agency it uses stating that the collection agency will adhere to the hospital's standards and practices. The agreement must also require that agency to comply with the hospital's definition and application of a "reasonable payment plan" *(see "Extended Payment Plan," page 8.17)*. [Health and Safety Code Section 127425(c)]

The above section of the law also contains a curious provision that states that in determining the amount of a debt a hospital may seek to recover from patients who are eligible under the hospital's charity care policy or discount payment policy, the hospital may consider only income and monetary assets as limited by the provisions relating to charity care and discounted payment. This likely means that a hospital cannot decide in the collection phase to recalculate the patient's liability based on income or assets that could not have legally been considered when first determining charity care or discount payment eligibility. This provision does not appear to preclude a hospital from collecting amounts due by executing against income or assets that may not be considered in establishing charity care or discount payment eligibility.

Credit Reporting and Civil Actions

If a patient is uninsured or provides information that he or she may be a patient with high medical costs, neither a hospital, the assignee of an account, nor a collection agency may, within 180 days of initial billing, report adverse information to a consumer credit reporting agency concerning, or commence a civil action against the patient [Health and Safety Code Section 127425(f)]. Hospitals and their collection agencies should take care to implement this provision to avoid liability that could arise from premature notice to credit reporting agencies.

Extension of Time Periods During Appeals

Pursuant to Health and Safety Code Section 127426:

> [t]he period described in section 127425 shall be extended if the patient has a pending appeal for coverage of the services, until a final determination of the appeal is made, if the patient makes a reasonable effort to communicate with the hospital about the progress of any pending appeals.

"Pending appeal" includes a grievance against a health care service plan or insurer, an independent medical review, a fair hearing for a review of a Medi-Cal claim, or an appeal regarding Medicare coverage.

It is not clear to which time period this provision refers. Most likely, it refers to the 180-day waiting period prior to providing notice to a credit reporting agency or commencing a civil action. This time period appears to be extended where the patient is appealing a coverage denial. *(See "Credit Reporting and Civil Actions," page 8.19.)* If this is correct, then the provision fails to address the question of how long the 180-day period is extended. If the appeal is resolved against the patient 200 days after initial billing, may the hospital immediately make a credit report or commence a civil action, or must the hospital wait another 180 days to take such action? Similarly, if the appeal is resolved against the patient 100 days after the initial billing, may the hospital first make a credit report or commence a civil action on the 180th day or the 280th day after the initial billing? Although the statute is silent on this issue, hospitals may reasonably assume the 180-day period begins after the patient's appeal is completed to afford the patient the full 180 days to make payment.

Compliance Tip: Within 180 days from initial billing, HFPP clearly prohibits hospitals from reporting negative information to a credit agency or beginning civil proceedings against patients who lack coverage or inform the hospital that they may have high medical costs. To ensure compliance, be sure that this requirement is clearly communicated to collection agencies.

Sending Accounts to Collection Agencies

A hospital may not send an account to a collection agency unless the agency agrees to comply with HFPP for a patient who:

> is attempting to qualify for eligibility under the hospital's charity care or discount payment policy and is attempting in good faith to settle an outstanding bill with the hospital by negotiating a reasonable payment plan or by making regular partial payments of a reasonable amount. [Health and Safety Code Section 127425(g)]

Hospitals may wish to require their collection agencies to agree to comply with HFPP for all patients. Otherwise, a hospital will be required to determine when a patient is:

1. Still attempting to qualify for charity care or discount payment; or
2. In good faith, attempting to settle a bill by negotiating a reasonable payment plan, or by making regular partial payments of a reasonable amount. This requires subjective determinations such as whether the patient is acting in good faith and whether the patient is making payments that are "regular" and "reasonable."

Notice Prior to Assigning a Patient Bill to Collections

Before assigning a patient bill to collections or selling patient debt, a hospital must send the patient a notice with the following information:

1. The date or dates of service for the bill.
2. The name of the entity to which the bill is being assigned or sold.
3. Information on how to obtain an itemized hospital bill from the hospital.
4. The name and plan type of the health coverage for the patient on record with the hospital at the time of services or, if the hospital does not have that information, a statement to that effect.
5. An application for the hospital's charity care and financial assistance.
6. The date or dates the patient was originally sent a notice about applying for financial assistance, the date or dates the patient was sent a financial assistance application, and, if applicable, the date a decision on the application was made.

[Health and Safety Code Section 127425(e)]

Under a new requirement established in 2021, a hospital cannot sell patient debt to a debt buyer (as that term is defined in Civil Code Section 1788.50) unless the following requirements are satisfied:

1. The hospital has determined that the patient is ineligible for financial assistance, or the patient has not responded to any attempts to bill or offer financial assistance for 180 days.
2. The sales agreement between the hospital and debt buyer includes contractual language pursuant to which the debt buyer agrees to return, and the hospital agrees to accept, any account in which the balance has been determined to be incorrect due to the availability of a third-party payer, or because the patient is eligible for charity care or financial assistance. A **"third-party payer"** includes a health plan or government health coverage program.
3. The debt buyer agrees to not resell or otherwise transfer the patient debt, except back to the originating hospital or a tax-exempt organization described in Section 127444. (That provision refers to a tax-exempt organization that abolishes the patient debt by cancelling indebtedness.) The debt buyer can also transfer the patient debt if the debt buyer is sold or merged with another entity.
4. The debt buyer agrees not to charge interest or fees on the patient debt.
5. The debt buyer is licensed as a debt collector by the California Department of Financial Protection and Innovation.

[Health and Safety Code Section 127425(a)].

Recalling Accounts from Collection Agencies

The HFPP law does not specify when an account should be recalled from a collection agency. However, California's Medicaid law states that if a patient account has been referred to an outside debt collector, and the hospital receives proof of a patient's Medi-Cal eligibility, the hospital must:

1. Notify the debt collector of the patient's Medi-Cal coverage;
2. Instruct the debt collector to cease collection efforts on the unpaid bill for the covered services; and
3. Notify the patient that the above steps were taken.

This prohibition does not apply to the Medi-Cal share of cost owed by a Medi-Cal beneficiary.

In addition, if a patient becomes eligible for Medi-Cal, information previously sent to a consumer-reporting agency by the hospital or the debt collector must be corrected within 30 days. [Welfare and Institutions Code Section 14019.4]

Wage Garnishments and Primary Residences

Hospitals and Their Affiliates. A hospital, or an assignee of the hospital which is an affiliate or subsidiary of the hospital, may not use wage garnishments or liens on primary residences to collect an unpaid hospital bill with respect to a patient who is eligible under the hospital's charity care or discount payment policies [Health and Safety Code Section 127425(h)(1)].

Collection Agencies. Substantial limitations are imposed on a collection agency's use of wage garnishments or liens on primary residences with respect to patients who are eligible for the hospital's charity care or discount payment policies.

Wage garnishment. A collection agency or other assignee that is not an affiliate or subsidiary of the hospital may use a wage garnishment only upon:

> order of the court upon noticed motion, supported by a declaration filed by the movant identifying the basis for which it believes that the patient has the ability to make payments on the judgment under the wage garnishment, which the court shall consider in light of the size of the judgment and additional information provided by the patient prior to, or at, the hearing concerning the patient's ability to pay, including information about probable future medical expenses based on the current condition of the patient and other obligations of the patient. [Health and Safety Code Section 127425(h)(2)(A)]

This provision imposes a substantial burden on a collection agency to obtain a wage garnishment and makes wage garnishments unobtainable or impractical in most situations.

Sale of primary residence. A collection agency or other assignee that is not an affiliate or subsidiary of the hospital may not notice, or conduct a sale of, a patient's primary residence:

1. During the life of the patient or their spouse;
2. During the period that a child of the patient is a minor; or
3. During the period a child of the patient who has attained the age of majority is unable to take care themself and resides in the dwelling as his or her primary residence [Health and Safety Code Section 127425(h)(2)(B)].

If a patient has more than one dwelling, the law specifies which one should be considered the primary residence [Health and Safety Code Section 127425(h)(2)(B)]. There is no limit on the value of the primary residence that is protected. Hospitals should consult with legal counsel on this issue.

Remedies Against Non-Patients

The limitations with respect to garnishments and sales of primary residences do not preclude a hospital, collection agency, debt buyer, or other assignee "from pursuing reimbursement and any enforcement remedy or remedies from third-party liability settlements, tortfeasors, or other legally responsible parties" [Health and Safety Code Section 127425(h)(3)]. This provision permits the use of wage garnishments and sales of primary residences without any restrictions against tortfeasors or "other legally responsible parties."

An **"other legally responsible party"** appears to include a guarantor. The statute does not state whether an "other legally responsible party" includes a family member who is legally responsible for the care, such as a parent or a spouse. It appears inconsistent with the overall design of the HFPP law to permit unlimited wage garnishments and sales of primary residences against family members who are guarantors, as HFPP evaluates the eligibility of patients for charity care and discount payment based on the family's income and medical expenses. Hospitals may choose to treat members of a patient's family in the same manner as the patient for purposes of wage garnishments and sales of primary residences, even though the language of the law on its face does not appear to offer a patient's family members any protections against wage garnishments and sales of primary residences (unless the primary residence of the responsible party is also the patient's primary residence).

Other Consumer Protections

HFPP does not "diminish or eliminate any protections consumers have under existing federal and state debt collection laws, or any other consumer protections available under state or federal law" [Health and Safety Code Section 127425(j)]. Thus, hospitals must continue to comply with other applicable laws. Not-for-profit hospitals must also comply with requirements regarding collections activities regulated by Internal Revenue Code Section 501(r).

E. Providing Notices

HFPP requires two types of notice of the charity care and discount payment policies: a written notice (handout) to patients and posted notices. Furthermore, HFPP requires hospitals to furnish patients who may be eligible for government programs with applications for those programs. Finally, HFPP requires hospitals to provide specified information along with the bill to every patient who has not provided proof of third-party coverage. These requirements are discussed below.

Written Notice to Patients

In providing written notices (handouts) to patients, hospitals must follow these guidelines:

1. Written notices must be provided to all patients, including those receiving outpatient and emergency care who are not admitted. The law does not specify when the notice must be given.

2. The notice must include information about the hospital's charity care and discount payment policies. At a minimum, this must include information about eligibility and contact information for a hospital employee or office from which the patient may obtain further information. In addition, the hospital's written discount policy must state that an emergency physician providing emergency services in the hospital is required to provide discounts to uninsured and high medical cost patients whose

incomes are at or below 400 percent of FPL. Although the EPFPP law is not entirely clear on this point, it appears that the hospital's notice to the patient should include this basic information about the emergency physician's obligation.

3. The written notice of charity and discounted care policies is in addition to the estimate of charges provided pursuant to Health and Safety Code Section 1339.585. *(See VII. "Providing Estimates to Patients," page 17.28.)*

4. The notice must be provided in English as well as other languages, consistent with Insurance Code Section 12693.30. This Insurance Code section, in turn, refers to Government Code Sections 7290-7299.8, and seems to require a hospital to provide the notice in any language that is the primary language of 5 percent or more of the hospital's patients [Government Code Section 7296.2]. In addition, hospitals must comply with all other state and federal laws regarding interpreter and translation services. *(See CHA's* Consent Manual *for details about state and federal language assistance requirements.)* [Health and Safety Code Section 127410(a)]

5. The written notice, or a summary of it, must also be provided when a hospital bills a patient. Health and Safety Code Section 127425(d) requires that "[a]t time of billing, a hospital shall provide a written summary consistent with Section 127410, which includes the same information concerning services and charges provided to all other patients who receive care at the hospital."

It is unclear whether this notice must be provided in billings to all patients. The last clause of the provision suggests that the notice need not be provided to all patients, as it requires that the summary include information about charges "provided to all *other* patients," indicating that the patients to whom the summary must be sent is a subset of *all* patients [Health and Safety Code Section 127425(d); emphasis added]. The provision, however, does not define the group of patients who must receive the summary. Further, this provision appears to be somewhat redundant to Health and Safety Code Section 127420(b), which requires that comprehensive information be provided at the time of billing to patients who have not provided proof of third-party coverage. *(See "Information to Accompany Bills to Patients Without Third-Party Coverage," page 8.26.)*

Compliance Tip: To ensure compliance, hospitals should give the written notice to all patients as part of the admission or registration process.

Hospitals may wish to provide a summary of the notice required by Health and Safety Code Section 127410(a) with the bill to all patients. However, the provision may reasonably be read in the context of the entire statute to require the summary only in billings to patients who have not provided proof of coverage.

The HFPP law also requires that "written correspondence to the patient required by" HFPP "shall also be in the language spoken by the patient, consistent with section 12693.30 of

the Insurance Code and applicable state and federal law" [Health and Safety Code Section 127410(a)]. So, for example, the correspondence addressed at "Notice Prior to Commencing Collection Activities," page 8.16, also must adhere to the primary language requirement as would all other correspondence that the hospital is required to send to patients under the HFPP.

Posted Notices

Notice of the hospital's "policy for financially qualified and self-pay patients" must be "clearly and conspicuously posted in locations that are visible to the public ..." [Health and Safety Code Section 127410(c)]. The statute does not specify what information the notice must include. The locations in the hospital that must have posted notices include, but are not limited to:

1. The emergency department, if the hospital has one
2. The billing office
3. The admissions office
4. Other outpatient settings, including observation units
5. On the hospital's internet website

The requirement that a posting must be placed in "other outpatient settings" appears to include all outpatient settings of the hospital, including all outpatient clinics, and appears to include ancillary departments furnishing services to outpatients. [Health and Safety Code Section 127410(b)]. The notice posted on the hospital's internet website must also include a link to the policy itself [Health and Safety Code Section 127410(b)]. If a patient would have been eligible for financial assistance under the policy that was available on the website at the time he or she received services, the patient must receive financial assistance [Health and Safety Code Section 127435].

AB 1020 and AB 532, which were enacted in 2021, contain a number of new provisions relating to the written notice provided to patients. The notice must contain the internet address for the Health Consumer Alliance (https://healthconsumer.org), and must explain the availability of organizations to help patients understand billing, payment. If the hospital participates in the presumptive eligibility program, the notice must also provide information regarding Medi-Cal and Covered California presumptive eligibility. Finally, the notice should also include the internet address for the hospital's list of shoppable services, consistent with 45 C.F.R. Section 180.60. [Health and Safety Code Section 127410(a)]

AB 1020 also inserted a new requirement that the notice be provided at the time of service if the patient is conscious and able to receive written notice. If the patient cannot receive notice at that time, the notice should be provided during the discharge process; or, if the patient is not admitted, when the patient leaves the facility. If the patient did not receive written notice by the time the patient left the facility, the notice should be mailed to the patient within 72 hours of providing services. [Health and Safety Code Section 127410(b)]

Compliance Tip: Although the law does not specify what information to include in posted notices, at a minimum, they should explain that the hospital has policies available for self-pay and other financially-qualified patients that may result in a reduction in the patient's liability, as well as contact information for obtaining additional information.

Providing Applications for Medi-Cal and Other Programs

HFPP requires hospitals to provide a statement indicating how patients may obtain applications for "the Medi-Cal program, coverage through the California Health Benefit Exchange [Covered California], or other state- or county-funded health coverage programs" to the patient [Health and Safety Code Section 127420(b)(4)]. The application must be provided to a patient who does not indicate coverage by a third-party payer, or who requests discounted payment or charity care. The application must be provided prior to discharge for inpatients and "to patients receiving emergency or outpatient care." [Health and Safety Code Section 127420(b)(4)]

This provision appears to require a hospital to provide relevant applications regardless of whether the patient requests or desires one. However, a hospital would most likely be considered to have satisfied this requirement if it furnished applications only for programs for which the patient might be eligible, since the statute uses the word "or" rather than "and" when describing the list of programs for which applications must be provided. Thus, for example, an elderly patient need not be furnished an application for California Children's Services (CCS). This provision, however, implies that a hospital must maintain applications for all state- or county-funded health coverage programs that possibly could be available. This would include, for example, a county indigent program, County Medical Services Program (for covered counties), and CCS, in addition to Medi-Cal.

Compliance Tip: Hospitals should err on the side of providing applications to all programs for which the patient could potentially be eligible — that is, provide more rather than fewer applications to the patient.

Information to Accompany Bills to Patients Without Third-Party Coverage

If a hospital bills a patient who has not provided proof of coverage by a third party, the bill must include a clear and conspicuous notice that includes all of the following:

1. A statement of charges for services rendered by the hospital.
2. A request that the patient inform the hospital if the patient has health insurance coverage, Medicare, Medi-Cal, or other coverage.
3. A statement that if the patient does not have health insurance coverage, he or she may be eligible for Medicare, Medi-Cal, coverage offered through the California Health Benefit Exchange (Covered California), CCS, other state-or county-funded health coverage, or charity care.

4. A statement indicating how the patient may obtain applications for the Medi-Cal program, coverage offered through the California Health Benefit Exchange (Covered California), or other state-or county-funded health coverage, and that the hospital will provide these applications. The hospital is also required to provide patients with a referral to a local consumer assistance center housed at legal services offices.
5. Information regarding the financially-qualified patient and charity care application, including the following[2]:
    a. A statement that indicates that if the patient lacks, or has inadequate, insurance, and meets certain low- and moderate-income requirements, the patient may qualify for discounted payment or charity care.
    b. The name and telephone number of a hospital employee or office from whom, or which, the patient may obtain information about the hospital's discount payment and charity care policies, and how to apply for that assistance.
    c. If a patient applies, or has a pending application for, another health coverage program at the same time that he or she applies for a hospital charity care or discount payment program, neither application will preclude eligibility for the other program.

[Health and Safety Code Section 127420(b)]

An emergency physician is deemed in compliance with this notice requirement if the following statement is included with the statement of charges:

> If you are uninsured or have high medical costs, please contact [name of person responsible for discount payment policy] at [area code and phone number] for information on discounts and programs for which you may be eligible, including the Medi-Cal program. If you have coverage, please tell us so that we may bill your plan.

If the emergency physician or assignee lacks the capacity to provide the notice above, he/she is deemed in compliance with the notice requirement if the required information is provided upon the patient's request, and if the following statement is printed on the bill in 14-point bold type: "If uninsured or high medical bill, call re: discount." It is unclear what "lacks the capacity to provide" the longer notice means.

[Health and Safety Code Section 127454(c)]

F. Reimbursing Overcharges to Patients

Health and Safety Code Section 127440 requires hospitals to reimburse patients amounts paid in excess of the amount due under HFPP including interest.

Return of Principal

The only clear limit on payments under HFPP is the requirement that qualifying patients not be charged more than the highest rate that the hospital would expect to be paid under

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2 This appears to mean information about the hospital's discounted payment program and charity care program. The term **"financially-qualified patient"** means a patient who is a self-pay patient or a patient with high medical costs, and below 400 percent of the FPL [Health and Safety Code Section 127400(c)]. This describes any patient who would be eligible for charity care or discounted payment, with a few exceptions.

various governmental programs *(however, see "Limitations on Patient Liability," page)*. If the hospital is paid more than this amount from a qualifying patient, the hospital must refund the overpayment, unless the overpayment is less than $5. The hospital is required to issue a refund to the patient within 30 days.

Payment of Interest

Health and Safety Code Section 127440 requires that a hospital pay interest with any refunded overpayment, at the rate provided in the Code of Civil Procedure Section 685.010, currently set at 10 percent annually. Interest accrues on the overpayment from the date payment is received by the hospital. The state has clarified that hospital liability for interest on patient overpayments is applicable only to patients that are eligible for discount or charity care under the HFPP.

G. OSHPD Reporting

HFPP requires each hospital to provide OSHPD with a copy of its charity care policy, discount payment policy, eligibility procedures for those policies, review process, and the application form for charity care or discount payment programs, as well as its debt collection policy [Health and Safety Code Section 127435].

OSHPD requires a hospital to submit this information at least every other year on January 1, or whenever a significant change is made. In addition, because of the changes arising from AB 1020, every hospital must submit its new policies prior to Jan. 1, 2023 [Health and Safety Code Section 127435].The significance of the change must be evaluated from the perspective of the anticipated impact on the population intended to benefit from the HFPP law (low-income uninsured or high-medical cost people) [Title 22, California Code of Regulations, Sections 96041, 96044 and 96045].

If, when updated reporting is required, no change has been made in the intervening two years, the hospital need only notify OSHPD of the lack of change.

OSHPD has adopted regulations requiring the online submission of the required information [Title 22, California Code of Regulations, Section 96040-96050]. For details, go to OSHPD's website at https://hcai.ca.gov/data-and-reports/cost-transparency/hospital-fair-pricing-policies/.

OSHPD publishes the information reported by hospitals on its website. (Note that OSHPD has changed Its name to the Department of Health Care Access and Affordability, although the Hospital Fair Pricing Policies law still refers to OSHPD.)

H. Effect on Customary Charges

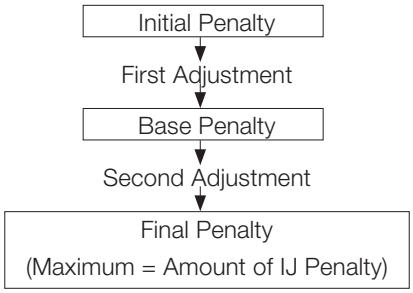
HFPP contains several provisions designed to protect hospitals from having charge reductions pursuant to a charity care or discount payment policy affect the hospital's customary or prevailing charges [Health and Safety Code Sections 127444-127446]. Hospitals should consult legal counsel if issues arise in this regard.

I. Penalties

The California Department of Public Health (CDPH) may issue administrative penalties against hospitals for violations of the HFPP law [Health and Safety Code Section 1280.3; Title 22, California Code of Regulations, Sections 70951-70960]. This portion of the manual describes how CDPH will calculate the amount of such penalties.

In determining the amount of the penalty, CDPH will consider three factors: the extent of noncompliance, the amount of financial harm to the patient, and the willfulness of the violation.

CDPH starts by determining an initial penalty and then adjusting it to produce an amount known as the "base penalty" (sometimes called the "adjusted initial penalty"). CDPH will then adjust the base penalty. The result of this second calculation is called the "adjusted base penalty" or the "final penalty." The base penalty (or "adjusted initial penalty") may exceed the statutory maximum, but the final penalty (or "adjusted base penalty") may not. The statutory maximum penalty is the amount of an immediate jeopardy penalty. [Title 22, California Code of Regulations, Sections 70953, 70956 and 70958] Each of these steps is explained more thoroughly below.



Calculating the Initial Penalty

CDPH determines the initial penalty for a violation of the HFPP law by considering whether the noncompliance is major, moderate, or minimal, as described below.

Major. The action or inaction deviates from the requirement to such an extent that the requirement is completely ignored and none of its provisions are complied with, or the function of the requirement is rendered ineffective because some of its provisions are not complied with. The initial penalty for this category is $25,000.

Moderate. The action or inaction deviates from the requirement, but it complies to some extent, although not all of its important provisions are complied with. The initial penalty for this category is $12,500.

Minimal. The action or inaction deviates somewhat from the requirement. The requirement functions nearly as intended, but not as well as if all provisions had been met. A violation in this category is a minor violation and no administrative penalty is assessed.

Adjusting the Initial Penalty

The initial penalty will be adjusted to determine the base penalty based upon the financial harm to the patient and the willfulness of the violation.

The initial penalty will be increased by 5 percent if the violation caused actual financial harm to the patient, based on information acquired by CDPH during its investigation.

The initial penalty will be increased by 10 percent if the deficiency was the result of a willful violation.

The base penalty may exceed the statutory maximum, although the final penalty may not.

Adjusting the Base Penalty

The base penalty will be adjusted to determine the final penalty. This adjustment is based upon whether the hospital immediately corrects the violation and upon the hospital's history of compliance with the HFPP law. [Title 22, California Code of Regulations, Section 70959]

1. **Immediate correction of the violation**

   When CDPH determines that a hospital subject to an administrative penalty promptly corrects the noncompliance, the base penalty will be reduced by 20 percent, if both of the following apply:

   a. The hospital identified and immediately corrected the noncompliance before it was identified by CDPH. Within 10 calendar days of the date that the hospital identified the noncompliance, the hospital must complete corrective action and steps necessary to prevent the violation from recurring. The hospital must promptly, and in detail, document the corrective action.

   b. A penalty was not imposed for a repeat deficiency that received a penalty reduction under these regulations within the 12-month period prior to the date of the violation.

2. **History of compliance**

   The base penalty will be increased by 10 percent if the hospital has had one or more other violations of the HFPP law within the three-year period immediately prior to the date of the violation.

Determining the Final Penalty

The calculations described above will result in the final penalty. The final penalty may not exceed the maximum penalty specified in Health and Safety Code Section 1280.3, which is $25,000 for a violation that does not constitute an immediate jeopardy (IJ), $75,000 for the hospital's first IJ penalty, $100,000 for the hospital's second IJ penalty, and $125,000 for the third and any subsequent IJ penalty. An IJ penalty is considered a first penalty if the date the violation occurred is more than three years from the date of the violation of the last issued IJ penalty, and if CDPH finds that the hospital has been in substantial compliance for three years prior to the date of the violation. It is not clear whether a violation of the California Hospital Fair Pricing Policies law can ever be considered to rise to the level of an immediate jeopardy — that is, serious injury or death to a patient.

Other Factors Influencing the Penalty Amount

Hospitals Affiliated With Health Plans

In assessing an administrative penalty against a health facility owned by a nonprofit corporation that shares an identical board of directors with a nonprofit health care service plan licensed pursuant to the Knox-Keene Act (for example, Kaiser), CDPH must consider whether the deficiency arises from an incident that is the subject of investigation of, or has resulted in a fine to the health care service plan by, the Department of Managed Health Care. If the deficiency results from the same incident, CDPH may adjust its penalty to take into consideration the penalty imposed by the Department of Managed Health Care. [Health and Safety Code Section 1280.6; Title 22, California Code of Regulations, Section 70958.1]

Small and Rural Hospitals

A small and rural hospital that has been assessed an administrative penalty may request:

1. Payment of the penalty extended over a period of time, if full payment would cause financial hardship; or
2. Reduction of the penalty, if extending the penalty payment over a period of time would cause financial hardship; or
3. Both a penalty payment plan and reduction of the penalty.

The small and rural hospital must submit its request in writing to CDPH within 10 days after the issuance of the administrative penalty. The request must describe the special circumstances showing financial hardship to the hospital and the potential severe adverse effects on access to quality care in the hospital.

CDPH will base its decision on information provided by the small and rural hospital and on hospital financial information from OSHPD or other governmental agency.

[Title 22, California Code of Regulations, Sections 70960 and 71703]

V. FEDERAL LAWS REGARDING FINANCIAL ASSISTANCE POLICIES

The Patient Protection and Affordable Care Act (ACA) of 2010 added new requirements for hospitals to qualify as tax-exempt under Internal Revenue Code (IRC) Section 501(c)(3) [26 U.S.C. Section 501(r)]. The new requirements concern financial assistance policies, limits on charges to specified patients, billing and collection restrictions, and patient notification. If a 501(c)(3) tax-exempt organization operates more than one hospital facility, each must meet the criteria of Section 501(r) separately. Any facility that fails to meet the criteria may be subject to a $50,000 excise tax, income tax for any year(s) out of compliance, or loss of tax-exempt status *(see H. "Enforcement," page 8.46)*.

On June 26, 2012, the IRS published proposed regulations offering guidance to tax-exempt hospitals regarding certain provisions of Section 501(r) [77 Fed. Reg. 38148 (June 26, 2012)]. The IRS issued final regulations on Dec. 31, 2014 [79 Fed. Reg. 78954 (Dec. 31, 2014)] (the Final Regulations). These regulations are described below and are found at 26 C.F.R. parts 1 and 53.

In addition to requirements regarding financial assistance policies, the Final Regulations require tax-exempt hospitals to conduct a community health needs assessment and adopt an implementation strategy to meet the needs identified by the assessment. This requirement is separate from the state law requiring hospitals to conduct a community needs assessment. The state and federal laws regarding community needs assessments are discussed in detail in chapter 9.

Further, the Final Regulations require hospitals to establish a written policy that requires the organization to provide, without discrimination, care for emergency medical conditions (as defined by the Emergency Medical Treatment and Active Labor Act, also known as EMTALA) to individuals regardless of their eligibility under the organization's FAP. The policy must also prohibit the hospital facility from engaging in actions that discourage individuals from seeking emergency medical care. Such prohibited activities include demanding that emergency department patients pay before receiving treatment for emergency medical

conditions and permitting debt collection activities in the emergency department or in other areas of the hospital facility where such activities could interfere with the provision, without discrimination, of emergency medical care. [Section 1.501(r)–4(c) of the Final Regulations] CHA has published *EMTALA — A Guide to Patient Anti-Dumping Laws* to help hospitals comply with the law. For additional information or to order the manual, go to www.calhospital.org/publications/emtala-manual/.

The hospital governing body must adopt the FAP, the billing and collections policy, and the emergency medical care policy.

A. Effective Date

IRC Section 501(r) applies to taxable years beginning after March 23, 2012. The Final Regulations apply to taxable years beginning after Dec. 29, 2015.

B. Financial Assistance Policies (FAPs) — Section 1.501(r)–4

The Final Regulations provide specific guidance regarding financial assistance policies for tax-exempt hospitals. Hospitals must establish a written FAP that applies to, at a minimum, all emergency and other medically necessary care provided by the hospital facility. The FAP must include:

1. Eligibility criteria for financial assistance, and whether this assistance includes free or discounted care;
2. The basis for calculating amounts charged to patients;
3. The method for applying for financial assistance;
4. In the case of a hospital facility that does not have a separate billing and collections policy, the actions that may be taken in the event of nonpayment, including actions related to obtaining payment, including, but not limited to:
    a. Any extraordinary collection actions (ECAs) *(see "What is an ECA?," page 8.39)*;
    b. The process and time frames for these actions, including the "reasonable efforts" the hospital will make to determine whether an individual is FAP-eligible before engaging in ECAs; and
    c. The office, department, committee or other body with the final authority or responsibility for determining that the hospital has made reasonable efforts to determine whether an individual is FAP-eligible and may, therefore, engage in ECAs. ("Reasonable efforts" are defined in the Regulations — the requirements and time frames are very detailed; *see D. "Billing and Collections Policies — Section 1.501(r)–6," page 8.39, for further information.*)
    d. The hospital may include this information in a separate billing and collections policy. In this case, the FAP must state that the actions the hospital may take in the event of nonpayment are described in a separate billing and collections policy, and explain how to obtain a free copy of that policy. In addition, if the billing and collections policy is separate from the FAP, the billing and collections policy must be available free on the hospital's website, on paper upon request in a manner similar to that described in "Publicizing the FAP," page 8.35, and translated as described in paragraph 5. on page 8.36.

5. If applicable, information the hospital uses to determine eligibility obtained from sources other than the individual seeking financial assistance, and the circumstances under which it uses prior eligibility determinations to determine presumptive eligibility; and

6. A list of any providers, other than the hospital itself, delivering emergency or other medically necessary care in the hospital that specifies which providers are covered by the FAP and which providers are not covered. *(See "Provider List," page 8.34.)*

[Section 1.501(r)-4(b)(1) of the Final Regulations]

In addition, the FAP must:

1. Specify all financial assistance available under the FAP, including all discounts and free care and, if applicable, the amount(s) (for example, gross charges) to which any discount percentages will be applied;

2. Specify all of the eligibility criteria that an individual must satisfy to receive each discount, free care, or other level of assistance;

3. State that following a determination of FAP-eligibility, an FAP-eligible individual will not be charged more for emergency or other medically necessary care than the amounts generally billed (AGB) to individuals who have insurance covering such care *(see C. "Limitations on Patient Charges — Section 1.501(r)–5," page 8.37, for more information about the AGB)*;

4. Describe the methodology the hospital facility uses to determine AGB; and

5. If the hospital facility uses the look-back method to determine AGB, either state the hospital facility's AGB percentage(s) and describe how the hospital facility calculated such percentage(s) or explain how members of the public may readily obtain this information in writing and free of charge.

[Section 1.501(r)-4(b)(2)(i) of the Final Regulations]

"Readily obtainable" means the information must be available free on the hospital's website, on paper upon request in a manner similar to that described in "Publicizing the FAP," page 8.35, and translated as described in paragraph 5. on page 8.36.

While some guidelines are offered for each above section, the hospital has discretion to develop its own FAP, and there are no mandates for specific eligibility criteria. Virtually all of the financial assistance policy requirements will be satisfied by a charity care and discount payment policy compliant with the California HFPP. *(See "Determining Maximum Payment," page 8.13, regarding possible conflicts in calculating maximum patient liability between the HFPP and Section 501(r).)*

A hospital organization may establish an FAP for a hospital facility that is identical to the FAP for other hospital facilities or a joint policy that is shared with multiple hospital facilities. If a joint policy is used, it must clearly identify each facility to which it applies. However, hospitals that have different AGB percentages or use different methods to calculate the AGB must specify this information in the FAP.

Method for Applying for Financial Assistance

A hospital's FAP must describe how an individual applies for financial assistance under the FAP. In addition, either the hospital's FAP or FAP application form (including accompanying

instructions) must describe the information and documentation the hospital may require an individual to provide as part of his or her FAP application and provide the contact information, including telephone number and physical location, of the hospital office or department that can provide the FAP and assistance.

A hospital may not deny financial assistance under its FAP based on an applicant's failure to provide information or documentation *unless that information or documentation is described in the FAP or FAP application form*. On the other hand, a hospital facility may grant financial assistance under its FAP notwithstanding an applicant's failure to provide information or documentation described in the FAP or FAP application form and may, for example, rely on other evidence of eligibility or an attestation by the applicant to determine that the applicant is FAP-eligible.

Provider List

The IRS has published clarification regarding the requirement for a hospital to include a provider list in its FAP policy. As mentioned in paragraph 6. on page , the list must include any providers, other than the hospital itself, delivering emergency or other medically necessary care in the hospital and specify which providers are and are not covered by the hospital's FAP. [IRS Notice 2015-46]

The IRS has stated that a hospital may list the names of individual doctors, practice groups, or any other entities that are providing emergency or medically necessary care in the hospital by the name used either to contract with the hospital or to bill patients. For example, if all doctors in a practice group that provides emergency care are covered by the hospital's FAP, the hospital may include the name of the practice group (rather than the name of each individual doctor) in its provider list and indicate which services of the group are covered. A hospital may specify providers by reference to a department or a type of services if the reference makes clear which services and providers are covered. For example, if all providers of all services in a hospital department are covered by the FAP, the hospital's FAP may include the department (rather than the specific name of doctors or practice groups) in its provider list and indicate that the services in that department are covered by the FAP. Similarly, if no providers of services in a department are covered by the FAP, the provider list may include the department and indicate that none of the services provided in that department are covered by the FAP.

If a provider is covered by a hospital's FAP in some circumstances but not in others, the hospital must describe the circumstances in which the care delivered by the provider will and will not be covered by the FAP.

A hospital's provider list need not indicate whether a particular provider may be covered by another entity's FAP.

Maintaining the List in a Separate Document

The list may be maintained in a document separate from the FAP, such as in an appendix, provided it includes the date when it was created or last updated. If the provider list is separate, the FAP must state that the list of providers is maintained in a separate document and explain how members of the public may readily obtain it free of charge, both online and on paper.

Updating the List

A hospital is required to have an authorized body, such as the board of directors, adopt the policy. If the only change made to an FAP is to update the provider list (whether it is in the FAP or a separate document), the FAP does not need to be adopted by an authorized body again.

Minor Omissions and Errors

Minor omissions and errors that are either inadvertent or due to reasonable cause are not considered failures to meet a requirement of this law if they are promptly corrected. Hospitals are not required to disclose minor omissions and errors. Omissions and errors will be considered minor and either inadvertent or due to reasonable cause if the hospital takes reasonable steps to ensure that its list is accurate. A hospital that updates its list and fixes errors at least quarterly will be considered to have corrected minor omissions and errors in a timely manner.

Publicizing the FAP

Measures a hospital must take to publicize the FAP include:

1. Posting the current FAP, the plain language summary of the FAP *(see "Plain Language Summary," page 8.36)*, and the FAP application form on the hospital's website. The documents must be downloadable and printable for free. Users must not be required to create an account, provide identifying information, or obtain special equipment in order to access the documents. If a patient asks how to access information about the FAP, the hospital must provide the direct website address or URL.
2. Making paper copies of the FAP, FAP application form, and the plain language summary of the FAP available upon request and without charge both by mail and in public locations in the hospital, including, at a minimum the emergency room (if any) and admissions areas.
3. Notifying and informing members of the hospital's community about the FAP in a manner reasonably calculated to reach those members who are most likely to require financial assistance from the hospital. This must include notification that the hospital offers financial assistance and how to obtain information about the FAP and application process. The hospital should consider the languages spoken by its community *(see below)*.
4. Informing patients by:
    a. Offering a paper copy of the plain language summary as part of the intake or discharge process.
    b. Including a conspicuous written notice on billing statements about the availability of financial assistance, including the phone number of the hospital office that can provide information about the FAP and application process, and the website address where the FAP and related documents are posted.
    c. Setting up conspicuous public displays that are reasonably calculated to attract patients' attention to notify patients about the FAP in public locations in the hospital, including, at a minimum, the emergency room (if any) and

admissions areas. This must include notification that the hospital offers financial assistance and how to obtain information about the FAP and the application process.

5. Accommodating all significant populations that have limited English proficiency (LEP) by translating the FAP, FAP application form, and plain language summary into the primary language(s) spoken by such populations. This requirement is satisfied if the translations are provided in the language spoken by each limited English proficiency (LEP) group that constitutes the lesser of 1,000 individuals or five percent of the community served by the hospital or the population likely to be affected or encountered by the hospital. If a hospital has a billing and collection policy that is separate from the FAP, it must also be translated and made available. The hospital may use any reasonable method to determine the number or percentage of LEP patients.

Plain Language Summary

"Plain language summary" of the FAP means a written statement that notifies an individual that the hospital offers financial assistance under an FAP and provides the following additional information in language that is clear, concise, and easy to understand:

1. A brief description of the eligibility requirements and assistance offered under the FAP.
2. A brief summary of how to apply for assistance under the FAP.
3. The direct website address (or URL) and physical locations where the individual can obtain copies of the FAP and FAP application form.
4. Instructions on how the individual can obtain a free copy of the FAP and FAP application form by mail.
5. The contact information, including phone number and physical location, of the hospital office or department that can provide information about the FAP and of either:
    a. The hospital office or department that can provide assistance with the FAP application process; or
    b. If the hospital doesn't provide assistance with the FAP application process, at least one nonprofit organization or government agency that the hospital has identified as an available source of assistance with FAP applications.
6. A statement of the availability of translations of the FAP, FAP application form, and plain language summary of the FAP in other languages, if applicable.
7. A statement that an FAP-eligible individual may not be charged more than AGB for emergency or other medically necessary care. [26 CFR 1.501(r)-1]

Providing Documents Electronically

A hospital may provide electronically any required FAP-related document or information to any individual who indicates he or she prefers to receive or access the document or information electronically. The information may be provided on an electronic screen, by email, or by providing the direct web site address, or URL, of the web page where the document or information is posted.

C. Limitations on Patient Charges — Section 1.501(r)–5

The Final Regulations clarify how much a tax-exempt hospital may bill FAP-eligible patients. Hospitals are required to limit amounts charged to these patients:

1. For emergency and other medically necessary care, an FAP-eligible patient cannot be charged more than the amount generally billed (AGB) to individuals with insurance coverage. For purposes of meeting the limitations on charges, a hospital may (but is not required to) use a definition of "medically necessary care" applicable under the laws of the state in which it is licensed, including the Medicaid definition, or a definition that refers to the generally accepted standards of medicine in the community or to an examining physician's determination.
2. For any other type of medical care covered under the FAP, the hospital must bill less than the gross charges for that care *(see "Gross Charges," page 8.39)*.

The purpose of this provision is to protect FAP-eligible patients from being billed more than what the hospital would have received if that patient had insurance. Hospitals subject to the California HFPP law must also comply with its limitation on billing *(see C. "Maximum Expected Payments Allowed Under the HFPP Law," page 8.12)*, in addition to the federal AGB limit.

The Final Regulations offer two methods for calculating AGB, the "look-back" method and the "prospective Medicare or Medicaid" method. These methods are described in "Look-Back Method," page 8.37 and "Prospective Medicare or Medicaid Method," page 8.39.

A hospital may use only one of these methods to determine AGB at any one time, but different hospital facilities operated by the same hospital organization may use different methods. A hospital may change the method it uses to determine AGB at any time.

NOTE: An FAP-eligible individual is considered to be "charged" only the amount he or she is personally responsible for paying, after all deductions, discounts (including discounts available under the FAP), and insurance reimbursements have been applied. Thus, in the case of an FAP-eligible individual who has health insurance coverage, a hospital facility will meet the requirements of these regulations if the FAP-eligible individual is not personally responsible for paying (for example, in the form of co-payments, co-insurance, and deductibles) more than AGB for the care after all reimbursements by the health insurer have been applied, even if the total amount paid by the FAP-eligible individual and his or her health insurer together exceeds AGB.

Look-Back Method

A hospital may determine AGB for any emergency or other medically necessary care it provides to an FAP-eligible individual by multiplying the hospital's gross charges for the care by one or more percentages of gross charges (AGB percentage(s)).

A hospital using this method must calculate its AGB percentage(s) at least annually by dividing the sum of the amounts of all of its claims for emergency and other medically necessary care that have been allowed by the payers described under "Health and Safety Code Section 127440 requires hospitals to reimburse patients amounts paid in excess of the amount due under HFPP including interest.," page 8.27, during a prior 12-month period by the sum of the associated gross charges for those claims.

Whether a claim is used in calculating a hospital's AGB percentage(s) depends on whether the claim was allowed by a health insurer during the 12-month period used in the calculation, not on whether the care resulting in the claim was provided during that 12-month period. If the amount a health insurer will allow for a claim has not been finally determined as of the last day of the 12-month period used to calculate the AGB percentage(s), a hospital should exclude the amount of the claim from that calculation and include it in the subsequent 12-month period during which the amount allowed is finally determined. When including allowed claims in calculating its AGB percentage(s), the hospital should include the full amount that has been allowed by the health insurer, including both the amount the insurer will pay or reimburse and the amount (if any) the individual is personally responsible for paying in the form of co-payments, co-insurance, and deductibles, regardless of whether or when the full amount allowed is actually paid and disregarding any discounts applied to the individual's portion.

Health Insurers Used in Calculating AGB Percentages

In calculating its AGB percentage, a hospital must include the claims allowed during a prior 12-month period by:

1. Medicare fee-for-service only, including portions paid by beneficiaries;
2. Medicare fee-for-service together with all private health insurers, including portions paid by insured individuals; or
3. Medicaid either alone or in combination with 1. or 2.

One or Multiple AGB Percentages

A hospital's AGB percentage that is calculated using the look-back method may be a single average percentage of gross charges for all emergency and other medically necessary care provided by the hospital. Alternatively, a hospital may calculate multiple AGB percentages for separate categories of care (such as inpatient and outpatient care or care provided by different departments) or for separate items or services, as long as the hospital calculates AGB percentages for all emergency and other medically necessary care provided by the hospital.

Start Date for Applying AGB Percentages

For purposes of determining AGB under the look-back method, with respect to any AGB percentage that a hospital has calculated, the hospital must begin applying the AGB percentage by the 120th day after the end of the 12-month period the hospital used in calculating the AGB percentage.

Use of All Claims for Medical Care

A hospital determining AGB under the look-back method may use claims allowed for all medical care during a prior 12-month period rather than just those allowed for emergency and other medically necessary care.

Determining AGB Percentages for More Than One Hospital Facility

Although generally a hospital organization must calculate AGB percentage(s) separately for each hospital facility it operates, hospital facilities that are covered under the same Medicare provider agreement (as defined in 42 C.F.R. Section 489.3 or any successor regulations) may calculate one AGB percentage (or multiple AGB percentages for separate categories of care

or for separate items or services) using the look-back method based on the claims and gross charges for all such hospital facilities and implement the AGB percentage(s) across all such hospital facilities.

Prospective Medicare or Medicaid Method

The second method for determining AGB is prospective and requires the hospital to estimate the amount it would be paid if the FAP-eligible individual were a Medicare fee-for-service beneficiary or a Medicaid beneficiary. Specifically, the hospital would set the AGB as the amount that Medicare or Medicaid and the beneficiary together would be expected to pay for the emergency or other medically necessary care at issue.

A hospital may determine the AGB by using the billing and coding process the hospital would use if the individual were a Medicare fee-for-service or Medicaid (Medi-Cal) beneficiary, and setting the AGB at the amount the hospital determines would be the total amount Medicare or Medicaid would allow for the care (including both the amount that would be reimbursed by Medicare or Medicaid and the amount the beneficiary would be personally responsible for paying in the form of co-payments, co-insurance, and deductibles). A hospital using the prospective Medicare/Medicaid method may base the AGB on Medicare fee-for-service or Medicaid or both, provided that if it uses both, its FAP describes the circumstances under which it will use Medicare fee-for-service or Medicaid in determining the AGB.

Gross Charges

A billing statement issued to an FAP-eligible individual for care that is covered under the FAP may state the gross charges for care and apply contractual allowances, discounts or deductions to the gross charges, so long as the amount the individual is personally responsible for paying is less than the gross charges.

Safe Harbor for Charging More than AGB

A safe harbor provision applies to hospitals that bill an individual more than the AGB if the charges in excess of the AGB were not made as a pre-condition of providing medically necessary care to the individual, the individual has not submitted a complete FAP application and the individual has not been determined by the hospital to be FAP-eligible. However, once the hospital determines the individual is FAP-eligible, it must reverse the charges and refund excess payments, if applicable, unless such excess payments are less than $5. The hospital must make this refund even if it has referred or sold this debt.

D. Billing and Collections Policies — Section 1.501(r)–6

The Final Regulations restrict certain billing and collection activities with respect to FAP-eligible patients. Hospitals are prohibited from engaging in extraordinary collections actions (ECAs) against an individual (or other person responsible for payment for the patient's care) before making "reasonable efforts" *(see "Reasonable Efforts," page 8.41)* to determine whether the individual is FAP-eligible. Though Section 1.501(r)-6 is directly applicable to hospitals engaging in ECAs, this section contains guidance regarding the FAP application period and refunds that is likely also applicable to hospitals even if they are not engaging in ECAs.

What is an ECA?

Some examples of ECAs include, but are not limited to:

1. Reporting adverse information to credit agencies.

2. Placing a lien on an individual's property. However, a lien that a hospital is entitled to assert under state law on the proceeds of a judgment, settlement, or compromise owed to an individual as a result of personal injuries for which the hospital provided care is not an ECA. Filing a claim in a patient's bankruptcy proceeding is not an ECA.
3. Foreclosing on real property.
4. Attaching or seizing an individual's bank account or any other personal property.
5. Commencing a civil action against an individual or writ of body attachment.
6. Causing an individual's arrest.
7. Deferring or denying medically necessary care because of non-payment of a bill for previously provided care covered under the hospital's FAP.
8. Requiring a payment before providing medically necessary care because of outstanding bills for previously provided care. However, pre-payment is allowed if the hospital can demonstrate it was required based on factors other than, and without regard to, nonpayment of previous bills.
9. Garnishing an individual's wages.
10. Certain sales of the patient's debt to another party *(see below)*.

Hospitals subject to the California HFPP law must also comply with its restriction on wage garnishments and sale of primary residence *(see "Wage Garnishments and Primary Residences," page 8.22)*.

Sale or Referral of Debt

A hospital will be deemed to have engaged in an ECA if any purchaser of the individual's debt, any debt collection agency or other party to which the hospital has referred the debt, or any substantially-related entity, has engaged in an ECA.

The sale of hospital debt is not an ECA if, prior to the sale:

1. The hospital has entered into a legally-binding written agreement with the purchaser pursuant to which the purchaser is prohibited from engaging in an ECA;
2. The purchaser is prohibited from charging interest on the debt in excess of the rate in effect under IRC Section 6621(a)(2);
3. The debt is returnable to or recallable by the hospital upon a determination by the hospital or the purchaser that the individual is FAP-eligible; and,
4. If the debt is not returned or recalled by the hospital and the individual is determined to be FAP-eligible, the purchaser is required to adhere to procedures specified in the agreement that ensure that the individual does not pay, and has no obligation to pay, the purchaser and the hospital together more than he or she is personally responsible for paying as an FAP-eligible individual.

These provisions may affect common hospital transactions that include sales of accounts receivable and should be considered in connection with such transactions.

Agreements For Selling or Referring Debt

With the exception of sales that are not considered ECAs, if a hospital sells or refers an individual's debt to another party, the hospital will have made reasonable efforts to determine whether the individual is FAP-eligible for the care only if it first enters into (and, to the extent applicable, enforces) a legally binding written agreement with the other party that is reasonably designed to ensure that no ECAs are taken until reasonable efforts have been made to determine whether the individual is FAP-eligible for the care. At a minimum, such an agreement must provide the following:

1. If the individual submits an FAP application after the referral or sale of the debt but before the end of the application period, the party will suspend ECAs as described in "Suspending ECAs with an FAP Application Pending," page 8.45.
2. If the individual submits an FAP application after the referral or sale of the debt but before the end of the application period and is determined to be FAP-eligible for the care, the party will do the following in a timely manner:
    a. Adhere to procedures specified in the agreement that ensure that the individual does not pay, and has no obligation to pay, the party and the hospital together more than he or she is required to pay for the care as an FAP-eligible individual.
    b. If applicable and if the party (rather than the hospital) has the authority to do so, take all reasonably available measures to reverse any ECA (other than the sale of a debt or an ECA that is returnable to or recallable by the hospital if the individual is determined to be FAP-eligible) as described in paragraph 3. page 8.44.
3. If the other party refers or sells the debt to yet another party during the application period, the other party will obtain a written agreement from that other party including all of the elements described in this paragraph.

Reasonable Efforts

A hospital is deemed to have made reasonable efforts to determine if an individual is FAP-eligible if either of the following applies:

1. The hospital has made a determination that the individual is FAP-eligible based on information not provided by the individual, or on a prior FAP-eligibility determination, and the individual is presumptively determined to be eligible for less than the most generous assistance, and the hospital:
    a. Notifies the individual regarding the basis for the presumptive determination and the way to apply for more generous assistance;
    b. Gives the individual a reasonable period of time to apply for generous assistance before initiating ECAs; and
    c. If the individual submits an application seeking more generous assistance during the application period, determines whether the individual is entitled to more generous assistance.

2. The hospital:

    a. Notifies the individual about the FAP as required by the regulations before initiating ECAs and refrains from initiating most ECAs for at least 120 days after the hospital provides the first post-discharge billing statement *(see "Required Notification to Patient," page 8.42)*;

    b. In the case of an individual who submits an incomplete application during the application period, notifies the individual in accordance with the regulations how to submit a complete application, gives the individual a reasonable opportunity to do so, and suspends ECAs as described in the regulations *(see "Incomplete FAP Applications," page 8.44*; and

    c. In the case of an individual who has submitted a complete application, determines whether the individual is FAP-eligible in accordance with the regulations, including:

        - Suspending any ECAs;
        - Making an eligibility determination and notifying the individual of the determination in writing;
        - Providing the individual with a statement indicating the amount the individual owes if the individual is determined to be eligible for other than free care;
        - Refunding any amount the individual has paid in excess of the amount he or she is determined to be personally responsible to pay, unless such amount is less than $5; and
        - Taking all reasonable measures to reverse any ECAs.

"Application period" means the period during which a hospital must accept and process an application for financial assistance in order to have made reasonable efforts to determine whether an individual is FAP-eligible. The application period begins on the date care is provided and ends on the later of the 240th day after the date that the first post-discharge billing statement is provided, or either:

1. In the case of an individual who the hospital is notifying pursuant prior to initiating an ECA, the deadline specified in the hospital's written notice to the patient *(see below)*; or
2. In the case of an individual who the hospital has presumptively determined to be eligible for less than the most generous assistance available under the FAP, the end of the reasonable period of time described in the hospital's notice to the patient *(see page 8.43)*.

The hospital may (but is not required to) accept and process an FAP application submitted outside of the application period.

Required Notification to Patient

As mentioned above, a hospital must make reasonable efforts to determine if an individual is FAP-eligible before engaging in ECAs. Part of "reasonable efforts" includes giving notification to the patient. The required notification, which must be completed at least 30 days prior to initiating an ECA, includes:

1. Providing the individual with a written notice that indicates financial assistance is available for eligible individuals, identifies the ECA(s) that the hospital (or other authorized party) intends to take to obtain payment, and states a deadline after which the ECA(s) may be initiated that is no earlier than 30 days after the date that the written notice is provided.
2. Providing the individual with a plain language summary of the FAP.
3. Making a reasonable effort to orally notify the individual about the hospital's FAP and how to obtain assistance with the application process.

The hospital may satisfy the notification requirement simultaneously for multiple episodes of care/multiple outstanding bills. However, if a hospital aggregates an individual's outstanding bills for multiple episodes of care before initiating one or more ECAs to obtain payment for those bills, it will have not have made reasonable efforts to determine whether the individual is FAP-eligible unless it refrains from initiating the ECA(s) until 120 days after it provided the first post-discharge billing statement for the most recent episode of care included in the aggregation.

If a hospital plans to defer or deny care due to nonpayment of a bill for prior care (which is an ECA), the hospital may notify the individual about its FAP less than 30 days in advance if the hospital does the following:

1. Otherwise meets the notification requirements but, instead of the notice described above, provides the individual with an FAP application form and a written notice indicating that financial assistance is available for eligible individuals and states the deadline, if any, after which the hospital will no longer accept and process an FAP application submitted (or, if applicable, completed) by the individual for the previously-provided care at issue. This deadline must be no earlier than the later of 30 days after the date that the written notice is provided or 240 days after the date that the first post-discharge billing statement for the previously-provided care was provided.
2. If the individual submits an FAP application for the previously-provided care on or before the deadline (or at any time, if the hospital didn't provide a deadline), processes the FAP application on an expedited basis.

Complete FAP Applications

If an individual submits a complete FAP application during the application period, the hospital must do the following in a timely manner:

1. Suspend any ECAs to obtain payment for the care as described in "Suspending ECAs with an FAP Application Pending," page 8.45.
2. Make a determination as to whether the individual is FAP-eligible and notify the individual in writing of this eligibility determination (including, if applicable, the assistance for which the individual is eligible) and the basis for this determination.

If the hospital determines the individual is FAP-eligible, it must do the following:

1. If the individual is determined to be eligible for assistance other than free care, provide the individual with a billing statement that indicates:

a. The amount the individual owes for the care as an FAP-eligible individual, and

b. How that amount was determined and states (or describes how the individual can get information regarding) the AGB for the care.

2. Refund any amount the individual paid for the care (whether to the hospital or any other party to whom the hospital has referred or sold the debt) that exceeds the amount he or she is determined to be responsible for paying as an FAP-eligible individual, unless this amount is less than $5 (or other amount set by the IRS).

3. Take all "reasonably available measures" to reverse any ECA (with the exception of a sale of debt and deferring/denying care or requiring payment before providing care due to outstanding bills) taken against the individual to obtain payment. Reasonably available measures generally include, but are not limited to measures to:

   a. Vacate any judgment against the individual;

   b. Lift any levy or lien on the individual's property, other than a lien against the proceeds of a judgment/settlement/compromise for personal injuries for which the hospital provided care; and

   c. Remove from the individual's credit report any adverse information that was reported to a consumer reporting agency or credit bureau.

Incomplete FAP Applications

If an individual submits an incomplete FAP application during the application period, the hospital will have satisfied its obligation to notify the individual about how to complete the FAP application and provide a reasonable opportunity to do so for purposes of undertaking ECAs only if the hospital does the following:

1. Suspends any ECAs to obtain payment for the care as described under "Suspending ECAs with an FAP Application Pending," page 8.45; and

2. Provides the individual with a written notice that describes the additional information and/or documentation required under the FAP or FAP application form that must be submitted to complete the FAP application and that includes the contact information, including telephone number and physical location, of the hospital office or department that can provide information about the FAP and where to obtain assistance with FAP applications.

If an individual who has submitted an incomplete FAP application during the application period subsequently completes the application during the application period (or, if later, within a reasonable time frame given to respond to requests for additional information and/or documentation), the individual will be considered to have submitted a complete FAP application during the application period, and the hospital will have made reasonable efforts to determine whether the individual is FAP-eligible only if it meets the requirements for processing complete FAP applications.

When No FAP Application is Submitted

Unless and until an individual submits an FAP application during the application period, any legal requirements that are conditioned on an individual's submitting an FAP application do not apply, and the hospital will have made reasonable efforts to determine whether the

individual is FAP-eligible for care, and may initiate one or more ECAs to obtain payment for the care, once it has met the requirements of the law that are not contingent on an individual's submission of an FAP application. For example, unless and until a hospital receives an FAP application from an individual during the application period, the hospital has made reasonable efforts to determine whether the individual is FAP-eligible for care (and thus may initiate ECAs to obtain payment for the care) once it has notified the individual about the FAP as described in "Required Notification to Patient," page 8.42.

Determining Medicaid Eligibility

If a hospital believes an individual who submits an FAP application may qualify for Medicaid, the hospital may postpone determining whether the individual is FAP-eligible until after the individual's Medicaid application has been completed and submitted and an eligibility determination has been made.

Suspending ECAs with an FAP Application Pending

If an individual submits an FAP application during the application period, the hospital (or other authorized party) will have properly suspended ECAs only if it does not initiate (or take further action on any previously initiated) ECAs (with the exception of deferring/denying care or requiring payment before providing care due to outstanding bills) to obtain payment for the care until either:

1. The hospital has determined whether the individual is FAP-eligible based on a complete FAP application and otherwise met the requirements described under "Complete FAP Applications," page 8.43); or
2. In the case of an incomplete FAP application, the individual has failed to respond to requests for additional information and/or documentation within a reasonable period of time given to respond to such requests.

Anti-Abuse Rule

A hospital will not have made reasonable efforts to determine whether an individual is FAP-eligible if the hospital bases its determination that the individual is not FAP-eligible on information that the hospital has reason to believe is unreliable or incorrect, or on information obtained from the individual under duress or through the use of coercive practices.

A coercive practice includes delaying or denying emergency medical care to an individual until he or she has provided information requested to determine whether the individual is FAP-eligible for the care being delayed or denied.

No Waiver

A signed waiver by an individual that he or she does not wish to apply for assistance under the FAP or receive information about the FAP does not constitute a determination that the individual is not FAP-eligible and will not satisfy the requirement to make reasonable efforts to determine whether the individual is FAP-eligible before engaging in ECAs.

E. Relationship to Related State Laws

Most California hospitals that are in compliance with state community benefits laws (described on page) and the Hospital Fair Pricing Policies (HFPP) laws described in this chapter are also in compliance with the federal requirements. However, compliance with the California laws does not ensure compliance with the federal requirements, as the

requirements of state and federal law, while overlapping, are not identical. Further, those hospitals that are exempt from the state community benefits law, such as public hospitals and small and rural hospitals, as defined in Health and Safety Code Section 124840, are required to comply with the federal requirements. Hospitals must continue to comply with applicable state laws that are stricter than the federal requirements.

F. Hospital Reporting Requirements

Hospital organizations will be required to describe in their IRS Form 990 (Return of Organization Exempt from Income Tax):

1. How they are addressing the needs identified in their community health needs assessments; and
2. Any such needs that are not being addressed, together with the reasons why such needs are not being addressed.

Hospital organizations will also be required to file audited financial statements with their IRS Form 990 submissions. For an organization that files a consolidated financial statement with other organizations, consolidated financial statements may be filed. (This is in addition to the information that hospitals report on Schedule H of IRS Form 990 regarding charity care, community benefits, bad debt and collection practices.)

G. Reports to Congress

The Secretary of the Treasury, in consultation with the Secretary of the Department of Health and Human Services, will submit an annual report to Congress containing information on the following:

1. Levels of charity care provided;
2. Bad debt expenses;
3. Unreimbursed costs for services provided with respect to means-tested government programs; and
4. Unreimbursed costs for services provided with respect to non-means-tested government programs.

The report will address private tax-exempt, taxable, and government-owned hospitals. In addition, the report will contain information with respect to private tax-exempt hospitals regarding costs incurred for community benefit activities.

H. Enforcement

Failure to meet the FAP or community benefits requirements of IRC Section 501(r) may result in excise taxes, revocation of tax-exempt status, or imposition of taxes on income for the taxable year or years during which the hospital facility was non-compliant [Section 1.501(r)-2(a)-(d) of the Final Regulations].

In determining whether revocation of exemption is appropriate, the IRS will consider all the relevant facts and circumstances, including, but not limited to, the following:

1. Whether the organization has previously failed to meet the requirements of Section 501(r), and, if so, whether the same type of failure previously occurred;
2. The size, scope, nature, and significance of the organization's failure(s);

3. In the case of an organization that operates more than one hospital facility, the number, size, and significance of the facilities that have failed to meet the applicable requirements relative to those that have complied with these requirements;
4. The reason for the failure(s);
5. Whether the organization had, prior to the failure(s), established practices and procedures (formal or informal) reasonably designed to promote and facilitate overall compliance with the requirements;
6. Whether the practices and procedures had been routinely followed and the failure(s) occurred through an oversight or mistake in applying them;
7. Whether the organization has implemented safeguards that are reasonably calculated to prevent similar failures from occurring in the future;
8. Whether the organization corrected the failure(s) as promptly after discovery as is reasonable given the nature of the failure(s); and
9. Whether the organization took the measures described in 7 and 8, above, to implement safeguards to prevent similar failures and correct the failures promptly after discovery before the IRS discovered the failure(s).

[Section 1.501(r)–2(a)(1)-(9) of the Final Regulations]

The IRS has released guidance on correction and disclosure procedures for hospitals to follow so that certain failures to meet IRC requirements regarding financial assistance policies will be excused. The guidance, Revenue Procedure 2015-21, updates and revises a draft revenue procedure issued on Dec. 31, 2013 (Notice 2014-3).

Revenue Procedure 2015-21, effective March 10, 2015, clarifies that minor omissions and errors that are either inadvertent or due to reasonable cause are not considered failures to meet the requirements of IRC Section 501(r) if they are corrected reasonably promptly upon discovery. Thus, they do not need to be disclosed to the IRS. Correction must include the establishment (or review and, if necessary, revision) of formal or informal practices or procedures that are reasonably designed to promote compliance with the law.

Other omissions and errors that may be more than minor, but are neither willful nor egregious, must be corrected and disclosed in accordance with the procedures in Revenue Procedure 2015-21 to be excused. However, even if the failure is excused the hospital may still be subject to an excise tax for failure to implement financial assistance policies and related laws as required by IRC Section 501(r)(3).

[Section 1.501(r)–2(b)-(c) of the Regulations; IRS Rev. Proc. 2015-21]

VI. COMPARISON OF STATE AND FEDERAL REQUIREMENTS FOR FINANCIAL ASSISTANCE POLICIES

Appendix FAP 3, “Comparison of California and IRS Requirements for Financial Assistance Policies,” contains a side-by-side analysis and comparison of questions and issues under existing California law related to discount payment and charity care policies, and the similar laws relating to financial assistance policies under IRC Section 501(r).

APPENDIX FAP 3

Comparison of California and IRS Requirements Regarding Financial Assistance Policies

Below is a side-by-side comparison of existing California law and the similar laws and final regulations under Section 501(r) of the IRC.

(1) What type of policy is required under each law?

CALIFORNIA	IRS
Each hospital must maintain an understandable written policy regarding discount payments for financially qualified patients, as well as an understandable written charity care policy. Health and Safety Code Section 127405(a)(1)	Under IRC Section 501(r)(4), a hospital facility must establish a written financial assistance policy (FAP) and a written emergency medical care policy. Section 1.501(r)-4(a) of the Final Regulations, published Dec. 31, 2014 [79 Fed. Reg. 78954 (Dec. 31, 2014)]. The Final Regulations are part of Title 26 of the Code of Federal Regulations.

(2) Which hospitals are covered by each law?

CALIFORNIA	IRS
Each hospital licensed under Health and Safety Code Section 1250 (a), (b), and (f). This includes each hospital licensed as a general acute care hospital, acute psychiatric hospital or special hospital. Exempt hospitals include those operated by the California Departments of Corrections and Rehabilitation and State Hospitals. Rural hospitals, as defined in Health and Safety Code Section 124840, may have less generous patient eligibility requirements (as discussed below). Even if separately licensed hospitals are owned by one entity, each separately licensed hospital must comply individually with the requirements.	A facility that is owned by an organization that is tax-exempt under Section 501(c)(3) and is required by a state to be licensed, registered, or similarly recognized as a hospital must comply with the requirements. Section 1.501(r)-1(b)(18) of the Final Regulations Even if separately licensed hospitals are owned by one entity, each separately licensed hospital must comply individually with the requirements.

(3) What type of care must be covered by the hospital's policy?

CALIFORNIA	IRS
Not specifically addressed. Probably applies to all hospital services.	The FAP must apply to all emergency and other medically necessary care provided by the hospital. Section 1.501(r)-4(b) of the Final Regulations

(4) What must be included in the hospital's policy?

CALIFORNIA	IRS
A hospital's discount payment policy must clearly state eligibility criteria based upon income consistent with the application of the federal poverty level. The discount payment policy must also include an extended payment plan to allow payment of the discounted price over time. The policy must provide that the hospital and the patient will negotiate the terms of the payment plan. If they cannot agree, a default payment plan applies. Health and Safety Code Section 127405(b) The charity care policy must state clearly the eligibility criteria for charity care. Assets, if considered, may not include retirement or deferred compensation plans qualified under the Internal Revenue Code, or nonqualified deferred compensation plans. The first ten thousand dollars ($10,000) of a patient's monetary assets and 50 percent of a patient's monetary assets over the first ten thousand dollars ($10,000) may not be counted in determining eligibility. Health and Safety Code Section 127405(c) The written policy regarding discount payments must include a statement that an emergency physician, as defined in Health and Safety Code Section 127450, who provides emergency medical services in a hospital is required by law to provide discounts to uninsured patients or patients with high medical costs who are at or below 350 percent of the federal poverty level. Health and Safety Code Section 127405(a)(1)(B)	The FAP must include: • The eligibility criteria for financial assistance and whether this assistance includes free or discounted care; • The basis for calculating amounts charged to patients; • The method for applying for financial assistance; • In the case of a hospital facility that does not have a separate billing and collections policy, the actions that may be taken related to obtaining payment, including, but not limited to, any extraordinary collection actions (ECAs); the process and time frames for these actions, including the "reasonable efforts" the hospital will make to determine whether an individual is FAP-eligible before engaging in ECAs; and the office, department, committee or other body with the final authority or responsibility for determining that the hospital has made reasonable efforts to determine whether an individual is FAP-eligible and may, therefore, engage in ECAs. (**"Reasonable efforts"** are defined in the Final Regulations — the requirements and time frames are very detailed; *see chapter 8 of the* California Hospital Compliance Manual *for further information.*) The hospital may include this information in a separate billing and collections policy. In this case, the FAP must state that the actions the hospital may take in the event of nonpayment are described in a separate billing and collections policy, and explain how to obtain a free copy of that policy; • If applicable, information the hospital uses to determine eligibility other than information from the individual seeking financial assistance, and the circumstances under which it uses prior eligibility determinations to determine presumptive eligibility; and • A list of any providers, other than the hospital itself, delivering emergency or other medically necessary care in the hospital that specifies which providers are covered by the FAP and which providers are not covered. Section 1.501(r)-4(b)(1) of the Final Regulations *(continued on next page)*

(4) What must be included in the hospital's policy? *(continued)*

CALIFORNIA	IRS
	In addition, the FAP must: • Specify all financial assistance available under the FAP, including all discount(s) and free care and, if applicable, the amount(s) (for example, gross charges) to which any discount percentages will be applied; • Specify all of the eligibility criteria that an individual must satisfy to receive each discount, free care, or other level of assistance; • State that following a determination of FAP-eligibility, a FAP-eligible individual will not be charged more for emergency or other medically necessary care than the amounts generally billed (AGB) to individuals who have insurance covering such care; • Describe the methodology the hospital facility uses to determine AGB; and • If the hospital facility uses the look-back method to determine AGB, either state the hospital facility's AGB percentage(s) and describe how the hospital facility calculated such percentage(s) or explain how members of the public may readily obtain this information in writing and free of charge. Section 1.501(r)-4(b)(2)(i) of the Final Regulations

(5) Are there specific requirements regarding eligibility for charity care and discount care?

CALIFORNIA	IRS
Yes. Uninsured patients or patients with high medical costs who are at or below 350 percent of the federal poverty level must be eligible to apply for participation under a hospital's charity care policy or discount payment policy. Health and Safety Code Section 127405(a)(1)(A) Rural hospitals may establish eligibility levels for financial assistance and charity care at less than 350 percent of the federal poverty level, as appropriate to maintain their financial and operational integrity. Health and Safety Code Section 127405(a)(2) For purposes of determining eligibility for discounted payment, documentation of income is limited to recent pay stubs or income tax returns and documentation of assets may include information on all monetary assets, but may not include statements on retirement or deferred compensation plans. Health and Safety Code Section 127405(e)(1)-(2)	No. The Regulations allow hospitals to develop appropriate eligibility criteria. The IRS specifically indicated that neither the statute nor the regulations establish specific eligibility criteria that a FAP must contain. [79 Fed. Reg. at 78972] In examples of appropriate eligibility criteria, the IRS indicated that eligibility based on family income could be appropriate. Section 1.501(r)-4(b)(2)(ii) of the Final Regulations

(6) What are the requirements and restrictions related to billing and collections activity?

CALIFORNIA	IRS
Each hospital must make all reasonable efforts to obtain from the patient (or his or her representative) information about whether private or public health insurance or sponsorship may fully or partially cover the charges for care rendered by the hospital to a patient, including: • Private health insurance, including coverage offered through the California Health Benefit Exchange (Covered California). • Medicare. • Medi-Cal, the Healthy Families program, the California Children's Services program, or other state-funded programs designed to provide health coverage. Health and Safety Code Section 127420(a) If a hospital bills a patient who has not provided proof of third party coverage, as a part of that billing, the hospital must provide the patient with a clear and conspicuous notice that includes all of the following: • A statement of charges for services rendered by the hospital. • A request that the patient inform the hospital if the patient has health insurance coverage, Medicare, Healthy Families, Medi-Cal, or other coverage. • A statement that if the consumer does not have health insurance coverage, the consumer may be eligible for Medicare, Healthy Families, Medi-Cal, California Children's Services Program, Covered California, other state- or county-funded programs, or charity care. • A statement indicating how patients may obtain applications for the Medi-Cal and Healthy Families programs, Covered California, or other state- or county-funded programs, and that the hospital will provide these applications. The hospital must also provide patients with a referral to a local consumer assistance center housed at legal services offices. If the patient does not indicate third-party payer coverage, or requests a discounted price or charity care, the hospital must provide an application for Medi-Cal, Healthy Families, or other state- or county-funded health coverage programs to the patient. This application must be provided prior to discharge if the patient has been admitted, and to patients receiving emergency or outpatient care. *(continued on next page)*	In general, hospitals must make "reasonable efforts," as described in the law, to determine whether an individual is eligible under a hospital's FAP before engaging in extraordinary collection actions (ECAs), either directly or indirectly through any purchaser of debt, collection agency or other party to which the hospital facility has referred the individual debt. The Regulations contain very detailed requirements and time frames regarding what constitutes "reasonable efforts." *(See chapter 8 of the* California Hospital Compliance Manual *for details.)* Section 1.501(r)-6(a) of the Final Regulations. ECAs include actions relating to seeking payment for care covered by the hospital's FAP that involve: • Selling an individual's debt to another party (however, exceptions may apply; *see chapter 8 of the* California Hospital Compliance Manual *for details)*; • Reporting adverse information about the individual to consumer credit reporting agencies; • Placing a lien on an individual's property. However, a lien that a hospital is entitled to assert under state law on the proceeds of a judgment, settlement, or compromise owed to an individual as a result of personal injuries for which the hospital provided care is not an ECA; • Foreclosing on real property; • Attaching or seizing an individual's bank account or other personal property; • Commencing a civil action against an individual; • Causing an individual's arrest or writ of body attachment; • Garnishing an individual's wages; *(continued on next page)*

(6) What are the requirements and restrictions related to billing and collections activity? *(continued)*

CALIFORNIA	IRS
• Information regarding the financially qualified patient and charity care application, including the following: – A statement that indicates that if the patient lacks, or has inadequate, insurance, and meets certain low- and moderate-income requirements, the patient may qualify for discounted payment or charity care. – The name and telephone number of a hospital employee or office from whom or which the patient may obtain information about the hospital's discount payment and charity care policies, and how to apply for that assistance. Health and Safety Code Section 127420(b) Each hospital must have a written policy regarding under whose authority patient debt is collected, whether the collection activity is conducted by the hospital, an affiliate or subsidiary of the hospital, or by an external collection agency. Health and Safety Code Section 127425(a) Each hospital is required to establish a written policy defining standards and practices for debt collection. Health and Safety Code Section 127425(b) Each hospital must obtain a written agreement from any collection agency used by the hospital that it will adhere to the hospital's standards and scope of practices, including the definition and application of a "reasonable payment plan." Health and Safety Code Section 127425(b) For a patient who lacks coverage or has high medical costs, the hospital or its agent may not report adverse information to a credit reporting agency or commence civil action against the patient for nonpayment at any time prior to 150 days after initial billing. Health and Safety Code Section 127425(d). The timeline for reporting must be extended if there is a pending appeal regarding the coverage for the services. Health and Safety Code Section 127426(a) For patients attempting to qualify for eligibility under a charity care or discount payment policy and attempting in good faith to settle an outstanding bill, the hospital may not send the unpaid bill to collections unless the collecting entity has agreed to comply with the HFPP law. Health and Safety Code Section 127425(e) *(continued on next page)*	*(continued)* • Deferring or denying medically necessary care because of non-payment of a bill for previously provided care covered under the hospital's FAP; • Requiring a payment before providing medically necessary care because of outstanding bills for previously provided care. Section 1.501(r)-6(b)(1)-(7) of the Final Regulations.

(6) What are the requirements and restrictions related to billing and collections activity? *(continued)*

CALIFORNIA	IRS
Any hospital, affiliate or subsidiary of the hospital, may not, in dealing with patients eligible under the hospital's charity care or discount payment policies, use wage garnishments or liens on primary residences as a means of collections. Health and Safety Code Section 127425(f)(1) A collection agency not affiliated with the hospital may not, in dealing with patients qualified under the hospital's charity care or discount payment policies, use as a means of collecting unpaid hospital bills, any of the following: • A wage garnishment, except by order of the court under limited circumstances where the patient is determined to have the ability to pay, taking into consideration potential future health conditions. • Notice or conduct a sale of the patient's primary residence during the life of the patient or certain family members of patient. Health and Safety Code Section 127425(f)(2) The hospital and the patient must negotiate a payment plan. If the hospital and the patient cannot agree, the law defines a **"reasonable payment plan,"** which means monthly payments that are not more than 10 percent of a patient's family income for a month, excluding deductions for "essential living expenses "(as defined in the law). Health and Safety Code Section 127400(i) Extended payment plans offered by a hospital to patients eligible under the hospital's charity care policy, discount payment policy, or any other policy adopted by the hospital for assisting low-income patients with no insurance or high medical costs, must be interest free. Health and Safety Code Section 127425(g) A hospital, collection agency, or assignee may not report adverse information to a consumer credit reporting agency or commence a civil action against the patient or responsible party for nonpayment prior to the time the extended payment plan is declared to be no longer operative. Health and Safety Code Section 127425(g) *(continued on next page)*	

(6) What are the requirements and restrictions related to billing and collections activity? *(continued)*

CALIFORNIA	IRS
Prior to commencing collections activities, the hospital or the party seeking to collect the debt must provide the patient with a clear and conspicuous written notice containing: • A plain language summary of the patient's rights pursuant to the HFPP law, the California Rosenthal Fair Debt Collection Practices Act, and the Federal Fair Debt Collection Practices Act. The summary must include a statement that the Federal Trade Commission enforces the Federal Fair Debt Collection Practices Act. • The summary is sufficient if it appears in substantially the following form: "State and Federal law require debt collectors to treat you fairly and prohibit debt collectors from making false statements or threats of violence, using obscene or profane language, and making improper communications with third parties, including your employer. Except under unusual circumstances, debt collectors may not contact you before 8:00 a.m. or after 9:00 p.m. In general, a debt collector may not give information about your debt to another person, other than your attorney or spouse. A debt collector may contact another person to confirm your location or to enforce a judgment. For more information about debt collection activities, you may contact the Federal Trade Commission by telephone at 1-877-FTC-HELP (382-4357) or online at www.ftc.gov." • A statement that nonprofit credit counseling services may be available in the area. Health and Safety Code Section 127430	

(7) What limitations on charges does each law require?

CALIFORNIA	IRS
Hospitals are required to limit charges to patients at or below 350 percent of the federal poverty level and eligible under its discount payment policy to the amount of payment the hospital would expect to receive for providing services from Medicare, Medi-Cal, the Healthy Families Program, or another government-sponsored health program of health benefits in which the hospital participates, whichever is greater. Where there is no established payment by Medicare or any other government-sponsored program, the hospital must establish an appropriate discounted payment. Health and Safety Code Section 127405(d).	Hospitals are restricted from billing patients eligible under its FAP for emergency or other medically necessary care to not more than the amounts generally (AGB) billed to individuals who have insurance coverage. For all other medical care, the charges must be less than the gross charges for such care. Section 1.501(r)–5(a) of the Final Regulations The regulations provide two methodologies for determining how AGB may be determined. A hospital may use only one method at a time, but may change methods at any time. • The first method is a "look-back" method based on actual past claims paid to the hospital facility by either Medicare fee-for-service only, Medicare fee-for-service together with all private health insurers paying claims to the hospital facility (including, in each case, any associated portions of these claims paid by Medicare beneficiaries or insured individuals), or Medicaid either alone or in combination with Medicare fee-for-services and/or private health insurers. • The second method for determining AGB is "prospective," and requires the hospital facility to estimate the amount it would be paid by Medicare and a Medicare fee-for-service beneficiary or Medicaid and a Medicaid beneficiary. A hospital may use a single average percentage of gross charges or multiple percentages for separate categories of care or separate items or services. **"Charged"** means the amount the patient is responsible for paying. The bill can show gross charges and contractual allowance, discounts, and other adjustments. For insured patients, the amount paid by the insurer plus the amount charged to the patient can exceed the maximum levels so long as the patient is not responsible for more than the allowed maximum. Section 1.501(r)-5 of the Final Regulations

(8) What are a hospital's obligations to refund charges?

CALIFORNIA	IRS
Hospitals are required to reimburse patients for payments above what is required by the FAP, including interest. However, a hospital is not required to reimburse the patient or pay interest if the amount due is less than five dollars ($5.00). The hospital must give the patient a credit for the amount due at least 60 days from the date the amount is due. Health and Safety Code Section 127440	All excess payments over and above what is owed under the FAP must be promptly refunded. Section 1.501(r)–6(c)(6)(i)(C)(2) of the Final Regulations

(9) What are the notification and publication requirements under each law?

CALIFORNIA	IRS
Each hospital must provide patients with a written notice that contains information about availability of the hospital's discount payment and charity care policies, including information about eligibility, as well as contact information for a hospital employee or office from which the person may obtain further information about these policies. Health and Safety Code Section 127410(a) The notice must also be provided to patients who receive emergency or outpatient care and who may be billed for that care, but who were not admitted. Health and Safety Code Section 127410(a) Notice of the hospital's policy for financially qualified and self-pay patients must be clearly and conspicuously posted in locations that are visible to the public, including, but not limited to, all of the following: • Emergency department, if any; • Billing office; • Admissions office; and • Other outpatient settings. Health and Safety Code Section 127410(b)	The FAP, FAP application form, and a plain language summary of the FAP must be made widely available on a website. Section 1.501(r)–4(b)(5)(i)(A) of the Final Regulations Paper copies of the FAP, FAP application form, and a plain language summary of the FAP must be made available upon request and without charge, both by mail and in public locations in the hospital facility (including, at a minimum, in the emergency room (if any) and admissions areas). Section 1.501(r)– 4(b)(5)(i)(B) of the Final Regulations The hospital must inform and notify members of the community served by the hospital facility about the FAP in a manner reasonably calculated to reach those members who are most likely to require financial assistance. Section 1.501(r)–4(b)(5)(i)(C) of the Final Regulations The hospital must notify and inform individuals who receive care from the hospital about the FAP by: 1. Offering a paper copy of the plain language summary of the FAP to patients as part of the intake or discharge process; 2. Including a conspicuous written notice on billing statements about the availability of financial assistance under the FAP, includes the telephone number of the hospital facility office that can provide information about the FAP and application process and the web site address; and 3. Setting up conspicuous public displays that notify and inform patients about the FAP in public locations in the hospital including, at a minimum, the emergency room (if any) and admissions areas. Section 1.501(r)-4(b)(5)(i)(D) of the Final Regulations Additional notice requirements apply before commencing extraordinary collection actions (ECAs) *(see chapter 8 of the* California Hospital Compliance Manual *for details)*. Section 1.501(r)-6(c) of the Final Regulations

(10) What are the language requirements under each law?

CALIFORNIA	IRS
All notices related to the FAP must be provided in any non-English language spoken by a substantial number (probably 5% or more) of persons served by the hospital. Health and Safety Code Section 127410(a).	The full FAP, the plain language summary, the application, and all notices related to the FAP must be provided in the language of any populations with limited English proficiency (LEP) that constitute the lesser of 1,000 individuals or 5 percent of the community served by the hospital facility or the population likely to be affected or encountered by the hospital. If a hospital has a billing and collection policy that is separate from the FAP, it must also be translated and made available. The hospital may use any reasonable method to determine the number or percentage of LEP patients. Section 1.501(r)-4(b)(5)(ii) of the Final Regulations

(11) What are the governing body authorization and implementation requirements under each law?

CALIFORNIA	IRS
No explicit requirements for governing body approval are mentioned in the law, but such approval is implicit in the overall statutory scheme.	A hospital organization is considered by the IRS to have "established" a FAP, a billing and collections policy, or an emergency medical care policy for a hospital facility only if: 1. An authorized body of the hospital organization has adopted the policy for the hospital facility and 2. The hospital facility has implemented the policy by consistently carrying it out. Section 1.501(r)–4(d)(1)-(3) of the Final Regulations

(12) Is agency reporting required under each law?

CALIFORNIA	IRS
Each hospital must provide to the Office of Statewide Health Planning and Development (OSHPD) copies of its discount payment policy, charity care policy, eligibility procedures for those policies, review process, and the application for charity care or discounted payment programs. This information must be provided at least biennially on or before January 1, or when a significant change is made. If no significant change has been made since the information was previously provided, notifying the office of the lack of change is sufficient. Health and Safety Code Section 127435	Although Section 501(r) of the Internal Revenue Code (IRC) and the Final Regulations do not include express reporting requirements, Schedule H to the Form 990 (Return for Organization Exempt from Income Tax) includes numerous questions about the hospital's FAP. *See www.irs.gov/pub/irs-pdf/i990sh.pdf*

(13) Penalties for failure to comply with each law.

CALIFORNIA	IRS
Compliance with HFPP law is a condition of licensure for hospitals. The California Department of Public Health (CDPH), Licensing and Certification Division, enforces licensing rules. CDPH may issue penalties between $10,000 and $31,625 per violation, depending upon the extent of non-compliance, the amount of financial harm to the patient, and the willfulness of the violation. Title 22, California Code of Regulations, Sections 70951-70960.	Failure to meet the obligations under Section 501(r) of the IRC may result in revocation of tax exempt status or imposition of taxes on income for the taxable year or years during which the hospital facility was a non-compliant facility. Section 1.501(r)-2(a)-(d) of the Final Regulations In determining whether revocation of exemption is appropriate, the IRS will consider all the relevant facts and circumstances, including, but not limited to, the following: • Whether the organization has previously failed to meet the requirements of Section 501(r), and, if so, whether the same type of failure previously occurred; • The size, scope, nature, and significance of the organization's failure(s); • In the case of an organization that operates more than one hospital facility, the number, size, and significance of the facilities that have failed to meet the applicable requirements relative to those that have complied with these requirements; • The reason for the failure(s); • Whether the organization had, prior to the failure(s), established practices and procedures (formal or informal) reasonably designed to promote and facilitate overall compliance with the requirements; • Whether the practices and procedures had been routinely followed and the failure(s) occurred through an oversight or mistake in applying them; • Whether the organization has implemented safeguards that are reasonably calculated to prevent similar failures from occurring in the future; • Whether the organization corrected the failure(s) as promptly after discovery as is reasonable given the nature of the failure(s); and • Whether the organization took measures to implement safeguards to prevent similar failures and correct the failures promptly after discovery before the IRS discovered the failure(s). Section 1.501(r)–2(a)(1)-(9) of the Final Regulations The Final Regulations also provide latitude for certain minor or inadvertent omissions and errors that are corrected prior to the IRS contacting the hospital for examination (audit), and allow certain failures to be excused if the hospital corrects and discloses the failures, provided the failures are not willful or egregious. Section 1.501(r)–2(b)-(c) of the Final Regulations; IRS Notice 2014-3

(14) Law and guidance regarding preemption

CALIFORNIA	IRS
The rights, remedies, and penalties established by the HFPP law does not supersede the rights, remedies, or penalties established under other laws. Health and Safety Code Section 127443 Nothing in Section 127425 of the HFPP law, which deals with billing and collection activities, diminishes or eliminates any protections consumers have under existing federal and state debt collection laws, or any other consumer protections available under state or federal law.	In its commentary to the Final Regulations, the IRS noted that many commenters argued that in states that have laws addressing some or most of the subject matter relating to financial assistance policies and debt collection, compliance with such laws should be sufficient. The IRS rejected these arguments, noting that commenters failed to cite any state laws that conflict with the regulations in a way that would make it impossible to comply with both the state and federal requirements. Thus, tax-exempt hospitals must comply with the federal regulations regardless of compliance with similar state laws.

(15) Effective dates for each law

CALIFORNIA	IRS
The HFPP law became effective on Jan. 1, 2007.	IRC Section 501(r) applies to taxable years beginning after March 23, 2012. The final regulations implementing that statute apply to taxable years beginning after Dec. 29, 2015. For taxable years beginning on or before Dec. 29, 2015, a hospital may rely on a reasonable, good faith interpretation of Section 501(r). A hospital will be deemed to have operated in accordance with a reasonable, good faith interpretation if it has complied with the provisions of the proposed regulations or Final Regulations.

9 Issues for Tax-Exempt Hospitals

I. Introduction 9.1

II. Requirements for Tax-Exempt Hospitals 9.3

III. Organizational and Operational Issues 9.3

A. Organizational Test 9.3

Exempt Purposes 9.3

Organizational Structure Issues 9.4

B. Operational Test 9.4

C. Impact of Illegal Activities 9.5

IV. Private Benefit and Inurement 9.5

A. Private Benefit 9.5

B. Private Inurement 9.6

Insiders 9.6

Examples of Types of Compensation or Benefit Transactions 9.7

V. Intermediate Sanctions 9.8

A. Excise Taxes 9.8

Correcting the Excess Benefit 9.9

B. Disqualified Person 9.9

C. Excess Benefit Transaction 9.10

Manager and the Manager's Participation 9.11

Rebuttable Presumption of Reasonableness 9.12

VI. Governance and Board Issues 9.13

A. Board Structure 9.13

B. Board Committees 9.14

C. Board Liability and Duties 9.14

Duty of Care 9.15

Duty of Inquiry 9.16

Duty of Loyalty 9.16

Duty of Prudent Investment 9.17

Summary of Board of Director Duties 9.18

D. Self-Dealing Transactions 9.18

Excluded Transactions 9.18

Approval of Self-Dealing Transactions 9.19

Remedies for Self-Dealing Transactions 9.20

E. Code of Conduct 9.20
F. Compensation of Directors 9.20

VII. Excise Tax on Executive Compensation 9.21
A. Covered Employee 9.21
B. Compensation 9.21
C. Excess Parachute Payment 9.21
D. Exception for Payment for Professional Medical Services 9.21
E. Tax Policy and Planning Considerations 9.22

VIII. Income From Unrelated Business 9.22
A. Taxable Income From Unrelated Trade or Business 9.22
B. Unrelated Trade or Business 9.22
C. Specific Examples for Tax-Exempt Nonprofit Hospitals 9.23
Snapshot of Whether Activities Typically Constitute UBIT 9.25
D. Calculation of Unrelated Business Income Tax (UBIT) 9.25
Calculation of UBIT Separately for Each Line of Unrelated Business 9.25
Net Operating Loss Deduction 9.25
Inclusion of Certain Fringe Benefits in the Calculation of Unrelated Business Income 9.26

IX. Subsidiaries, Partnerships 9.26
A. For-Profit Subsidiaries 9.26
Attribution of Subsidiary's Activities to Tax-Exempt Parent 9.27
B. Joint Ventures and Partnerships 9.27
Partnership or Joint Venture 9.27
Partnerships and Tax Exemption 9.28
Partnership, Joint Ventures and Private Inurement 9.28
Whole Hospital Joint Ventures or Partnerships 9.30
Summary of Significant Factors Determining the Permissibility of Participation in Partnership 9.31
IRS Church Plan Exemption Pension Issues 9.31
C. Accountable Care Organizations 9.32

X. Political, Lobbying and Legislative Activities 9.34
A. Prohibited Political Activities 9.34
Political Fundraising — Prohibited 9.34
Endorsements or Position Statements — Prohibited 9.34
Publication or Distribution of Partisan Materials — Prohibited 9.35
Use of Facilities and Resources for Partisan Purposes — Prohibited 9.35
Partisan Education or Registration Activities — Prohibited 9.35

B. Generally Permitted Political Activities 9.35
Nonpartisan Education Activities — Generally Permitted 9.35
Nonpartisan Registration Activities — Generally Permitted 9.35
Individual Activity by Organization Leaders — Generally Permitted 9.36
Candidate Appearances — Generally Permitted 9.36
Public Forums — Generally Permitted 9.37
Speaking as a Non-Candidate — Generally Permitted 9.37
Establishment of a 501(c)(4) Corporation — Generally Permitted 9.37
C. Other Considerations in Determining What Activities are Permitted 9.38
Issue Advocacy vs. Political Campaign Intervention 9.38
Business Activity 9.39
Websites 9.39
D. Lobbying/Legislative Activities 9.40
Measuring Lobbying Activity: Substantial Part Test 9.40
Measuring Lobbying Activity: Expenditure Test 9.41
Educational Materials 9.41
Attempts to Influence Judicial Appointments by Exempt Organizations 9.42

XI. Tax Reporting, Filing and Notification Requirements 9.42
A. Federal Tax Filings 9.42
Form 990 ..... 9.42
Schedule H 9.43
Schedules A, D, J, K, L and O 9.45
B. State Tax Filings 9.46
C. State Reporting Requirements 9.46
Secretary of State 9.46
Attorney General 9.46
Sale or Transfer of Nonprofit Hospital 9.47
D. Public Inspection Rights 9.47
E. Record Retention Requirements 9.48
F. California Nonprofit Integrity Act of 2004 ..... 9.48

XII. Community Benefits Requirements 9.49
A. California Community Benefits Law 9.49
Background 9.49
Which Hospitals are Covered? 9.49
Annual Reporting Requirement 9.50
Definitions 9.51

B. Federal Community Benefits Law 9.53
Community Health Needs Assessment 9.53
Implementation Strategy 9.57
Reporting 9.58
Penalties 9.59
C. Comparison of State and Federal Requirements for Community Health Needs Assessments and Plans 9.59

XIII. Tax-Exempt Financing Considerations 9.59
A. Overview 9.59
B. Continuing Federal Requirements 9.60
Limit on Private Business Use 9.60
Management or Service Contracts 9.61
Partnerships 9.63
Limit on Changed Use 9.64
Arbitrage and Related Reporting Requirements 9.64
Document Retention 9.65
C. California Requirements 9.65
D. Common Continuing Contractual Restrictions 9.66

XIV. California Property Tax Exemption 9.66
A. Overview 9.66
B. Welfare Exemption Requirements 9.66
Qualifying Organization 9.66
Qualifying Purpose 9.67
Exclusive Use 9.67
C. Filing Requirements 9.68

FORMS & APPENDICES

HC 9-B Summary of Significant Factors Determining the Permissibility of Participation in Partnership
FAP 2 Comparison of California and IRS Requirements for Community Health Needs Assessments and Plans

9 Issues for Tax-Exempt Hospitals

I. INTRODUCTION

This chapter focuses on nonprofit, tax-exempt hospitals. Because nonprofit hospitals in California are typically formed as nonprofit corporations, this chapter assumes that a nonprofit hospital reviewing these materials is organized as a nonprofit corporation. References in this chapter to a **"nonprofit hospital"** refer to a hospital operated by a nonprofit corporation that has tax-exempt status under federal and state laws.

This chapter discusses the primary compliance issues that are specific to nonprofit hospitals, including:

1. Organizational and Operational Issues
2. Private Benefit and Inurement
3. Intermediate Sanctions
4. Governance and Board Issues
5. Unrelated Business Income Tax Issues
6. Subsidiaries, Joint Ventures and Partnerships
7. Political, Lobbying and Legislative Activities
8. Tax Reporting, Filing and Notification Requirements
9. Community Benefits Requirements
10. Tax-Exempt Financing Considerations
11. California Property Tax Exemption

Start-up organizational and related issues, issues relating to donations or contributions, and issues related to foundations, are generally beyond the scope of this chapter. Also, many of the issues confronting nonprofit hospitals in connection with nonprofit and tax-exempt status involve sophisticated, factually-specific case-by-case analysis. Accordingly, this chapter serves only as guidance and assistance in identifying common issues that a nonprofit hospital may confront in its day-to-day operations that are unique to its exempt status.

More information and guidance can be obtained on various topics of interest for California nonprofit corporations and tax-exempt organizations from the California Attorney General's Office and the IRS, respectively, at https://oag.ca.gov/charities and www.irs.gov/charities-non-profits/charitable-organizations. The information provided at the California Attorney General's website includes information about the full life cycle of a nonprofit corporation as well as registration and fundraising matters. The IRS website includes specific guidance relevant to the topics summarized in this chapter, including:

1. Exemption requirements (charitable purpose, no inurement, no private benefit);
2. Application for Recognition of Exemption;
3. Unrelated business income tax;
4. Exempt organizations and required filings; and
5. The restriction of political campaign intervention by exempt organizations.

Key Chapter Compliance Tips:

1. Ensure that the nonprofit corporation has a code of conduct/conflict of interest policy *(see chapter 1)* and conducts annual audits of director, officer and key employee arrangements to ensure that any contracts or arrangements with such individuals have been approved consistent with IRS guidelines and state law.
2. Ensure that a majority of the nonprofit corporation's directors are not interested persons within the meaning of Corporations Code Section 5227.
3. Periodically assess the nonprofit corporation's ancillary businesses to assess whether they will result in taxable income from an unrelated trade or business and file appropriate Form 990-T with the IRS if the nonprofit corporation is engaged in a taxable unrelated trade or business.
4. Periodically assess the nonprofit corporation's joint ventures and partnerships to evaluate whether they are becoming a primary revenue center for the nonprofit corporation and whether they are structured consistent with the nonprofit corporation's tax-exempt status. This assessment should consider the governance structure of the joint venture and the operating practices of the joint venture. Key considerations include whether the nonprofit corporation maintains majority governing control over the joint venture, whether the nonprofit corporation is generally serving a charitable purpose through the joint venture, and whether the joint venture only incidentally benefits the for-profit participants.
5. Periodically assess the nonprofit corporation's compensation arrangements with officers, key highly compensated employees, and physicians to ensure that they do not result in private inurement or inappropriate private benefit. Consider establishing a compensation committee of the board to review the compensation of such persons or, if already established, assess whether the compensation committee is acting independently and in compliance with state law, the corporation's bylaws, and if applicable, the committee's charter.
6. Ensure that the nonprofit corporation complies with all state and federal requirements pertaining to community health needs assessments and community benefits. *(See chapter 8 for Information about requirements pertaining to implementation of financial assistance, billing, debt collection, and extraordinary collection activities policies.)*
7. Nonprofit corporations that are subject to tax-exempt bond financing should adopt policies, procedures and/or best practices to ensure that the nonprofit corporation does not take actions contrary to the requirements associated with such bonds, or that may threaten the bonds' tax-exempt treatment, including, for example, with respect to proposed arrangements involving management or service contracts or use of any bond-financed facilities.

II. REQUIREMENTS FOR TAX-EXEMPT HOSPITALS

A nonprofit organization operating the hospital must comply with various requirements, including the following:

1. The organization must be organized exclusively for proper tax-exempt purposes.
2. The organization must be operated exclusively for a proper tax-exempt purpose and may not be operated primarily to undertake an unrelated trade or business.
3. The organization's net earnings must not inure to the benefit of any private individual.
4. The organization may not engage in substantial lobbying activities.
5. The organization may not intervene or participate in political campaigns on behalf of, or in opposition to, any candidate for public office.

These requirements are described in this chapter.

III. ORGANIZATIONAL AND OPERATIONAL ISSUES

A. Organizational Test

Exempt Purposes

The permitted exempt purposes under Internal Revenue Code Section 501(c)(3) include the following, among others:

1. Charitable;
2. Religious;
3. Educational; and
4. Scientific.

Although exempt purposes for religious, educational and scientific purposes may have some application to a nonprofit hospital, the exemption for charity is the broadest and most common exempt purpose applicable to nonprofit hospitals, and has been recognized to include the promotion of health [Revenue Ruling 69-545, 1969-2 C.B. 117; Revenue Ruling 83-157, 1983-2 C.B. 94].

The qualification of a hospital under the charitable purpose requirement has been determined by analyzing the "community benefit" provided by the hospital [Revenue Ruling 69-545, 1969-2 C.B. 117; Revenue Ruling 83-157, 1983-2 C.B. 94]. The factors which have been recognized as evidence that the community benefit standard has been met have been evolving ones. However, the following factors have been held to be important indications that a hospital benefits the community:

1. Creation and maintenance of an open emergency room and provision of charity care;
2. Participation in Medicaid and Medicare; and
3. Promotion or expansion of community health care services.

California's community benefits law is described in A. "California Community Benefits Law," page 9.49. State and federal laws regarding fair pricing policies (charity care or discounted care) are described in chapter 8.

Organizational Structure Issues

A nonprofit hospital must be organized as a "separate entity" for exempt purposes. The "separate entity" requirement will generally be met for nonprofit hospitals formed as nonprofit corporations. In addition, a nonprofit hospital's organizational documents must:

1. Limit the purposes of the organization to charitable or other exempt purposes;
2. Not permit the organization to undertake activities that do not further its exempt purposes, except to an insubstantial extent;
3. Not permit the organization to:
    a. Intervene or undertake activities participating in political campaigns on behalf of, or in opposition to, any candidate for public office, or
    b. Devote more than an insubstantial part of its activities to attempting to influence legislation; and
4. Provide that its assets will, upon dissolution of the organization, be dedicated to one or more appropriate exempt purposes or exempt organizations.

[Treasury Regulations Section 1.501(c)(3)-1(b)]

Corporations that are properly organized as California nonprofit corporations (typically, public benefit or religious corporations) generally will meet the organizational requirements for tax exemption purposes. While these requirements must generally be reflected in the articles of incorporation of a nonprofit hospital, other organizational documents, including bylaws, committee charters, and policies and procedures, must also be drafted consistent with the organization's exempt purposes.

B. Operational Test

To obtain and maintain tax exemption, a nonprofit hospital is required to be operated exclusively for exempt purposes [Treasury Regulations Section 1.501(c)(3)-1(c)(1)]. Under applicable tax regulations, this requirement means that the organization must engage primarily in activities that accomplish one or more permitted exempt purposes. Conversely, a nonprofit hospital will not be regarded as meeting the operational test if more than an insubstantial part of its activities fails to further an exempt purpose.

A key component of the operations test analysis is to look at the various activities of a nonprofit hospital and determine whether they are undertaken to support the exempt purpose. Another consideration relevant to this analysis is a determination of how important a particular activity is to the exempt purpose. Many activities, such as provision of patient care, are integral to a nonprofit hospital's exempt purpose. Other activities, such as business office activities (i.e., billing, collection, and personnel), although not directly charitable activities, are arguably required for the charitable activities and are clearly supportive of a nonprofit hospital's exempt purposes. However, other more independent activities will need to be analyzed based on how important they are to the exempt purpose.

Activities by a nonprofit hospital that are not in support of the exempt purpose must be limited to an insubstantial portion of the hospital's activities. Whether this general requirement is satisfied requires a factually-intensive analysis, consistent with many of the other issues addressed in this chapter. In analyzing these issues, the IRS may look at a wide variety of the organization's documents, including minutes, agreements, financial statements, reports and

memoranda. When a nonprofit hospital is considering any activities that may be subject to characterization as not supporting the organization's exempt purpose, a nonprofit hospital should seek the expertise of its professional advisors. Activities that are not in support of the nonprofit hospital's exempt purpose also implicate unrelated business income taxation requirements. *(See VIII. "Income From Unrelated Business," page 9.22, for more examples of arrangements that may or may not support the nonprofit hospital's tax-exempt purpose.)*

C. Impact of Illegal Activities

Nonprofit hospitals should be aware that their tax exemption can be jeopardized if their activities are contrary to public policy, including illegal acts, as such acts have been declared to be inconsistent with the requirements that an exempt organization be organized and operated to further a charitable purpose [*Bob Jones University v. United States*, 461 U.S. 574, 103 S.Ct. 2017 (1983); Revenue Ruling 75-384, 1975-2 C.B. 204; General Counsel Memorandum (GCM) 39862 (Nov. 22, 1991); Revenue Ruling 97-21, 1997-1 C.B. 121]. Accordingly, violation of state or federal laws by a nonprofit hospital could threaten the tax-exempt status of the offending nonprofit hospital, in addition to exposing the hospital to criminal, civil and administrative sanctions.

A nonprofit hospital's exemption could similarly be jeopardized by the illegal activities of its employees if those actions are authorized or ratified, or otherwise endorsed or encouraged, by the board of directors. Conversely, an employee's illegal acts that are not planned, authorized or ratified by the organization may not threaten its exemption.

Accordingly, as with other compliance areas, a nonprofit hospital can mitigate the significance of any possible illegal activity by employees, by adopting and enforcing a compliance or similar policy, or code of conduct, that clearly mandates compliance with applicable laws and establishes a process for enforcement, as further addressed below. *(See also chapter 1, "Hospital Compliance Plans.")*

IV. PRIVATE BENEFIT AND INUREMENT

A. Private Benefit

A nonprofit hospital must not be organized or operated for the benefit of any private interests, such as any creators or members of the organization, or other persons controlled, directly or indirectly, by such private interests [Treasury Regulations Section 1.501(c)(3)-1(d)(1)(ii)]. Instead, the organization must serve a charitable class of the public. The IRS has recognized that a hospital serves the requisite public interest, consistent with charitable exemption, if it makes its facilities and services accessible to all persons able to pay for the services and provides access to the hospital's emergency room without regard for ability to pay, even though the entire community may not benefit [Rev. Ruling 69-545].

The IRS has indicated that one factor tending to show that a hospital qualifies for tax-exempt status is maintenance of an open medical staff with privileges available to all qualified physicians. Conversely, one factor tending to show a hospital is not entitled to tax-exempt status is restricting the number of physicians admitted to the medical staff. [Rev. Ruling 69-545]

The concept of private benefit derives from the fact that to be tax-exempt, an organization must be operated primarily for charitable purposes. For a private benefit to be a risk to

tax-exemption, it must be insubstantial, or incidental to achieving an exempt purpose. Tax law and the IRS recognize that there may be incidental private benefit necessary to achieve exempt purposes. For example, the IRS has announced that it does not treat the benefits an exempt hospital provides to its medical staff physicians, in the form of electronic health records software and technical support services, as impermissible private benefit if the benefits fall within the range of electronic health records items and services that are permissible under Department of Health and Human Services regulations. [Memorandum dated May 11, 2007, from the Director of the Exempt Organizations Division of the IRS to the Directors of Exempt Organizations Examinations and Rulings].

A nonprofit hospital's activities that benefit private individuals must be incidental to exempt purposes in both a qualitative and quantitative sense. According to the IRS, private benefit is qualitatively incidental if it is necessary to an activity that benefits the public at large, and private benefit is quantitatively incidental if it is insubstantial when compared to the public benefit conferred. [Private Letter Ruling 9231047]. Because of the importance of this issue to a nonprofit hospital's tax exemption and the fact-specific analysis involved, any doubtful proposed action or undertaking that could be considered to involve impermissible private benefit should be carefully analyzed prior to implementation.

B. Private Inurement

As noted above, no part of a nonprofit hospital's net earnings can inure to the benefit of any private shareholder or entity. This is known as the prohibition on inurement. Unlike the private benefit rules discussed above, private inurement:

1. Applies only where there is an "insider" involved, and
2. Lacks any threshold as to insubstantiality — any amount of private inurement is prohibited.

Insiders

An insider is a person who controls or can influence the decisions of the exempt organization. The clearest examples of insiders include the members of the organization's board of directors and senior executives. For further guidance in considering which parties may be insiders, a nonprofit hospital should look to the intermediate sanctions rules under Internal Revenue Code Section 4958 and related regulations, which provide useful guidance in their definition of a "disqualified person," as discussed below in connection with intermediate sanctions. *(See V. "Intermediate Sanctions," page 9.8.)*

Nonprofit hospitals should also pay special attention to physician leaders, who may or may not constitute insiders. The IRS has previously taken the overly broad position that all physicians on the medical staff may be insiders with respect to a tax-exempt hospital [GCM 39498 (April 24, 1986)]. Physicians should be treated as insiders if they exercise clear influence over the decisions of a nonprofit hospital. Examples of this influence by physicians may include their membership on the governing body or a committee of the governing body, and their services as key officers, medical directors, and program directors. These types of relationships should be reviewed based on the specific facts and circumstances of each case, with the benefit of input from the hospital's legal and tax advisors.

In any case, the more conservative approach of treating physicians as insiders, and scrutinizing their arrangements, accordingly, for tax purposes is advisable. Such an approach

dovetails with the similar principles to be considered in addressing the fraud and abuse considerations of physician referral laws *(see chapter 6, "Physician Self-Referral Laws")*.

Examples of Types of Compensation or Benefit Transactions

Inurement rules have been broadly interpreted to cover transfers of cash, assets, or other benefits to an insider, for any purpose other than reasonable compensation, including services or goods provided. The following examples may involve private inurement, depending on the specific circumstances. In all cases, it is important for nonprofit hospitals to retain supporting documentation in connection with determination of fair value, as addressed in connection with intermediate sanctions *(see V. "Intermediate Sanctions," page 9.8)*.

Compensation Arrangements

A nonprofit hospital may pay insiders for their services, provided the compensation and benefits paid are fair market value (i.e., comparable to what a third party would pay for such services in an arrangement negotiated at arm's-length). If the compensation exceeds fair market value, such arrangement could expose the hospital to claims of private inurement. Moreover, the organization must make sure that these types of arrangements are approved without violation of any conflict of interest requirements, as further addressed in this chapter.

Physician Recruitment

The recruitment of physicians by nonprofit hospitals raises potential issues of private benefit and inurement. However, the IRS has indicated that physician recruitment arrangements by tax-exempt hospitals, if appropriately structured, may be consistent with the organization's tax-exempt status. The two primary factors the IRS considers when analyzing physician recruitment are whether the physician being recruited will satisfy a community need and whether the incentives the hospital provides to the physician are reasonable. [GCM 39498 (April 24, 1986); Rev. Ruling 97-21]

Other Contracts for Goods or Services

Similar rules apply to any contract for services or goods involving an insider, again based on the fair market value paid for such goods or services, and the hospital's ability to establish such fair value. Importantly, contractual nuances apply to a contract with a new party who has no prior connection as an insider and who negotiated the contract on an arm's-length basis. Such an initial transaction will not constitute an insider transaction invoking inurement analysis even if, by virtue of the contract, the new party may thereafter exercise influence over the organization's decision making. However, if the new party does exercise such influence by virtue of the contract, any additional or modified arrangements with such party would need to comply with the private inurement requirements. *(See C. "Excess Benefit Transaction," page 9.10, for more information about the initial contract exception.)*

Sale of Assets

If a nonprofit hospital sells any assets to, or buys any assets from, an insider, the sale must be made in return for fair market value and on fair market value terms.

Management Contracts

A management or administrative services contract may or may not, in and of itself, cause the manager to be an insider. Whether a management or administrative services agreement causes the manager to be an insider depends on the specific terms of each contract,

including in particular, the degree to which the manager is granted control over the organization. Because of the need for such deal-specific analysis, a nonprofit hospital should seek the advice of its professional advisors in connection with any proposed management arrangements. Furthermore, it is generally recommended that any management agreements, whenever feasible, be structured consistent with the compensation, term, board overlap and other requirements set forth in Rev. Proc 2016-44, which made significant modifications to the guidance in Revenue Procedure 97-13 [Rev. Proc. 2016-44; Rev. Proc. 97-13, 1997-5 Int. Rev. Bull. 18, as modified by Rev. Proc. 2001-39, 2001-28 Int. Rev. Bull. 38, and as amplified by IRS Notice 2014-67]. *(See "Management or Service Contracts," page , for a further discussion of Rev. Proc. 2016-44.)*

Although transactions with insiders of the preceding types can be properly structured, any such transactions should be carefully analyzed for compliance with inurement issues as well as conflict of interest or similar requirements. This is an area of increased focus by the IRS, as evidenced by the development of the revised Form 990, including Schedule H. The revised Form 990, first used for the 2008 tax year, has required much more extensive reporting of insider compensation, as addressed in greater detail below. *(See VII. "Excise Tax on Executive Compensation," page 9.21.)* Accordingly, it is recommended that, whenever feasible, a nonprofit hospital seek to develop compensation or benefit arrangements with insiders in conformity with the rebuttable presumption guidelines under the intermediate sanctions regulations (discussed under "Rebuttable Presumption of Reasonableness," page 9.12), and seek the advice of its professional advisors in connection with such arrangements.

V. INTERMEDIATE SANCTIONS

Prior to 1996, if a hospital violated any requirements of its tax-exempt status, the IRS had only the blunt instrument of revoking an organization's tax-exempt status completely. Now, intermediate sanctions may be imposed — either in addition to or instead of revocation of the exempt status of the organization — with the addition of Section 4958 to the Internal Revenue Code in 1996. This section permits the IRS to impose excise taxes on disqualified persons who engage in transactions with the hospital and receive an excess benefit. Excise taxes may also be imposed on managers (e.g., directors and officers) who knowingly approved such a transaction.

The relevant rules and requirements are set forth in Internal Revenue Code Section 4958, and the detailed set of related regulations promulgated thereunder (collectively, the "Intermediate Sanctions Rules") [Internal Revenue Code Section 4958; Treasury Regulations Section 53.4958 *et seq.*]. The term used in the intermediate sanctions regulations to refer to an "insider" is "disqualified person," which is discussed below.

A. Excise Taxes

Any disqualified person who enters into an excess benefit transaction with a tax-exempt public charity (e.g., a nonprofit hospital or health system entity) is subject to an excise tax equal to 25 percent of the amount of the excess benefit. In addition, if the excess benefit is not returned or otherwise corrected within required time frames, the disqualified person can also be subject to an excise tax equal to 200 percent of the excess benefit.

Correcting the Excess Benefit

The excess benefit is corrected by rescinding or undoing the excess benefit, so that the exempt entity is put back into a position no worse than it would have been if the disqualified person had been acting with the highest fiduciary standard with respect to the organization. Typically, this requires cash payments back to the exempt organization and/or return of property received from the organization, plus interest on the excess benefit, using an interest rate at least equal to the IRS's applicable federal rate, compounded annually.

Also, an excise tax equal to 10 percent of the excess benefit, but not in excess of $20,000 per excess benefit transaction, can be imposed on the managers of the exempt organization who participated in the excess benefit transaction knowingly, willfully and without reasonable cause.

B. Disqualified Person

For purposes of the Intermediate Sanctions Rules, a disqualified person is analogous to an insider under the general inurement analysis, although a more detailed definition is provided under the Intermediate Sanctions Rules. Generally, a **"disqualified person"** is any person who, or entity which, is in a position to exercise substantial influence over the exempt organization's affairs at any time during the five years preceding the date of the transaction in question, as well as any "family member" of a disqualified person, and certain entities where such persons own more than 35 percent of the combined voting power, profits interest, or beneficial interest. Family members include any spouses; brothers and sisters and their spouses; ancestors; children, grandchildren, great-grandchildren, and all of their spouses.

The following persons, or category of persons, are specifically deemed to have the necessary substantial influence over the organization to be a disqualified person:

1. Governing body members, such as directors or trustees;
2. The president, CEO, COO, CFO (or treasurer) of the organization;
3. Any other person who implements decisions of the governing body or supervises management or operations of the organization's operation; or
4. For a hospital participating in a provider-sponsored organization (PSO), any person with a material financial interest in the PSO.

The following persons and organizations are specifically deemed not to be able to exercise substantial influence:

1. Other organizations that are exempt from tax under Section 501(c)(3) or 501(c)(4) of the Internal Revenue Code;
2. Employees who are not highly compensated employees (as defined in applicable pension rules) or substantial contributors, counting only contributions received during the current and the four preceding taxable years, who do not otherwise meet the definition of a disqualified person.

If a person does not fall squarely within the categories of specifically included or specifically excluded persons summarized above, determination of whether a person is in a position to exert influence over the affairs of the organization is subject to a case-by-case analysis, based on an analysis of all applicable facts and circumstances. In connection with such

a case-specific analysis, facts and circumstances tending to show that a person has substantial influence include the following:

1. The person founded the organization;
2. The person is a substantial contributor to the organization (as defined in Internal Revenue Code Section 507(d)(2)(A)), taking into account only contributions received by the organization during the current taxable year and the four preceding taxable years;
3. The person's compensation is primarily based on revenues derived from an activity of the organization or department or part controlled by the person;
4. The person has, or shares authority to control or determine, a substantial portion of the organization's capital expenditures, operating budget, or compensation for employees;
5. The person manages a discrete segment or activity of the organization that represents a substantial portion of the organization's activities, assets, income or expenses, as compared to the organization as a whole;
6. The person owns a controlling interest (measured either by vote or value) in an organization (corporation, partnership, trust) that is a disqualified person;
7. The person is a non-stock organization (such as a social club, homeowners association, etc.) controlled, directly or indirectly, by one or more disqualified persons.

Conversely, facts and circumstances indicating that a person has no substantial influence over the exempt entity, include, without limitation:

1. The organization is a religious organization and the person has taken a "bona fide" vow of poverty as an employee or agent, or on behalf of the organization;
2. The person is a contractor, such as an attorney or accountant whose sole relationship to the organization is providing professional advice; and
3. The direct supervisor of the individual is not a disqualified person.

Treasury Regulations Section 53.4958-3(g) provides helpful examples of how these factors are applied; see, e.g., examples 10 and 11 (applying the facts and circumstances analysis to physicians on the medical staff of a nonprofit hospital).

C. Excess Benefit Transaction

An **"excess benefit transaction"** is a transaction in which the benefits provided, directly or indirectly, by the exempt organization to the disqualified person exceed the value of the services and other consideration received by the exempt organization from the disqualified person, taking into account all consideration and benefits exchanged by the parties. Under an **"initial contract exception,"** the intermediate sanction regulations will not apply to an initial contract involving fixed payments that is negotiated at arm's length (e.g., where the contracting party was not a disqualified person prior to entering into the contract).

However, if a nonprofit hospital plans to rely on the initial contract exception, a careful reading and application of the Intermediate Sanctions Rules should be undertaken, as the regulations establish specific requirements regarding what constitutes fixed payments, permissible

termination provisions and other applicable requirements. Also, this exception will not apply to subsequent modification or renewals of the initial contract. A nonprofit hospital should consult its legal and/or tax advisors if attempting to determine whether the benefit proposed to be exchanged in a transaction will result in an excess benefit, as the regulations contain very detailed rules concerning the types of benefits to be counted, and some that should not be counted, as well as very specific rules for valuing the economic benefits exchanged by the parties.

Manager and the Manager's Participation

An organization manager (defined as a director, trustee, or officer, and may also include any individual who has powers or responsibilities similar to those of directors, trustees or officers of the organization [Internal Revenue Code Section 4958(f)(2); Treasury Regulations Section 53.4958-1(d)(2)]) may participate in an excess benefit transaction by actively supporting it, or by inaction, if the manager is under a duty to speak or act but did not. Abstention is considered consent to a transaction. If a manager has opposed the transaction in a manner consistent with his/her responsibilities to the organization, the manager will not be considered to have participated in the action. The manager can be liable for the applicable excise tax if the manager's participation is shown to have been undertaken (i) knowingly, (ii) willfully, and (iii) without reasonable cause, as discussed below.

Knowingly Participating

A manager will be regarded as having knowingly participated in the excess benefit transaction if the manager:

1. Has actual knowledge of sufficient facts such that, based solely on those facts, the transaction would be an excess benefit transaction;
2. Is aware that the transaction may violate Internal Revenue Code Section 4958; and
3. Negligently fails to make reasonable attempts to determine whether the transaction is an excess benefit transaction, or is aware that it is such a transaction.

The knowledge requirement does not mean the manager should have known. Rather, the knowledge requirement means that it must be shown that the manager actually did know. If an organization's manager relies on a reasoned written opinion of an appropriate professional (such as an attorney), addressing applicable facts, the manager's participation usually will not be considered knowing, provided that the professional was provided a full disclosure of the applicable facts.

Willfully Participating

The manager will be regarded as willfully participating in the excess benefit transaction if the participation is voluntary, conscious and intentional. A specific intent to violate the intermediate sanctions law is not required.

Reasonable Cause

If the manager exercises responsibility on behalf of the organization and uses ordinary business care and prudence, the manager's participation will be considered due to reasonable cause, and the manager generally will not be held personally liable.

Rebuttable Presumption of Reasonableness

The Intermediate Sanctions Rules also establish a rebuttable presumption that any transaction complying with qualifying requirements is not an excess benefit transaction. The key components needed to take advantage of this rebuttable presumption are:

1. The compensation arrangement or terms of transfer are approved, in advance, by an authorized body or committee of the exempt organization, composed entirely of individuals without a conflict of interest concerning the proposed transaction;
2. The authorized board or committee obtained and relied upon appropriate data as to comparability in making its determination; and
3. The board or committee adequately documented the basis for its determination, concurrently with making the decision.

If these three requirements are met, the burden, with respect to the transaction, shifts to the government to prove that the compensation was unreasonable.

With respect to the first requirement, the **"authorized body"** means the governing body or one of its committees that is authorized to act of behalf of the governing body under applicable state law, or other parties authorized by the governing body to act on its behalf. In order for a member of the governing body not to have a conflict of interest with respect to the applicable transaction, he or she must:

1. Not be a disqualified person participating in the proposed transaction;
2. Not be an employee of, or compensated by, such a disqualified person;
3. Not have a financial interest affected by the proposed transaction; and
4. Not approve a transaction involving a disqualified person in connection with the proposed transaction who has or will approve another transaction providing economic benefits to such member.

To rely on appropriate data, as noted in the second requirement, the board or committee must consider data sufficient to determine whether the proposed compensation is reasonable, in its entirety. For direct compensation arrangements, salary surveys may be relevant. For transactions involving sale or transfer of property, appraisals may be relevant.

As noted in the third requirement, the authorized board must properly document its decision in order to take advantage of the rebuttable presumption of reasonableness. The documents must reflect and address the following:

1. The terms of the approved transaction and date of approval;
2. The members who were present during debate on the transaction and the members approving it;
3. The comparability data obtained and relied on, and how it was obtained; and
4. All actions taken with respect to the proposed transaction by members who had a conflict of interest.

The documentation must be prepared by the earlier of the body's next meeting or 60 days after the final actions were taken.

VI. GOVERNANCE AND BOARD ISSUES

Under California law, nonprofit hospitals organized as nonprofit corporations are commonly formed as California nonprofit public benefit corporations, pursuant to the California Nonprofit Public Benefit Corporations Law, commencing at Corporations Code Section 5110 *et seq.*, or as nonprofit religious corporations pursuant to California Nonprofit Religious Corporations Law, commencing at Corporations Code Section 9110 *et seq.* When addressing issues related to California nonprofit corporations in this chapter, the focus is on these two forms of nonprofit corporations, unless otherwise specified.

Under California law, the board of directors of a nonprofit corporation is charged with overall responsibility for the management of the business and affairs of the corporation.

In exercising this authority, the board of directors is bound by limitations in the articles of incorporation and bylaws of the corporation. The board of directors, acting as a group or through committees, is responsible for, among other things, managing the corporation, delegating authority to and supervising the officers as to their duties and the conduct of the corporation's activities. The board of directors is charged with appointing executive officers of the corporation, and has authority to retain or discharge these officers. In contrast, the corporate officers are charged with day-to-day responsibility for the business operations of the corporation and hospital and for the implementation of policies and directives adopted by the board of directors.

The authority of the board of directors to manage the affairs and business of a nonprofit corporation is subject only to those matters that require member approval by law or the corporation's charter documents, if a nonprofit corporation has members. Where a nonprofit corporation does not have members, the authority of the board of directors is restricted only by the requirements of the directors' fiduciary duties and by the California Attorney General's authority to control and provide supervision of nonprofit corporations holding assets in charitable trust, such as nonprofit hospitals. However, the California Attorney General's authority to provide oversight to religious nonprofit hospitals is subject to certain constitutional restraints, due to First Amendment protections. A nonprofit corporation generally defines its classes of members, and their attendant rights, in its articles of incorporation and bylaws, and the organization is required to maintain records of its members at its principal office.

A. Board Structure

There is no specific statutory minimum or maximum number of directors for a nonprofit corporation. The articles of incorporation and the bylaws of a nonprofit corporation may establish the specific number of directors or may establish a minimum or maximum number and provide for the board of directors or the corporation's members, if any, to establish the specific number within the minimum or maximum limits.

There is no universal best size for a nonprofit corporate board and the optimal size depends on the nature and mission of the corporation. Larger boards provide for more diverse representation and reduce the risk of factional domination of board policy, but may be difficult to manage and may lead to difficulty in building consensus. On the other hand, small boards risk domination by an individual board member or a small contingent within the board and may limit a nonprofit hospital's ability to take required actions through the vote of independent board members.

Another consideration in determining board size is the ease with which the board will be able to satisfy quorum requirements. The quorum for the transaction of business is generally a majority of the authorized number of directors, although it may be less, as provided by the corporation's charter documents, but may not be less than one-fifth (1/5), or two (whichever is larger) of the total authorized directors for public benefit companies. Similarly, for religious nonprofit corporations, the quorum can be reduced except that a majority of all directors present at the meeting is required for the board to approve an action.

In public benefit nonprofit corporations, no more than 49 percent of the directors may be interested persons. **"Interested person"** means:

> Any person currently being compensated by the corporation for services rendered to it within the previous 12 months, whether as a full- or part-time employee, independent contractor, or otherwise, excluding any reasonable compensation paid to a director as director; or (2) Any brother, sister, ancestor, descendant, spouse, brother-in-law, sister-in-law, son-in-law, daughter-in-law, mother-in-law, or father-in-law of any such person. [Corporations Code Section 5227(b)]

To prevent violation of this provision, it is a best practice for nonprofit public benefit corporations that operate hospitals to require prospective board members and current board members to complete an annual questionnaire before board elections, specifying the following:

1. Any compensation that the director or a close family member has received for services rendered to the corporation;
2. Any similar services contemplated in the next year; and
3. Any similar services previously rendered by, or anticipated to be rendered by, an entity or business with which the director or a close family member is associated.

B. Board Committees

The bylaws of a nonprofit corporation may authorize, or the board of directors may, by resolution, authorize, the formation of committees that are given authority to act on behalf of the board of directors with respect to some, but not all of, the matters which can be considered by the board. Such committees must include as voting members only current board members [Corporations Code Section 5212(b)]. In addition, the board of directors or bylaws of a nonprofit corporation may establish advisory committees, which do not exercise the authority of the board. Unlike committees with authority to act on behalf of the board of directors, advisory committees may include non-board members.

C. Board Liability and Duties

Directors of a nonprofit corporation have obligations under state law that govern their actions on behalf of the corporation, in addition to requirements that may apply to maintain tax exemption. To the extent that they act within the requirements of the law, as summarized below, directors are accorded the important benefit of freedom from financial liability for their actions and decisions as directors.

In addition, a director of a California nonprofit corporation who serves without compensation is not subject to personal liability for monetary damages to a party damaged by the acts or omissions of the director, so long as the acts or omissions meet the following conditions:

1. They are within the scope of the director's duties;
2. They are performed in good faith;
3. They are not reckless, wanton, intentional or grossly negligent; and
4. Any damages are covered by a liability insurance policy maintained by the corporation.

Under California law, the general duties of a director of a nonprofit public benefit corporation are as follows:

> A director shall perform the duties of a director, including duties as a member of any committee of the board upon which the director may serve, in good faith, in a manner that director believes to be in the best interests of the corporation and with such care, including reasonable inquiry, as an ordinarily prudent person in a like position would use under similar circumstances. [Corporations Code Section 5231(a)]

For religious corporations, this standard is slightly modified in that a director is not held to an ordinarily prudent person standard, but must act "with such care, including reasonable inquiry, as is appropriate under the circumstances." [Corporations Code Section 9241(a)]

This legal standard is generally understood to embrace four duties that directors owe to the corporation and its constituencies:

1. A duty of care.
2. A duty of inquiry.
3. A duty of loyalty.
4. A duty of prudent investment.

These duties are owed to the corporation itself, any statutory members of the corporation, and the public at large. In addition, as further addressed below, the directors and officers of the corporation owe a duty to avoid self-dealing transactions that inure to the benefit of any insider or a close relative of such insider, which is analogous to the private benefit or private inurement concepts addressed above.

Duty of Care

Director Conduct

The duty of care is best expressed in terms of the seriousness that each director brings to his or her responsibilities. Some indicators of whether a director has satisfied this duty are regular attendance at meetings, participating in a vote on important matters, reviewing reports, financial statements and other materials submitted to the directors for consideration, gaining and maintaining familiarity with the assets, properties and objectives of the corporation and information relevant to the corporation's activities, and serving on the same basis on committees to which the director may be appointed.

The standard for the duty of care for nonprofit public benefit corporations is that of a reasonably prudent person serving in a similar capacity under similar circumstances. For religious corporations, the standard is determined based upon the circumstances. So long as the director acts in a manner that is consistent with the applicable standard of prudence, and that would be judged reasonable when viewed by others, the director has generally met the duty of care. Compliance with the other duties described below is also evidence of the exercise of care.

Management Oversight

The duty of care also requires that the director take reasonable measures to ensure that a nonprofit corporation's hospital is managed and directed in a manner consistent with its mission. Satisfaction of this obligation requires that a director consider the qualifications and performance of individuals chosen as officers of the corporation and exercise financial oversight through review, comment, and endorsement of strategic plans and similar plans of the corporation, as well as its budgets, to ensure that they are consistent with the mission of the corporation. The director must also consider the interests of constituencies and the public in the activities of the corporation, and assist in making decisions that take these factors into account in determining the best interests of the corporation.

Duty of Inquiry

The duty of inquiry requires that a director take such steps as are necessary to be sufficiently informed to make decisions on behalf of the corporation and participate in the board's activities. This obligation may be satisfied by the director undertaking investigation of proposed decisions, for example by asking investigative questions at board meetings, as well as the director's review of reports and information prepared for the benefit of the board of directors in order to support a decision. The director must draw on any knowledge he or she possesses in evaluating information and reports. For example, an individual trained in a specialty which is the subject of a report must read it from the perspective of an expert in that field. However, in areas in which the director has no expertise, the standard for conduct is that of a similarly situated prudent person.

Reliance on Reports and Advisors

Members of the board of directors are entitled to rely on the reports of committees of the board, as well as information received from officers of the corporation, agents and advisors (including legal counsel and accounting professionals), and, as to religious corporations, religious authorities and ministers, rabbis, priests, imams or others with a position or duties in the religious organization. In the case of reliance on officers or employees of the corporation, the director must believe that the individual is reliable and competent in the matters presented. Advice from experts may be relied upon if the director believes that the subject matter of the report or opinion is within the person's professional or expert competence.

Finally, a director may rely on a report from a committee on which the director does not serve, if:

1. The report is within the designated authority of the committee;
2. The director believes that the committee merits the director's confidence; and
3. The director acts in good faith and without any knowledge that would cause reliance to be unwarranted.

As noted above, a director must evaluate any report or other material on which the director seeks to rely based on specialized relevant knowledge the director may possess.

Duty of Loyalty

The duty of loyalty generally has three aspects:

1. Protection of the corporation's interests in its business, properties, assets, employees and legal rights;

2. Avoidance of conflicts of interest or self-dealing on the part of the director; and
3. Serving the interests of the corporation and not the interests of any other person or group that caused the director to be selected.

Conflicts of Interest

In discharging the duty of loyalty, a director must avoid all conflicts of interests. To this end, directors should:

1. Abstain from voting on matters as to which he or she has a material and direct financial interest that will be affected by the outcome;
2. Submit to the board of directors annual reports of business and other affiliations that relate to the corporation's affairs; and
3. Promptly report any actual or possible conflicts of interest to the board of directors.

A related responsibility of directors is to bring potential opportunities to further the mission or activities of the corporation to the board of directors or officers for consideration prior to pursuing these opportunities for his or her own personal business interests.

Preservation of Corporate Interests

Each director must place the best interests of the corporation and its constituencies (including the public) ahead of other personal interests of the director. Aside from the circumstances described above concerning transactions in which the director has a financial interest, this obligation extends to the manner in which the director conducts himself or herself in the affairs of the corporation and in voting on important decisions.

Duty of Prudent Investment

General Duty

As a general matter, the directors of a nonprofit corporation are required, in the management of the corporation's investments, to avoid speculation and to comply with any applicable standards in the corporation's articles of incorporation, bylaws, the terms of any gift or grant of funds to the corporation, or law. For religious corporations, this standard is modified in that a director is held only to the general standard of care applicable to directors of religious corporations.

Avoidance of speculation requires that the board of directors give primary consideration to the probable income and probable safety of the corporation's capital, with regard for the permanent disposition of the funds. The board of directors must consider both the long-term and short-term expenditure needs for the mission and the appropriateness of higher risk investment as part of an overall strategy for its capital.

Compliance with the standard of conduct of the directors will be measured on the basis of investment strategy rather than any individual investment selected by the board of directors or its advisors. The board of directors has authority to delegate investment responsibility to a committee and to contact investment advisors, banks, trust companies and similar institutions for management and investment of its funds.

Special Circumstances

In the case of donated funds for which a gift instrument specifies a particular investment or strategy, as well as in a circumstance in which the gift is in the form of investment assets

rather than cash, the directors are considered to have discharged their duty of prudent investment by conforming their investment decisions to the terms of the gift or grant, including holding the investment asset.

It is permissible for the board to seek authority from a donor for changes in the investment strategy applicable to a gift, or seek release from investment terms in a gift, if the board of directors determines such a course of action to be appropriate. If it is not possible to obtain a release from the donor, due to death or incapacity, the corporation may seek a court order to that effect.

Summary of Board of Director Duties

Board of Director Duties	Examples
Duty of Care	Regular attendance at, and preparation for, board meetings
Duty of Inquiry	Read materials provided to the board, request information and/or reports and ask questions
Duty of Loyalty	Disclose and abstain from voting where director has a direct or indirect financial interest or other conflict
Duty of Prudent Investment	Consider both long-term and short-term financial needs of organization

Additional information regarding governance may be found in chapter 2, "Governing Boards."

D. Self-Dealing Transactions

Stringent penalties are levied on directors of nonprofit corporations that operate hospitals who engage in self-dealing transactions involving that corporation. Unless subject to an exception, **"self-dealing transactions"** are transactions to which the corporation is a party and in which one or more of its directors has a material financial interest. Under California law, a director of a public benefit corporation or religious corporation with a material financial interest in a transaction is an **"interested director."** Similarly, transactions that benefit an interested director's immediate family are likely prohibited. Accordingly, in addition to possibly threatening a nonprofit hospital's tax-exemption and the assessment of excise taxes under federal law, as addressed above, self-dealing transactions can violate, and expose the interested director to liability under, California corporate law as further addressed on the following page. [Corporations Code Sections 5233 and 9243]

Excluded Transactions

The following types of transactions are excluded from the definition of "self-dealing transactions" under California law:

1. An action of the board fixing the compensation of a director as a director or officer of the corporation;
2. A transaction which is part of a public, charitable program or religious program (as applicable) of the corporation if it:
    a. Is approved or authorized by the corporation in good faith and without unjustified favoritism; and
    b. Results in a benefit to one or more directors or their families because they are in the class of persons intended to be benefited by the public, charitable or religious program; and

3. A transaction, of which the interested director or directors have no actual knowledge, and which does not exceed the lesser of 1 percent of the gross receipts of the corporation for the preceding fiscal year or $100,000.

However, a nonprofit hospital must keep in mind that, although the preceding transactions are excluded under California law and reflect principles similar to those applicable under exemption requirements, any such transactions must also be undertaken in a manner consistent with exemption requirements, including prohibitions on inurement.

Approval of Self-Dealing Transactions

Nonprofit corporations operating hospitals may engage, under California law, in self-dealing transactions if the transaction is approved or validated by certain methods, including any of the following:

1. The California Attorney General, either before or after the transaction is consummated;
2. A court, either before or after the transaction is consummated;
3. By the board of directors of a nonprofit corporation, after the consummation of the transaction, if before the transaction was consummated, the following conditions were satisfied:
    a. A committee or person authorized by the board of directors approved the transaction in good faith (after approval of the members, if a religious corporation and if there are any members);
    b. It was not reasonably practicable to obtain approval of the board prior to entering into the transaction; and
    c. The board, after determining in good faith that the previous two conditions were satisfied, ratified the transaction at its next meeting by a vote of the majority of the directors then in office without counting the vote of the interested director or directors; or
4. By the board of directors of a nonprofit corporation, before consummation of the transaction, upon a vote of the majority of the uninterested directors, if such directors received and reviewed the material facts concerning the transaction and the following facts are established:
    a. The corporation entered into the transaction for its own benefit;
    b. The transaction was fair and reasonable as to the corporation at the time the corporation entered into the transaction; and
    c. Prior to authorizing or approving the transaction the board considered, and in good faith determined after reasonable investigation under the circumstances, that the corporation could not have obtained a more advantageous arrangement with reasonable effort under the circumstances or the corporation in fact could not have obtained a more advantageous arrangement with reasonable effort under the circumstances.

Again, however, although the preceding may be validated under California law, any such actions will still need to comply with applicable tax exemption requirements, including prohibitions on private benefit and private inurement.

Remedies for Self-Dealing Transactions

Self-dealing transactions are not void or voidable. Rather, interested directors involved in self-dealing transactions are subject to the following remedies:

1. Accounting for any profits made from such transaction, and paying them to the corporation;
2. Paying the corporation the value of the use of any of its property used in such transaction; and
3. Returning or replacing any property lost to the corporation as a result of such transaction, together with any income or appreciation lost to the corporation by reason of such transaction, or accounting for any proceeds of sale of such property, and paying the proceeds to the corporation together with interest at the legal rate. The court may also award prejudgment interest. In addition, the court may, in its discretion, grant exemplary damages for a fraudulent or malicious violation.

[Corporations Code Sections 5233 and 9243]

E. Code of Conduct

In light of the requirements applicable to nonprofit hospitals and their boards under exemption requirements and California nonprofit corporate law, it is a best practice for nonprofit corporations that operate a hospital to adopt a formal code of conduct or similar policies. Codes of conduct typically apply to all directors, officers and employees of a corporation and require a clearly delineated commitment to compliance with all applicable laws and regulations; address conflict of interest scenarios and rules, business ethics, workplace behavior and whistleblower protections; and provide a clear statement of what is and what is not acceptable behavior and what actions to take when a director, officer or employee observes unacceptable conduct by others or is faced with a potential compliance issue. Codes of conduct are discussed in chapter 1, "Hospital Compliance Plans."

F. Compensation of Directors

Directors of nonprofit corporations that operate hospitals may be compensated for their services, although it is not unusual for directors to serve without compensation other than reimbursement of reasonable expenses incurred in the performance of their duties. If compensated, the terms of the directors' compensation should be stated in the bylaws or, if not prohibited in the bylaws, by resolution of the board of directors. Tax-exempt nonprofit public benefit corporations that operate hospitals are not prohibited from compensating their directors, so long as the compensation is reasonable and compliant with other requirements, including those regarding private benefit or inurement, as addressed above. The IRS determines reasonableness based on an examination of compensation paid to directors of similar nonprofit hospitals with a similar public or charitable purpose.

As discussed above, excessive compensation may cause a finding of impermissible private inurement, which can result in loss of a nonprofit corporation's tax-exempt status. Accordingly, the best practice for compensated directors is to develop their compensation to take advantage of the rebuttable presumption of reasonableness under the intermediate sanctions rules *(see "Rebuttable Presumption of Reasonableness," page 9.12)*. In addition, as discussed above, the directors have reduced liability risks if they serve as uncompensated volunteers *(see C. "Board Liability and Duties," page 9.14)*.

VII. EXCISE TAX ON EXECUTIVE COMPENSATION

The Tax Cuts and Jobs Act of 2017 imposes on all tax-exempt organization employers an excise tax of 21 percent on:

1. The amount of compensation over $1,000,000 paid to a "covered employee," and
2. Any "excess parachute payment" made to any covered employee.

[Internal Revenue Code Section 4960]

The excise tax applies to amounts paid by an exempt organization after Dec. 31, 2017. The excise tax is payable by the organization, not the covered employee. The tax is reported on IRS Form 4720.

A. Covered Employee

A **"covered employee"** is any employee or former employee that:

1. Is one of the five highest compensated employees of the tax-exempt organization during the tax year, or
2. Was a covered employee of the tax-exempt organization or any predecessor for any preceding tax year beginning after Dec. 31, 2016.

This "look back" concept means that an exempt organization may have more than five covered employees in any particular year, since an employee that was previously one of the top five will continue to be a covered employee indefinitely, even if no longer one of the top five. [IRS Notice 2019-09] The law does not apply to independent contractors, but organizations should be careful to ensure that their staff have been properly categorized as independent contractors before assuming that a staff member's compensation will not be subject to this law.

The IRS issued proposed regulations that restate certain statutory definitions and provide clarifications and additional guidance on exceptions for tax-exempt organizations in determining which employees are covered employees. The regulations were published on June 11, 2020, and have not yet been finalized.

B. Compensation

Compensation for purposes of the excise tax on pay over $1,000,000, includes wages, bonuses, and other taxable compensation, and includes any form of deferred compensation when it vests, whether or not it is paid. So, for example, deferred compensation subject to Section 457(f) of the Internal Revenue Code will be subject to the excise tax when it becomes vested. Related employers are aggregated for purposes of determining the total compensation paid to an executive, so that splitting the payments among related entities will not avoid the excise tax.

C. Excess Parachute Payment

"Excess parachute payment" means any payment triggered by separation from employment which exceeds three times the five-year average of annual total compensation for that employee.

D. Exception for Payment for Professional Medical Services

The excise tax does not apply to amounts paid to licensed physicians or other licensed medical professionals, such as nurse practitioners, dentists or other medical professionals

licensed under state law, solely for the performance of professional medical services. The excise tax applies only to payments for administrative and executive services provided by such professionals. The IRS expects tax-exempt organizations to allocate the income paid to medical professionals that perform both professional and administrative services in good faith, if not separately allocated in the contract. [IRS Notice 2019-09]

E. Tax Policy and Planning Considerations

The excise tax is intended to put tax-exempt organizations in a position similar to public companies when it comes to executive compensation. Public corporations cannot deduct compensation in excess of $1,000,000 or excess parachute payments for certain employees, so this change effectively generates tax on those excess amounts when paid by tax-exempt entities.

When considering compensation which will or could trigger the new excise tax, tax-exempt organizations should take extra care to meet the requirements for obtaining the rebuttable presumption of reasonableness and procure an independent reasonableness opinion. *(See V. "Intermediate Sanctions," page 9.8.)*

VIII. INCOME FROM UNRELATED BUSINESS

Tax-exempt nonprofit corporations that operate hospitals may, to an appropriate degree, engage in activities that are unrelated to their specific exempt purposes. However, doing so may create a tax liability tied to the income generated by the unrelated business conducted by the tax-exempt nonprofit corporation.

A. Taxable Income From Unrelated Trade or Business

Tax-exempt nonprofit corporations are permitted to engage in limited activities that are not substantially related to their exempt purposes, so long as the unrelated business is not significant [Internal Revenue Code Section 513(a)]. This type of limited non-exempt undertaking is called an "unrelated trade or business." A nonprofit hospital is generally deemed to have unrelated business taxable income when it realizes gross income from any regularly conducted trade or business that is not substantially related to its hospital and other exempt purposes. Examples are provided under C. "Specific Examples for Tax-Exempt Nonprofit Hospitals," page 9.23.

Income from unrelated business generated by tax-exempt nonprofit corporations is taxed (the unrelated business income tax, or UBIT) to eliminate a source of unfair competition with for-profit businesses. Organizations with unrelated business income are required to file a Form 990-T (in addition to other filing requirements). This places unrelated business activities of tax-exempt organizations on the same tax basis as the non-exempt business activities with which they compete.

B. Unrelated Trade or Business

Where a tax-exempt corporation has unrelated trade or business income that is substantial, the corporation may face possible loss of its tax-exempt status. An unrelated trade or business is a venture that is frequently undertaken by an exempt corporation and that is not substantially related, other than through the production of funds, to the corporation's exercise or performance of its exempt purposes. The simple fact that an activity creates a source of

income that is used to further a mission-related activity is not sufficient to make the activity is related to a nonprofit's charitable purpose.

Typically, a trade or business is an endeavor that involves selling goods or services to produce income. Additionally, trade or business activities must be carried on with the intention of making a profit. A trade or business may be part of a larger enterprise. Being a part of a larger endeavor that is conducted to further an exempt purpose does not make a trade or business lose its separate identity.

Activities consistent with the operation of a nonprofit hospital and provision of health care and charity care to hospital patients would likely be deemed to be related businesses and not subject to unrelated business income. However, providing rehabilitation services for other providers' patients, fitness centers and pharmaceuticals to the general public (as opposed to patients) would generally be deemed to be unrelated business income.

Another issue is whether the trade or business is regularly carried on. If it is not regularly carried on, it will not be considered a trade or business. To determine this, the frequency and continuity of the trade or business is compared with similar activities of a non-exempt corporation. [Treasury Regulations Section 1.513-1(c)(1)] Infrequent conduct will generally not be considered regular. Moreover, conduct that is performed only for a short period of the time (so long as it is not seasonally conducted on a regular basis) or that is conducted without competitive or promotional efforts often will not be considered to be regularly carried on. Additionally, an activity is not considered an unrelated trade or business if unpaid volunteers perform substantially all the work without compensation.

C. Specific Examples for Tax-Exempt Nonprofit Hospitals

The following are examples of programs that have been deemed to either create or not to create unrelated business income for tax-exempt hospitals:

1. A tax-exempt nonprofit hospital may operate a gift shop, generally patronized by patients, visitors of patients, and hospital employees, without incurring unrelated business income [Revenue Ruling 69-267].
2. A tax-exempt nonprofit hospital may operate a cafeteria and coffee shop primarily for employees and staff without incurring unrelated business income [Revenue Ruling 69-268].
3. A tax-exempt nonprofit hospital may operate a parking lot for its patients and visitors without incurring unrelated business income [Revenue Ruling 69-269].
4. A tax-exempt nonprofit hospital may operate a guest hotel for the benefit of patients and their relatives and friends without incurring unrelated business income [Private Letter Ruling 9404029].
5. A tax-exempt nonprofit hospital may operate an outpatient clinic for its faculty practice physicians without incurring unrelated business income [Private Letter Ruling 200211051].
6. A tax-exempt nonprofit hospital may develop condominium residences to be used as short-term living quarters by its patients without incurring unrelated business income [Private Letter Ruling 8427105].

7. Generally, the sale of pharmaceuticals by a tax-exempt hospital to private patients of physicians who have offices in a medical building owned by the hospital constitutes a taxable unelated business. The same would apply to sales to the general public. [Revenue Ruling 68-375] In contrast, the sale of pharmaceuticals to hospital patients is permissible. In addition, where the hospital has trouble attracting physicians to its practice, it may be permitted to provide pharmaceuticals to private patients of physicians who work in the hospital. [*Hi-Plains Hosp. v. United States*, 670 F.2d 528 (5th Cir. 1982)].

8. Depending on the specific facts and circumstances, diagnostic testing that is otherwise available in the community, but is provided at the hospital for private office patients of the hospital's staff physicians, typically will be deemed to be unrelated business income [Revenue Ruling 85-110; *see Private Letter Ruling 9851054*].

9. A tax-exempt nonprofit hospital was permitted to operate a health club that provided a community-wide benefit without incurring unrelated business income [Technical Advice Memorandum 8505002]. However, where the fees for the health club are high and effectively restrict use of the club to a limited segment of the community, the operation of the health club will be deemed to generate unrelated business income [Revenue Ruling 79-360].

10. Tax-exempt hospitals often perform services, such as data processing, purchasing, warehousing, billing and collection, food, laboratory, personnel (including selection, testing, training, and educational), printing, clinical communications, industrial engineering, records center, etc., for other hospitals. Under certain circumstances, these services may not result in unrelated trade or business income for the tax-exempt hospital providing these services for other tax-exempt hospitals if:

    a. The services are provided at a fee that does not exceed actual costs including straight-line depreciation and a reasonable rate of return on capital goods used to provide the service,

    b. The services are furnished solely to hospitals that have facilities to not serve more than 100 inpatients, and

    c. The services are consistent with the recipient hospital's exempt function.

    [Internal Revenue Code Section 513(e); Revenue Ruling 69-633]

    This exception, however, does not apply to services not listed in 26 U.S.C. Section 501(e)(1)(A) (which include, without limitation, the services referenced above), such as laundry services. An exempt hospital performing laundry services for another hospital is engaged in an unrelated trade or business, and the income generated from services provided to a hospital that is not tax-exempt is considered unrelated business income. [Internal Revenue Code Section 513(a)(2)]

As the preceding discussion shows, the question of whether a particular activity of a nonprofit hospital constitutes an unrelated trade or business involves a factually specific case-by-case analysis, some of which have been addressed by the IRS. Accordingly, a nonprofit hospital should seek the assistance of its legal and tax advisors in connection with any question or

uncertainty over whether a particular activity constitutes an unrelated trade or business and related requirements for reporting, and payment of taxes, in connection with such unrelated trade or business.

Snapshot of Whether Activities Typically Constitute UBIT

Activity	Typically UBIT?
Gift shop in hospital	No
Cafeteria and coffee shop in hospital	No
Parking lot	No
Guest hotel for patients' families	No
Outpatient clinic	No
Condos for patients	No
Pharmaceutical sales to non-hospital patients	Yes
Diagnostic testing for non-hospital patients	Yes
Health club serving a limited segment of community	Yes

D. Calculation of Unrelated Business Income Tax (UBIT)

The Tax Cuts and Jobs Act of 2017 made significant changes to the computation of the unrelated business taxable income for tax years beginning after Dec. 31, 2017.

Calculation of UBIT Separately for Each Line of Unrelated Business

A tax-exempt organization must now compute unrelated taxable business income separately for each unrelated business [Internal Revenue Code 512(a)(6)]. Previous law allowed tax-exempt organizations to use a deduction from one unrelated business to offset income from another unrelated business. It is not yet clear what distinguishes separate lines of unrelated business; so far, the only guidance from the Internal Revenue Service is IRS Notice 2018-67, which outlines reasonable, good faith approaches for making such determinations. Nonprofit hospitals should consider:

1. Reviewing all their unrelated business income producing activities to identify and assess deductible expenses attributable to each activity, and
2. Consolidating multiple unrelated businesses into a single taxable corporate subsidiary so that deductible expenses can again be aggregated used to offset income from all unrelated business activities.

Net Operating Loss Deduction

Carrybacks of net operating losses (NOLs) incurred in 2018 and beyond are no longer permitted (previously, NOLs could be carried back two years to offset income recognized in the past). In addition, the carryforward of any NOL incurred in 2018 or later may be used against only 80 percent of taxable income (under prior law, NOLs could be used to offset 100 percent of income). Because NOLs can no longer be used to entirely eliminate income produced by an unrelated business, tax-exempt organizations with significant NOL carryforwards may become subject to a tax on at least 20 percent of their unrelated business income.

Inclusion of Certain Fringe Benefits in the Calculation of Unrelated Business Income

The Tax Cuts & Jobs Act also made changes to certain fringe benefits offered to employees (if the amounts would not be deductible under Section 274 of the Internal Revenue Code). Unrelated business income could be incurred for qualified transportation fringe benefits [Internal Revenue Code Section 512(a)(7)]. However, the Taxpayer Certainty and Disaster Tax Relief Act of 2019 repealed Internal Revenue Code Section 512(a)(7) retroactive effect to the date of its enactment.

Organizations should file an amended Form 990-T to claim a refund for any taxes paid related to such qualified transportation fringe benefits.

IX. SUBSIDIARIES, PARTNERSHIPS

A hospital or other health care entity may use a subsidiary, joint venture, partnership, or a combination of these, to streamline management, enhance patient care, raise capital or for other bona fide purposes.

The use of related entities in the health care field is a common practice. Nevertheless, the use of related entities by nonprofit hospitals faces a high level of scrutiny, with the potential risk of the loss of tax-exempt status if not properly structured and operated. In particular, use by nonprofit hospitals of for-profit subsidiaries, or participation by nonprofit hospitals in joint ventures or partnerships with for-profit partners, involve risks that must be analyzed on a case-by-case basis, based on a factually-specific analysis, with the assistance of the hospital's legal and tax advisors.

This section presents a summary of the risks, and many risk factors and considerations, associated with the use of for-profit subsidiaries and participation in joint ventures and partnerships with for-profit parties.

A. For-Profit Subsidiaries

A nonprofit hospital employing assets in a manner that constitutes unrelated business activity may choose to spin off such assets into a related for-profit organization, being mindful of the dangers of capitalization of a for-profit entity using tax-exempt assets. In particular, a nonprofit hospital board must elect to do so in conformity with its fiduciary responsibilities and consistent with the prohibitions on private inurement and private benefit, to avoid jeopardizing a nonprofit parent's tax exemption. For example, previous IRS rulings indicate that only a very small percentage of an exempt organization's resources, usually only cash, may be transferred to a for-profit subsidiary. *(See, e.g., Private Letter Ruling 8709051.)* Also, a nonprofit parent must comport to the standard of the prudent investor, investing or lending only an amount of resources that is reasonable and with an expected rate of return that is reasonable. Additionally, it is recommended that the subsidiary furthers the exempt purpose of the parent. *(See, e.g., Private Letter Ruling 8709051.)*

Likewise, the compensation of an employee of a for-profit subsidiary may not exceed a reasonable and necessary salary or wage. If an individual is an employee of both the parent and subsidiary organizations, a reasonable allocation of compensation (including the costs of certain employee benefits) between the entities is required. Also, joint compensation of an employee in excess of $100,000 may be subject to an IRS reporting requirement pursuant to Form 990 (Part VII).

A nonprofit parent company and a for-profit subsidiary generally may share resources such as office facilities, equipment and supplies, without adverse consequences to a nonprofit parent. However, all relevant costs must be allocated on the basis of actual use, and each organization must pay fair market value for the resources used, preferably by means of the tax-exempt parent reimbursing the for-profit subsidiary for the parent's use of resources.

Attribution of Subsidiary's Activities to Tax-Exempt Parent

The existence of a for-profit subsidiary can have an adverse impact on the exempt status of a tax-exempt parent organization. Where a nonprofit parent so controls the affairs of the subsidiary that it is merely an extension of the parent, the subsidiary may be regarded by the IRS as a sham by the parent, and not as a separate entity, with tax consequences as if the two "entities" were one. Thus, it is important for separate tax treatment of both entities and the tax-exempt status of the parent that the purposes for which a subsidiary is formed is genuine and is reflected in all operations and business functions.

The standard used by the IRS to determine the tax-exempt status of a tax-exempt parent of a for-profit subsidiary is two-fold:

1. The subsidiary must engage in an independent, bona fide function, rather than serve as a mere instrumentality of the parent; and
2. The parent must not actively participate in the day-to-day management of the subsidiary.

(See, e.g., GCM 39598 (Jan. 23, 1987), and GCM 39776 (Jan. 24, 1989).)

Typical related risk factors include situations where:

1. The parent controls the subsidiary through ownership of stock or the power to appoint the subsidiary's board of directors; and
2. The entities' directors or officers are the same.

Although these factors do not automatically lead to attribution of the for-profit subsidiary's activities to the tax-exempt parent, caution must be exercised so as to avoid scrutiny and the potential loss of tax-exempt status by the parent.

B. Joint Ventures and Partnerships

Joint ventures and partnerships are two vehicles sometimes employed by nonprofit hospitals. Participation in joint ventures and partnerships by nonprofit hospitals, while permitted under appropriate circumstances, raises important potential issues, including potential private inurement, private benefit, and unrelated business tax issues, with potentially adverse consequences on the exempt status of a nonprofit partner or joint venturer.

This is especially true in the health care field, where a nonprofit hospital may directly or indirectly partner with physicians practicing at the exempt hospital, or where a facility or service is acquired, financed, owned, operated, maintained or utilized by a combination of exempt and nonexempt entities.

Partnership or Joint Venture

A **"partnership"** is defined in federal tax law to include:

> a syndicate, group, pool, joint venture, or other unincorporated organization, through or by means of which any business, financial operation, or venture is carried on, and which is not … a trust or estate or a corporation. [Internal Revenue Code Section 7701(a)(2)]

Partnerships can either be general or limited, depending on the extent of the liability of the individual partners for the liabilities of the partnership as a whole. The two types of partnership also differ with respect to the tax treatment of contributions or investments by individual partners.

A **"joint venture"** is an association of two or more persons with intent to carry out a single specific business venture for joint profit, for which purpose they combine their efforts, property, money, skills, and knowledge. Although a joint venture may be undertaken without creating a formal partnership, trust or corporation, references in this section to joint ventures refer to joint business ventures undertaken through a partnership or limited liability company.

It is important for a nonprofit hospital to be aware that partnerships may be formed, as a matter of law, by certain arrangements with others, even where the parties do not formally document or identify the arrangements as a partnership. The law can impose the partnership or joint venture form on any relationship, irrespective of the parties' true intention or desire to carry out a relationship of a different nature. In determining whether a partnership or a joint venture exists for tax purposes, as a matter of law, courts usually look at all of the circumstances to see whether the parties intended to join together for purposes of carrying out a business and sharing in the profits or losses.

This concept is important because, although a tax-exempt organization may intend to structure an income-producing contractual relationship with one or more parties, the IRS may, depending on the pertinent facts and circumstances, contend that the arrangement constitutes a de facto partnership or joint venture, in which case the various risks associated with participation in a partnership will be present, as discussed below.

Partnerships and Tax Exemption

Aside from unrelated business income issues, as addressed above, the most common federal tax issue concerning tax-exempt organizations in partnerships with one or more taxable partners is its impact on the tax-exempt status of the tax-exempt partner. In this regard, the concern of the IRS is that substantial private inurement and private benefits can be provided to the taxable partners in a partnership with a tax-exempt partner.

The position of the IRS is that an exempt organization may participate as a general partner in a limited partnership without per se loss of tax-exempt status. However, the exempt organization could, by such participation, lose its exempt status unless:

1. The tax-exempt organization is serving a charitable purpose through the partnership; and
2. The partnership arrangement permits the tax-exempt organization to act:
    a. Exclusively in furtherance of its tax-exempt purposes, and
    b. Only incidentally for the benefit of the for-profit partners.

Partnership, Joint Ventures and Private Inurement

In addition to addressing its primary concern that a joint venture is serving a charitable purpose through the joint venture, the IRS may scrutinize the transaction for private inurement or private benefit, with an emphasis on the specific structuring of the partnership agreement. If a private benefit is conferred by a partnership in which a tax-exempt organization is a general partner, the private benefit must be incidental in both a qualitative

and quantitative sense. In order to be incidental in a qualitative sense, it must be a necessary concomitant of the activity which benefits the public, such that the activity can be accomplished only by benefiting certain private individuals. To be incidental in a qualitative sense, the private benefit must not be substantial after considering the overall public benefit conferred by the activity.

In 1992, the IRS developed guidelines for use by IRS agents in the examination of tax-exempt hospitals [IRS Exempt Organizations Examination Guidelines Handbook (commonly known as the "Hospital Audit Guidelines"), IRM 7(10)69 Section 333.4(2), reproduced in Ann. 92-83, 1992-22 I.R.B. 59]. The Hospital Audit Guidelines addressed factors to be considered in determining whether the tax-exempt hospitals meet the community benefit standard, with a focus on private inurement and private benefit issues. The Hospital Audit Guidelines included steps to take to determine if there is unreasonable compensation and the effects of entering into joint venture arrangements. The Hospital Audit Guidelines observe that "[j]oint ventures between taxable and exempt parties must be carefully examined for [private] inurement and private benefit." These guidelines advise the IRS examining agent to review the facts to determine whether the venture serves a charitable purpose, whether and how participation by the tax-exempt entity furthers its exempt purpose, and whether the arrangement permits the exempt entity to act exclusively in furtherance of its exempt purposes.

The Hospital Audit Guidelines summarize possible fact situations in this setting that may cause private inurement to arise:

1. Participation in the venture imposes on the tax-exempt health care organization obligations that conflict with its exempt purposes;
2. There is a disproportionate allocation of profits and losses to the nonexempt partners;
3. The exempt partner makes loans to the partnership that are commercially unreasonable (because of low interest rate or inadequate security);
4. The exempt partner provides property or services to the partnership at less than fair market value; and/or
5. A nonexempt partner receives more than reasonable compensation for the sale of property or services to the joint venture.

The IRS has also identified the following legitimate purposes for involvement of a hospital in a partnership or joint venture:

1. Raising needed capital;
2. Bringing new services or a new provider to a community;
3. Sharing risk inherent in a new activity; and/or
4. Pooling diverse areas of expertise.

Prior pronouncements from the IRS reflect the following factors favored by the IRS (as indicating a permissible arrangement):

1. A limited contractual liability of the tax-exempt partner;
2. A limited (reasonable) rate of return on the investment by the limited partners;

3. A right of first refusal by the tax-exempt organization on the disposition of an asset of the partnership;
4. The involvement of other general partners obligated to protect the interests of the limited partners; and
5. The absence of any obligation to return the limited partners' capital from the resources of the exempt partner.

Whole Hospital Joint Ventures or Partnerships

In the context of "whole hospital" joint ventures, where an exempt hospital contributes all of a facility's assets to a joint venture, the IRS has stated that the operative test is a nonprofit's control over the joint venture [Revenue Ruling 98-15, 1998-12 I.R.B. 6 (1998); *St. David's Health Care System v. United States*, 349 F.3d 232 (5th Cir. 2003)].

Revenue Ruling 98-15 addresses joint venture tax issues by means of two examples. In each example, an exempt organization that owns and operates a hospital facility, seeking to enhance its operations, contributes substantially all of its hospital assets to a Limited Liability Company (LLC) that is jointly owned by the contributing exempt organization and a for-profit organization. Situation 1 describes a "good" joint venture that results in favorable treatment for the exempt organization, including continued tax-exempt status. Situation 2 results in adverse consequences for the exempt organization, including loss of tax-exempt status.

Key features of Situation 1 favorable to the exempt organization:

1. The LLC organizational documents require the pursuit of charitable purposes and elevation of that pursuit above pursuit of financial return. The dedication of LLC activities to charitable purposes is clearly a prerequisite.
2. The exempt organization had sufficient governance and control rights to ensure pursuit of charitable activities through its majority position on the LLC governing board and its control over the LLC's management company.
3. The exempt organization would not be a private foundation. Attribution of the LLC's activities to the exempt organization would result in the exempt organization continuing to further its permissible exempt purposes.
4. The allocations of LLC income were not subject to UBIT since the LLC's activity was deemed to further charitable purposes.

Key features of Situation 2 unfavorable to the exempt organization and its continued exempt treatment:

1. The LLC organizational documents did not require the LLC to operate in furtherance of charitable purposes or to subordinate pursuit of financial gain to charitable purposes.
2. The governing board composition, evenly split between the exempt organization and for-profit organization appointees, did not ensure that the exempt organization could enforce the pursuit of charitable activities.
3. The governing board did not have approval rights over all major decisions, leaving much of the LLC's governance to the management company's discretion.

4. The management company was a related party to the for-profit organization, plus the terms of the management agreement allowed the management company to renew the arrangement unilaterally, eliminating much of the exempt organization's ability to control the management function.

5. The LLC's CEO and CFO were both executives of an affiliate of the for-profit organization, which the IRS felt contributed to control of LLC by individuals who were not sensitive to the pursuit of charitable activities.

Summary of Significant Factors Determining the Permissibility of Participation in Partnership

It is clear from the applicable IRS guidance and some leading court cases that potential partnerships or joint ventures between a nonprofit hospital and taxable partners need to be carefully analyzed in each case to make sure that they are properly structured consistent with the charitable purpose of the participating nonprofit hospital and to avoid private benefit or inurement. *(See* St. David's Health Care System v. United States*, 349 F.3d 232 (5th Cir. 2003).* St. David's *involved a formal partnership agreement, but its analysis, for our purposes, is equally instructive as to both partnerships and joint ventures.)* The relevant issues and positive and negative factors, which are significant in determining whether participation in a partnership or a joint venture compromises a nonprofit hospital's exemption, are summarized in the chart found at the end of this chapter, CHA Appendix HC 9-B, "Summary of Significant Factors Determining the Permissibility of Participation in Partnership." As noted in the chart, many of these factors inherently relate to the control and day-to-day management of the partnership, as reflected in the partnership's structure, organization and operations.

IRS Church Plan Exemption Pension Issues

Another issue of potential concern for nonprofit hospitals that are either religiously affiliated or are involved in joint ventures or other transactions with such entities involves potential challenge to the "church plan" exemption from applicability of the Employee Retirement Income Security Act (ERISA), 29 U.S.C. Sections 1001 *et seq.*, to pensions held by nonprofit hospitals that have a religious affiliation. ERISA includes a specific exemption from its requirements for church plans (i.e., a pension plan of a church). A church plan is defined as "a plan established and maintained ... for its employees (or their beneficiaries) by a church or by a convention or association of churches which is exempt from tax" under the Internal Revenue Code [29 U.S.C. Section 1002(33)(A)].

Several cases have called into question whether certain nonprofit hospital organizations, as qualifying agencies of a church, may properly claim to be protected by this exemption, or whether only a church itself may establish a church plan. The majority of lower federal courts have followed a "broad interpretation," holding that church plans do not have to be established by churches as long as the plans are properly maintained by a church-affiliated organization [see e.g., *Lann v. Trinity Health Corp.*, No. PJM 14-2237, 2015 WL 6468197, at *1 (D. Md. Feb. 24, 2015); *Overall v. Ascension*, 23 F.Supp. 3d 816 (E.D. Mich. 2014); *Medina v. Catholic Health Initiatives*, 147 F.Supp. 3d 1190 (D. Colo. December 2015); *Thorkelson v. Publishing House of Evangelical Lutheran Church in America*, 764 F.Supp. 2d 1119 (D. Minn. 2011); *Hall v. USAble Life*, 774 F.Supp. 2d 953 (E.D. Ark. 2011)].

More recently, three federal courts have arrived at a "narrow interpretation," holding that ERISA requires church plans to be "established" by churches, regardless of how the plans

are later "maintained" [*Stapleton v. Advocate Health Care Network*, 817 F.3d 517 (7th Cir. 2016), cert. granted (U.S., Dec. 2, 2016, No. 16-74) 2016 WL 3856099; *Rollins v. Dignity Health*, 830 F.3d 900 (9th Cir. 2016), cert. granted (U.S., Dec. 2, 2016, No. 16-258) 2016 WL 4540399; *Kaplan v. Saint Peter's Healthcare System*, 810 F.3d 175 (3d Cir. 2015), cert. granted (U.S., Dec. 2, 2016, No. 16-86) 2016 WL 3906477)]. In each case, the plan sponsors appealed and the United States Supreme Court consolidated the three cases. On June 5, 2017, the Supreme Court reversed the lower courts and held that a pension plan maintained by an organization which is controlled or associated with a church qualifies as a church plan, regardless of who established it [*Advocate Health Care Network v. Stapleton*, 137 S. Ct. 1652 (2017)].

For now, retirement plans of nonprofit hospitals that are either religiously affiliated or are involved with such entities are not subject to ERISA requirements. However, church plan sponsors should periodically consider the structure, and operating history of their plans to assess potential vulnerabilities to claims that they are subject to ERISA. In addition, as part of the due diligence of transactions or joint ventures involving a nonprofit hospital that has a religious affiliation, the retirement plans of such organizations should be carefully reviewed against applicable ERISA exemptions.

C. Accountable Care Organizations

The IRS has provided initial, fairly basic guidance regarding the application of Section 501(c)(3) of the Internal Revenue Code to tax-exempt organizations participating in the Medicare Shared Savings Program (MSSP) through an accountable care organization (ACO) [IRS Notice 2011-20; IRS Fact Sheet FS 2011-11]. The MSSP, enacted under the ACA, was established to promote accountability for care, coordination of Medicare services, and investment in infrastructure to achieve high quality and efficient care.

Under the ACA, groups of health care service providers and suppliers that have established a mechanism for shared governance and that meet criteria specified by the federal Department of Health and Human Services (DHHS) are eligible to participate as ACOs under the MSSP. ACOs participating in the MSSP manage and coordinate care for their assigned Medicare fee-for-service beneficiaries. The providers and suppliers in the ACO continue to receive Medicare fee-for-service payments. In addition, an ACO that meets quality performance standards and has achieved specified savings is eligible to receive a portion of the savings achieved from the MSSP.

While not yet codified as regulations, in its Notices, the IRS states that, as a general matter, it will not consider a tax-exempt organization's participation in the MSSP through an ACO to result in inurement or impermissible private benefit to the private party ACO participants where:

1. The terms of the tax-exempt organization's participation in the MSSP through the ACO (including its share of MSSP payments or losses and expenses) are set forth in advance in a written agreement negotiated at arm's length.
2. CMS has accepted the ACO into, and has not terminated the ACO from, the MSSP.
3. The tax-exempt organization's share of economic benefits derived from the ACO (including its share of MSSP payments) is proportional to the benefits or contributions the tax-exempt organization provides to the ACO.

4. The tax-exempt organization's share of the ACO's losses (including its share of MSSP losses) does not exceed the share of ACO economic benefits to which the tax-exempt organization is entitled.

5. All contracts and transactions entered into by the tax-exempt organization with the ACO and the ACO's participants, and by the ACO with the ACO's participants and any other parties, are at fair market value.

The IRS also addresses whether the receipt of MSSP payments by tax-exempt organizations in ACOs would be subject to UBIT. The IRS states that whether the MSSP payments will be subject to UBIT depends on whether the activities generating the MSSP payments are substantially related to the exercise or performance of the tax-exempt organization's charitable purposes. The IRS states that it expects that, absent inurement or impermissible private benefit, any MSSP payments received by a tax-exempt organization from an ACO would derive from activities that are substantially related to the performance of the charitable purpose, as long as the ACO meets all of the eligibility requirements established by CMS for participation in the MSSP. [IRS Notice 2011-20]

On Oct. 24, 2014, the IRS released an advance version of IRS Notice 2014-67. Notice 2014-67 contains private use guidelines for ACOs participating in the MSSP. Similar to the safe harbor set out in IRS Notice 2011-20 and IRS Fact Sheet FS 2011-11 regarding the inurement or impermissible private benefit to private parties, Notice 2014-67 provides interim guidance that a 501(c)(3) hospital, financed with tax-exempt bonds and participating in the MSSP through ACOs with for-profit participants, will not, in and of itself, result in private business use of the tax-exempt bond financed facility, if six requirements are met. Requirements 1-5 are the same as the five requirements set out in IRS Notice 2011-20 and IRS Fact Sheet FS 2011-11. The sixth requirement that must also be met is that the tax-exempt organization does not contribute or otherwise transfer the property financed with tax-exempt bonds to the ACO unless the ACO is an entity that is a governmental person, or in the case of qualified 501(c)(3) bonds, either a governmental person or a 501(c)(3) organization. *(See B. "Continuing Federal Requirements," page 9.60.)*

This interim guidance relays that Notice 2014-67 applies to bonds subject to Sections 141 or 145(a)(2)(B) of the Internal Revenue Code sold on or after Jan. 22, 2015 and may be applied to such bonds sold before Jan. 22, 2015.

The IRS guidance is limited to participation in ACOs that are part of the MSSP, and does not apply to tax-exempt hospitals when they enter into and operate shared savings arrangements with private, commercial health insurance payers. The IRS has indicated that these types of activities are unlikely to lessen the burdens of government, and that negotiation with private health insurers on behalf of unrelated parties is generally not a charitable activity, regardless of whether such an agreement involves a program aimed at achieving cost savings in health care delivery. The IRS has, however, recognized that some non-MSSP activities may further or be substantially related to an exempt purpose of a tax-exempt organization. For example, the IRS recognizes that an ACO participating in shared savings arrangements with a state Medicaid program may well be furthering the charitable purpose of relieving the poor or underprivileged.

In April 2016, the IRS released Private Letter Ruling 201615022, denying Section 501(c)(3) tax-exempt status to a health system affiliate formed to function as an ACO in relation to

commercial payers. In the ruling, the IRS concluded that the commercial ACO, despite its aims of improving the quality of health care, reducing costs and increasing patient satisfaction for the patient populations served by the ACO's providers, did not qualify for Section 501(c)(3) status. In the Private Letter Ruling, the IRS concluded that the ACO did not exclusively promote the health of the community as a whole, but rather primarily benefitted the ACO's network physicians, approximately half of whom were not employed within the nonprofit health system that founded the ACO, by virtue of negotiating commercial payer contracts on their behalf. The ruling confirms that tax-exempt organizations that participate in commercial ACOs should continue to carefully consider:

1. Which type of legal entity to use to structure the commercial ACO and its intended income tax classification;
2. Whether the commercial ACO may qualify for tax-exempt status;
3. Whether the commercial ACO will generate UBIT; and
4. Whether the commercial ACO will represent a substantial enough portion of a tax-exempt organization's operations to jeopardize the overall organization's tax-exempt status.

X. POLITICAL, LOBBYING AND LEGISLATIVE ACTIVITIES

While nonprofit tax-exempt hospitals are prohibited, to some extent, from engaging in political, lobbying and legislative activities, there are opportunities for nonprofits to lobby or influence legislation that furthers their mission in a manner described in this section. Violation of the rules governing political intervention or lobbying may result in loss of tax-exempt status and the imposition of an excise tax.

There are numerous gray areas for hospitals to consider, and there are different sets of rules for political campaign activities and lobbying. Accordingly, any questions regarding possible political or lobbying activities should be addressed to a nonprofit hospital's legal or tax advisors. However, an overview of many of the issues to consider relating to political or lobbying activities are summarized below.

A. Prohibited Political Activities

Prohibited political campaign intervention includes any and all activities that favor or oppose one or more candidates for public office. Nonprofit hospitals are absolutely prohibited from directly or indirectly participating in, or intervening in, any political campaign on behalf of, or in opposition to, any candidate for elective public office. Below are specific examples of activities that generally violate the prohibition.

Political Fundraising — Prohibited

Nonprofit hospitals may not make or solicit contributions to political campaign funds.

Endorsements or Position Statements — Prohibited

Nonprofit hospitals and their representatives may not endorse, directly or indirectly, or rate, political candidates and may not make statements, either orally or in writing, in favor of, or in opposition to, any candidate for public office.

Publication or Distribution of Partisan Materials — Prohibited

Nonprofit hospitals may not publish or distribute statements made by others that favor or oppose any candidate for public office.

Use of Facilities and Resources for Partisan Purposes — Prohibited

Nonprofit hospitals may not allow a candidate to use the hospital's assets, facilities, or other resources, if other candidates are not given an equivalent opportunity.

Partisan Education or Registration Activities — Prohibited

Voter education or registration activities that favor one candidate over another, oppose a candidate in some manner, or have the effect of favoring a candidate or group of candidates, are prohibited.

Violation of the prohibition on political campaign intervention may result in denial or revocation of tax-exempt status and the imposition of excise tax.

In *Citizens United v. Federal Election Comm'n*, 558 U.S. 310 (2010), the United States Supreme Court invalidated on First Amendment grounds election-related restrictions on corporate and union spending contained in the Bipartisan Campaign Reform Act of 2002 (also known as the McCain-Feingold legislation). *Citizens United* limited the permissible scope of governmental restriction on political speech, including speech of nonprofit organizations.

However, the decision did not apply to Internal Revenue Code Section 501(c)(3) organizations since it did not invalidate the provisions from the Internal Revenue Code that are the source of the limitations on political activities of Internal Revenue Code Section 501(c)(3) organizations. Thus, under current law, the broad limitations on the political activities of Internal Revenue Code Section 501(c)(3) organizations remain intact.

B. Generally Permitted Political Activities

Certain nonpartisan activities or expenditures may be permitted, depending on the facts and the circumstances. Below are specific examples of activities that may be permissible.

Nonpartisan Education Activities — Generally Permitted

Nonprofit hospitals may conduct voter education activities, such as publishing voter education guides, so long as they are conducted in a non-partisan manner.

Nonpartisan Registration Activities — Generally Permitted

Activities designed to encourage people to participate in the electoral process, such as voter registration and get-out-the-vote drives, do not violate the prohibition, as long as they are not conducted in a partisan manner.

Example: A hospital sets up a booth at a local fair where citizens can register to vote. The signs and banners in and around the booth give only the name of the hospital, the date of the next election, and notice of opportunity to register. No reference to any candidate or political party is made by volunteers staffing the booth or in the materials available at the booth, other than the official voter registration forms. This hospital is not in violation of the prohibition.

Individual Activity by Organization Leaders — Generally Permitted

According to the IRS, the political campaign prohibition is not intended to restrict free expression on political matters by leaders of organizations speaking for themselves, as individuals. Nor are leaders prohibited from speaking about important public policy issues. However, leaders may not make partisan comments in official organization publications or at official functions of the organization. To avoid potential attribution of their comments outside of organization functions and publications, organization leaders who speak or write in their individual capacity are encouraged to clearly indicate that their comments are personal and not intended to represent the views of the organization.

Example: The CEO of a nonprofit hospital is well known in the community. A candidate for public office, whom the CEO personally endorses, obtains the permission of this CEO and five other prominent health care industry leaders to publish a full page ad in the local newspaper listing the names of the five leaders. The ad states "Titles and affiliations of each individual are provided for identification purposes only." The ad is paid for by the candidate's committee. Because the ad was not paid for by a nonprofit hospital, the ad is not in an official publication of the hospital, and the endorsement is made by the CEO in a personal capacity, the ad does not constitute political intervention.

Candidate Appearances — Generally Permitted

A nonprofit hospital may invite political candidates to speak at its events, if certain conditions are met. Political candidates may be invited in their capacity as candidates, or in their individual capacity. Candidates may also appear without an invitation at hospital events that are open to the public.

In these circumstances, hospital leaders must ensure that candidates adhere to rules governing nonprofit hospitals, which differ from election laws — the primary concern of the candidate. When a hospital has invited a candidate to speak, the hospital must ensure that:

1. It provides an equal opportunity to other political candidates seeking the same office.
2. It does not indicate any support for, or opposition to, the candidate. This should be stated clearly when the candidate is introduced and in all communications concerning the candidate's attendance.
3. No political fundraising occurs.

In determining whether candidates are given an equal opportunity to participate, a nonprofit hospital should consider the nature of the event to which each candidate is invited, in addition to the manner of the presentation.

Example: A hospital that invites one candidate to speak at its well-attended annual banquet, but invites the opposing candidate to speak at a sparsely attended general meeting, will likely have violated the political campaign prohibition, even if the manner of presentation for both speakers is otherwise neutral.

Public Forums — Generally Permitted

A public forum involving several candidates for public office may qualify as an exempt educational activity. However, if the forum is operated to show a bias for or against any candidate, then the forum would be a political campaign intervention.

When a nonprofit hospital invites several candidates for the same office to speak at a forum it should consider:

1. Whether questions for the candidate are prepared and presented by an independent, nonpartisan panel;
2. Whether the topics discussed by the candidates cover a broad range of issues that the candidates would address if elected to the office sought, and are of public interest;
3. Whether the candidates are asked to agree or disagree with positions, agendas, platforms or statements of a nonprofit hospital; and
4. Whether a moderator comments on the questions or otherwise implies approval or disapproval of the candidates.

Speaking as a Non-Candidate — Generally Permitted

A nonprofit hospital may invite political candidates to speak in a non-candidate capacity. For instance, a political candidate may be a public figure because he or she:

1. Currently holds, or formerly held, public office;
2. Is considered an expert in a non-political field; or
3. Is a celebrity or has led a distinguished military, legal, or public service career.

When a candidate is invited to speak at an event in a non-candidate capacity, it is not necessary for the organization to provide equal access to all political candidates. However, the organization must ensure that:

1. The individual is chosen to speak solely for reasons other than his or her candidacy, and speaks only in a non-candidate capacity;
2. Neither the individual nor any representative of the organization makes any mention of his or her candidacy or the election; and
3. No campaign activity occurs in connection with the candidate's attendance.

In addition, the organization should maintain a nonpartisan atmosphere at the event, clearly indicate the capacity in which the candidate is appearing, and not mention the individual's political candidacy or the upcoming election in the communications announcing the candidate's attendance at the event.

Establishment of a 501(c)(4) Corporation — Generally Permitted

A 501(c)(4) corporation, also known as a social welfare organization, is permitted to engage in lobbying as its primary activity, and is also permitted to engage in political activities. A 501(c)(3) corporation may establish and control a 501(c)(4) corporation to conduct lobbying and still maintain its tax-exempt status. In Private Letter Ruling 201127013, the 501(c)(3) organization was an integrated health care system with a number of tax-exempt subsidiaries. Neither the parent nor the subsidiaries participated in political activities. The ruling held that

the establishment by the parent of a separate 501(c)(4) corporation which, as an incidental part of its activities, would form and maintain political action committees, would not result in a loss of tax-exempt status for the parent, so long as the organizations operated independently and satisfied certain other requirements. The ruling also held that the establishment by the parent and its subsidiaries of a voluntary payroll deduction plan under which their employees could elect to contribute to any Section 527 political organization through deductions in their paychecks, would not result in a loss of tax-exempt status. However, a 501(c)(3) corporation cannot establish a Section 527 political organization to conduct political activities that it otherwise could not directly conduct. [*See S. Rep. No. 93-1374, 93rd Cong., 2d. Sess. 30 (1974), 1975-1 C.B. 517, 534, and Treasury Regulations Section 1.527-6(g)*]

Using affiliates to conduct lobbying requires careful planning and strict adherence to protocols respecting the separateness of the organizations. For example, each entity must maintain its own records and accounts. If there are overlapping paid officers, directors and/or employees, their time must be allocated between the organizations based on the activities they perform for each entity, and shared goods, services and facilities must be reasonably allocated.

C. Other Considerations in Determining What Activities are Permitted

Issue Advocacy vs. Political Campaign Intervention

Nonprofit hospitals may take positions on public policy issues. Taking a position on a policy issue is legally different from taking a position on a candidate (a person). Nonprofit hospitals may take a position on policy issues, including issues that divide candidates in an election for public office. However, hospitals must avoid any issue advocacy that functions as political campaign intervention. Even if a statement does not expressly tell an audience to vote for or against a specific candidate, an organization delivering the statement is at risk of violating the political campaign intervention prohibition if there is any message favoring or opposing a candidate. A statement can identify a candidate not only by stating the candidate's name, but also by other means such as showing a picture of the candidate, referring to political party affiliations, or other distinctive features of a candidate's platform or biography.

Key factors in determining whether a communication results in prohibited political campaign intervention include:

1. Whether the statement identifies one or more candidates for a given public office;
2. Whether the statement expresses approval or disapproval for one or more candidates' positions and/or actions;
3. Whether the statement is delivered close in time to the election, and/or makes reference to voting or the election;
4. Whether the issue addressed in the communication has been raised as an issue distinguishing candidates for a given office;
5. Whether the communication is part of an ongoing series of communications by the organization on the same issue that are made independent of the timing of any election; and
6. Whether the timing of the communication and identification of the candidate are related to a non-electoral event such as a scheduled vote on specific legislation by an officeholder who also happens to be a candidate for public office.

A communication is particularly at risk of political campaign intervention when it makes reference to candidates or voting in a specific upcoming election.

Business Activity

The question of whether an activity constitutes participation or intervention in a political campaign may also arise in the context of a business activity of a nonprofit hospital, such as selling or renting of mailing lists, the leasing of office space, or the acceptance of paid political advertising. In this context, some of the factors to be considered in determining whether the organization has engaged in political campaign intervention include the following:

1. Whether the goods, services or facility are available to candidates in the same election on an equal basis;
2. Whether the goods, services or facility are available only to candidates and not to the general public;
3. Whether the fees charged to candidates are at the organization's customary and usual rates; and
4. Whether an activity is an ongoing activity of the organization or whether it is conducted only for a particular candidate.

Websites

If a nonprofit hospital posts something on its website that favors or opposes a candidate for public office, the hospital will be treated the same as if it distributed printed material, oral statements or broadcasts that favored or opposed a candidate.

A nonprofit hospital should also monitor other websites with which it has established a link. According to the IRS, when an organization establishes a link to another website, the organization is responsible for the consequences of establishing and maintaining that link, even if the organization does not have control over the linked site. The facts to be considered include the context for the link on the organization's website, whether all candidates are represented, any exempt purpose served by offering the link, and the directness of the links between the organization's website and the web page that contains material favoring or opposing a candidate for public office.

Example: Nonprofit Hospital N maintains a website that includes such information as medical staff listings, directions to Hospital N, and descriptions of its specialty health programs, major research projects, and other community outreach programs. On one page of the website, Hospital N describes its treatment program for a particular disease. At the end of the page, it includes a section with links to other websites, titled "More information." These links include links to other hospitals that have treatment programs for this disease, research organizations seeking cures for the disease, and articles about treatment programs. This section includes a link to an article on the website of O, a major national newspaper, praising Hospital N's treatment program for the disease. The page containing the article on O's website contains no reference to any candidate or election and has no direct links to candidate or election information. Elsewhere on O's website, there is a page displaying editorials that O has published. Several of the editorials endorse candidates in an election that has not yet occurred. Hospital N has not intervened in a political campaign by maintaining the link to the article on O's website because the link is provided for the exempt purpose of educating the public about Hospital N's programs and neither the context of the link, nor the relationship between Hospital N and O, nor the arrangement of the links going from Hospital N's website to the endorsement on O's website indicate that Hospital N was favoring or opposing any candidate.

D. Lobbying/Legislative Activities

In general, no organization may qualify for Internal Revenue Code Section 501(c)(3) if a substantial part of its activities is attempting to influence legislation. Legislation includes any action by Congress, any state legislature, any local council, or similar governing body, with respect to acts, bills, resolutions, or similar items (such as legislative confirmation of appointive office), or by the public in referendum, ballot initiative, constitutional amendment, or similar procedure. It does not include actions by executive, judicial, or administrative bodies.

A hospital will be regarded as attempting to influence legislation if it contacts, or urges the public to contact, members or employees of a legislative body for the purpose of proposing, supporting, or opposing legislation, or if the organization advocates the adoption or rejection of legislation.

Nonprofit hospitals are permitted to devote part of their activities to lobbying, which is defined as an attempt to influence legislation. For example, hospitals may conduct educational meetings, distribute educational materials or otherwise consider public policy issues in an educational manner.

Measuring Lobbying Activity: Substantial Part Test

Whether an organization's attempts to influence legislation constitute a substantial part of its overall activities is determined on the basis of all the pertinent facts and circumstances in each case. The IRS considers a variety of factors, including the time devoted (by both compensated and volunteer workers) and the expenditures devoted by the organization to the activity. Because these issues are dependent on specific factual and legal analysis, a

nonprofit hospital should seek advice from its professional advisors prior to undertaking any potential lobbying activities.

Under the substantial part test, an organization that conducts excessive lobbying activity in any taxable year may lose its tax-exempt status, resulting in all of its income being subject to tax.

Further, a tax equal to 5 percent of the lobbying expenditures for the year may be imposed against organization managers, jointly and severally, who agree to the making of such expenditures knowing that the expenditures would likely result in the loss of tax-exempt status.

Measuring Lobbying Activity: Expenditure Test

Nonprofit hospitals may elect the expenditure test under Internal Revenue Code Section 501(h) as an alternative method for measuring lobbying activity. Under the expenditure test, the extent of an organization's lobbying activity will not jeopardize its tax-exempt status, provided its expenditures, related to such activity, do not normally exceed the following limits. [Internal Revenue Code Section 4911]

The maximum amount that may be spent on total lobbying expenditures in any taxable year is the lesser of $1 million or the amount determined by the following table:

If the exempt purpose expenditures are:	**The maximum lobbying nontaxable amount is:**
Not over $500,000	20% of the exempt purpose expenditures
Over $500,000, but not over $1 million	$100,000, plus 15% of the excess of the exempt purpose expenditures over $500,000
Over $1 million, but not over $1.5 million	$175,000 plus 10% of the excess of the exempt purpose expenditures over $1 million
Over $1.5 million	$225,000 plus 5% of the excess of the exempt purpose expenditures over $1.5 million

Grassroots lobbying expenditures are also limited to no more than 25 percent of the total lobbying limit. Hospitals electing to use the expenditure test must file Form 5768, "Election/Revocation of Election by an Eligible Internal Revenue Code Section 501(c)(3) Organization to Make Expenditures to Influence Legislation," at any time during the tax year for which it is to be effective. The election remains in effect for succeeding years unless it is revoked by the hospital. Revocation of the election is effective beginning with the year following the year in which the revocation is filed. The electing hospital must also retain records concerning the lobbying expenditures, consistent with IRS requirements.

Under the expenditure test, a nonprofit hospital that engages in excessive lobbying activity over a four-year period may lose its tax-exempt status, making all of its income for that period subject to tax. Should the hospital exceed its lobbying expenditure dollar limit in a particular year, it must pay an excise tax equal to 25 percent of the excess.

Educational Materials

Hospitals may involve themselves in issues of public policy without the activity being considered as lobbying. For example, organizations may conduct educational meetings,

prepare and distribute educational material, or otherwise consider public policy issues in an educational manner without jeopardizing their tax-exempt status.

Organizations may also distribute voter guides. Voter guides, generally, are distributed during an election campaign and provide information on how all candidates stand on various issues. These guides may be distributed with the purpose of educating voters; however, they may not be used to attempt to favor or oppose candidates for public elected office.

Attempts to Influence Judicial Appointments by Exempt Organizations

Attempts to influence Senate confirmation of a federal judicial appointment are not considered campaign intervention, which is specifically forbidden. However, because attempts to influence Senate confirmation are considered lobbying, they are subject to the following rules on lobbying:

1. Nonprofit hospitals may engage in lobbying in furtherance of their exempt purposes; and
2. The lobbying may not be a substantial part of the organization's activities.

XI. TAX REPORTING, FILING AND NOTIFICATION REQUIREMENTS

A. Federal Tax Filings

Form 990

Subject to certain limited exceptions, tax-exempt entities are required to file annual returns with the Internal Revenue Service on IRS Form 990, "Return of Organization Exempt from Income Tax." Certain exceptions exist, including for churches and governmental units and their affiliates. Also, based on certain income and asset holding requirements, exempt organizations may be eligible to file a Form 990-N or Form 990-EZ, rather than a full Form 990. However, an organization that operates one or more "hospital facilities" (a facility that is required to be licensed, registered, or similarly recognized by a state as a hospital) must file a Form 990, along with Schedule H, as addressed further below.

The 2019 Form 990 is available on the IRS website at www.irs.gov/pub/irs-pdf/f990.pdf and each schedule to the 990 is also separately available on the IRS website.

The Form 990 is due no later than the 15th day of the fifth month after the close of the organization's taxable year, subject to certain limited filing extension rights. For tax years beginning on or after July 2, 2019, section 3101 of P.L. 116-25 requires that returns by exempt organizations be filed electronically. If you are filing Form 990 for a tax year beginning on or after July 2, 2019, you must file the return electronically.

The Form 990 calls for detailed disclosure of financial, operational and governance information. There are many questions that call for narrative descriptions, which should be thoughtfully drafted and reviewed in light of the fact that the Form 990 is subject to public inspection *(see D. "Public Inspection Rights," page 9.47)*. In December 2007, the IRS approved the use of a newly redesigned Form 990. The redesigned Form 990 includes additional as well as more detailed disclosures and schedules, particularly in regard to hospital and medical care activities and joint venture activities undertaken by the filing organization. According to the IRS, the redesign of Form 990 is based on three guiding principles:

1. Enhancing transparency to provide the IRS and the public with a realistic picture of the organization;
2. Promoting compliance by accurately reflecting the organization's operations so the IRS may efficiently assess the risk of noncompliance; and
3. Minimizing the burden on filing organizations.

Failure to file the Form 990 on time, to include required information in the form, or to show correct information can result in the imposition of penalties of up to $50,000 depending on the size of the organization, the length of the failure to file and the nature of the misrepresentation or omission of information. Responsible persons for the failure to file may also face penalties of up to $5,000. Failure to file for three years in a row results in automatic revocation of tax-exempt status. Penalties also exist for filing fraudulent returns or making fraudulent statements.

The ACA requires nonprofit hospital organizations to include the following additional information in their 990s:

1. A description of how the organization is addressing the needs identified in each community health needs assessment conducted under Internal Revenue Code Section 501(r)(3) (conducted every three years, as discussed below) and a description of any health needs that are not being addressed together with the reasons why the needs are not being addressed;
2. Its audited financial statements (or, in the case of an organization with financial statements consolidated with other organizations, the audited consolidated financial statement). Thus, it appears that nonprofit hospital organizations that have not previously prepared audited financial statements are now required to do so annually in connection with the filing of their 990s; and
3. The amount of the excise tax imposed on the organization under Internal Revenue Code Section 4959 during the taxable year.

[Internal Revenue Code Section 6033(b)(15); Treasury Regulations Section 1.6033-2(a)(2)(ii)(l)]

Schedule H

One of the key features of the revised Form 990 for hospitals is Schedule H, which all tax-exempt nonprofit hospitals must complete. The IRS determined that it was necessary to expand Form 990 to include more information from tax-exempt hospitals and health care entities because the IRS believed that, under the prior Form 990, there was inadequate reporting of information regarding community benefit activities or services to the public by such entities consistent with the benefits of tax exemption. Thus, Schedule H includes reporting information regarding a number of categories broken up into six parts.

Part I of Schedule H requests information generally about charity care and other community benefits and the related costs. In particular, it seeks information regarding the following:

1. Whether the hospital has a financial assistance policy and whether it was written;
2. The guidelines (eligibility criteria) for the financial assistance policy, if any, including whether it was based on federal poverty guidelines;

3. Whether the financial assistance policy that applied to the largest number of patients provided for free or discounted care;
4. Whether the hospital budgets amounts for free or discounted care under its financial assistance policy;
5. Whether the hospital prepared a community benefit report and if it was available to the public;
6. The costs of charity care, including unreimbursed Medicaid costs;
7. Other unreimbursed costs for other means-tested government programs; and
8. Other community benefits, such as community health improvement services, health profession education, subsidized health services, research, and cash and in-kind contributions for community benefits. Notably, on Dec. 18, 2015, the IRS confirmed that "[s]ome housing improvements and other spending on social determinants of health that meet a documented community need may qualify as a community benefit ..."

Part II of Schedule H requests information regarding community building activities, such as the following:

1. Physical improvements and housing;
2. Economic development;
3. Community support;
4. Environmental improvements;
5. Leadership development and training of the community;
6. Coalition building;
7. Community health improvement advocacy;
8. Workforce development; and
9. Any other community building activities the hospital wishes to identify.

Part III requests information regarding bad debt expenses, Medicare revenue and general collection practices, including whether the organization has specific collection practices pertaining to patients who are known to qualify for charity care or financial assistance.

Part IV requests information regarding management companies and joint ventures, including percentage ownership and/or control by the tax-exempt entity, certain interested persons and physicians.

Part V requests information regarding all the facilities operated by, or affiliated with, the tax-exempt entity. Part V also includes Section B for reporting, on a hospital facility-by-hospital facility basis, information concerning the hospital facility's community health needs assessment, financial assistance policy, billing and collections, emergency medical care policy, and charges for medical care for individuals eligible for assistance under the financial assistance policy.

Part VI requires certain supplemental information to be completed, including the following:

1. Supplementing some of the responses to the earlier parts of Schedule H;

2. Describing how the hospital determines the health care needs of the community it serves (Needs Assessment);
3. Describing how the hospital makes patients aware that they may be eligible for assistance under the hospital's financial assistance policy (Patient Education of Eligibility for Assistance);
4. Describing the community the hospital serves in terms of geography and demographic information (Community Information);
5. Providing any other information regarding how the organization promotes the health of the community, such as open medical staff, community board, use of surplus funds etc. (Promotion of Community Health);
6. If the organization is part of an affiliated health care system, describing the respective roles of the organization and its affiliates in promoting the health of the community served; and
7. If applicable, identifying all states to which the organization must make a community benefit report.

The revised Form 990 and Schedule H greatly increase the reporting requirements of nonprofit tax-exempt hospitals. For this reason, tax-exempt hospitals should work closely with their internal compliance officers, if any (or strongly consider appointing one), chief financial officers, outside auditors and legal counsel to address the issues raised by the reporting requirements of Schedule H.

In particular, because of the extensive reporting requirements regarding joint ventures, financial relationships, corporate governance and key employees, tax-exempt hospitals should continue to carefully review their joint ventures and financial relationships, compensation of key employees (which may include payments made to physicians or medical groups), and their corporate governance policies.

The American Hospital Association has prepared a helpful online tool regarding completing Schedule H, which is available at https://www.aha.org/2008-10-22-irs-form-990-and-schedule-h.

Schedules A, D, J, K, L and O

Form 990 also includes four other schedules of particular interest to nonprofit tax-exempt hospitals. Schedule A requires certain information regarding the organization's status as a public charity. Schedule D requires certain disclosures to supplement financial statements. In particular, if an organization has uncertain tax positions under Financial Accounting Standards Board Interpretation No. 48 (FIN 48), including liabilities related to unrelated business income, that entity will need to provide the text of any footnote describing the uncertain tax position(s). Schedule J requires disclosure of compensation to officers, directors, and certain employees. In addition, tax-exempt health care entities that have engaged in tax-exempt bond financing must file Schedule K. Among other things, Schedule K requires information regarding certain bond financings and the use of the proceeds from such financings. Schedule L requires information disclosure regarding certain business transactions with interested persons. Schedule O is a catch-all schedule; the IRS also requires that it be completed. In Schedule O, the organization may provide further explanation of other responses and explain significant changes. Schedule O also requires an explanation of the process used by management and directors to review the Form 990. Other schedules may

also apply, depending on the exempt organization's specific operations.

B. State Tax Filings

Subject to certain exceptions, all tax-exempt California corporations must file Franchise Tax Board (FTB) Form 199, "California Exempt Organization Annual Information Return." Certain exceptions exist, including for churches and the exclusively religious activities of a religious order. In addition, exempt organizations, other than private foundations, may be eligible to file Form 199N if gross receipts are equal to or less than $50,000 (different threshold amounts apply for organizations in existence for fewer than three years).

An exempt corporation must also file FTB Form 109 if it has gross taxable income from an unrelated trade or business of more than $1,000.

The returns are due by the 15th day of the fifth full calendar month following the close of the corporation's taxable year.

Monetary penalties may be imposed for failure to timely file. Failure to file by the 12th month following the close of the organization's taxable year may result in suspension of the corporation's powers, rights, privileges and exempt status.

The forms and accompanying instructions are available on FTB's website at www.ftb.ca.gov.

C. State Reporting Requirements

Secretary of State

Within 90 days of the entity's registration date and every two years thereafter, California nonprofit corporations are required to file with the California Secretary of State a Statement of Information (Form SI-100) setting forth the name and address of its chief executive officer, secretary and chief financial officer; the street address of its principal California office; and the name and (if the agent is not a corporation) address of its agent for service of process. The statement and accompanying instructions are available on the Secretary of State's website at www.sos.ca.gov/business/be/forms.htm and can be filled in and filed online.

Failure to file the statement on time can result in the imposition of penalties and in the suspension of the corporation's powers and privileges until the failure to file is cured.

Attorney General

Every charitable nonprofit corporation holding assets for charitable purposes that is required to initially register with the California Attorney General's Office within 30 days of receiving the assets by submitting Form CT_1 to the Attorney General's Registry of Charitable Trusts (registration checklist is available at https://www.oag.ca.gov/charities). Thereafter, the nonprofit corporation is required to annually file a Form RRF-1, regardless of whether the corporation files a Form 990.

However, nonprofit corporations and organizations not required by law to register with the Attorney General are not required to file the RRF-1. These include a charitable corporation organized and operated primarily as a hospital. Therefore, nonprofit hospitals are generally exempt from Form CT-1 and Form RRF-1 filing requirements. However, other nonprofit health care affiliates of a hospital, such as philanthropic foundations and medical practice foundations, are not exempt. Forms, filing requirements and related information are available on the California Attorney General's website at https://oag.ca.gov/charities/forms.

In addition, the IRS may disclose to appropriate state officers, including the Attorney General and others, certain information about organizations, such as revocation of an organization's tax-exempt status, notice of a tax deficiency, and information regarding applicants for recognition of tax-exempt status.

The California Attorney General's office has a website that provides links to resources and other materials helpful to management and directors of nonprofit corporations. This website may be found at https://oag.ca.gov/charities/resources#management.

Sale or Transfer of Nonprofit Hospital

California law requires the Attorney General's review and consent to any sale or other transfer (which could include, without limitation, a lease or transfer of governance or control) of a health facility owned or operated by a nonprofit corporation whose assets are held in public trust. This requirement covers health facilities that are licensed to provide 24-hour care such as hospitals and skilled nursing facilities.

The review process includes public meetings and, when necessary, preparation of expert reports. The Attorney General's decision often requires the continuation of existing levels of charity care, continued operation of emergency rooms and other actions necessary to avoid adverse effects on health care in the local community.

Additional information concerning the transfer of nonprofit hospital facilities is available on the Attorney General's website at http://oag.ca.gov/charities/nonprofithosp.

D. Public Inspection Rights

An organization must make available copies of its Form 990s, as well as their Form 990-Ts, if applicable, during regular business hours at the organization's principal business office, and at any regional or district offices that have three or more employees, during the three-year period beginning on the Form 990's filing date.

If an individual member of the public makes a written request, the organization must provide the individual with a copy of the Form 990 within 30 days, without charge, other than reasonable copying and mailing charges. If the request is made in person, the organization must provide a copy immediately. In disclosing copies of its Form 990, an organization need not disclose any contributor's name or address.

An organization must also make available for public inspection a copy of its tax-exemption application form and information submitted in support of the application. The IRS's written determination letter on the organization's application is also generally open to public inspection at the organization's principal office although the organization may delete or redact certain sensitive information, including trade secrets and information which, if disclosed, would clearly constitute an invasion of privacy.

An organization can generally fulfill its obligation to provide copies of its exemption application and its annual information by posting its tax application and tax returns on its website or as part of a database of similar documents of other tax-exempt organizations on a website maintained by another entity (such as GuideStar; *see www.guidestar.org*). The copies must be able to be accessed, downloaded, viewed and printed without a fee (e.g., as a PDF). However, even if the organization makes the application and annual information available

in such fashion, it will still have to comply with the rules for making such documentation available for inspection (but not copying), as addressed above.

E. Record Retention Requirements

Every California nonprofit corporation must keep current copies of its articles and bylaws at its principal office. A corporation must also keep adequate and correct books and records of accounts, records of its members, and minutes of meetings of its members, board of directors and board committees. These records are generally subject to inspection by the organization's members, directors, and the Attorney General.

F. California Nonprofit Integrity Act of 2004

The California Nonprofit Integrity Act of 2004 (the "Act") (amending and adding to the Supervision of Trustees and Fundraisers for Charitable Purposes Act) affects nonprofit corporations and other charitable organizations in various ways, including the regulation of fundraising activities and the imposition of certain audit and other financial oversight requirements [Government Code Sections 12580-12599.8].

Among other things, the Act requires that charitable corporations with gross revenues of $2 million or more prepare annual financial statements audited by an independent certified public accountant (CPA) following generally-accepted auditing standards. If the accounting firm and CPA performing the audit also provide non-audit services to a nonprofit, the accounting firm and CPA must follow the independence standards in the Yellow Book issued by the U.S. Comptroller General. The audited financial statements must be made available for inspection by the California Attorney General and the public no later than nine months after the close of the fiscal year they cover. Charities with gross revenues of $2 million or more in any fiscal year that are required to register and file reports with the California Attorney General must establish and maintain an audit committee.

The Act provides that its filing, registration, and reporting provisions do not apply to a nonprofit corporation or unincorporated association organized and operated primarily as a hospital [Government Code Section 12583]. Even though a nonprofit hospital may not be required to register and file reports with the Attorney General under such hospital registration and filing exception, it may be prudent for the hospital to follow the Act's audit committee standards as guidelines.

Under the Act's provisions, the audit committee may include persons who are not members of the governing board, but cannot include staff members, the president or chief executive officer, or the treasurer or chief financial officer of the organization. If an organization has a finance committee, members of that committee may serve on the audit committee, but cannot comprise 50 percent or more of the audit committee. In addition, the chairperson of the audit committee may not be a member of the finance committee. The audit committee, under the governing board's supervision, is responsible for making recommendations to the board on the hiring and firing of independent CPAs. The audit committee can negotiate the independent CPA's compensation on behalf of the governing board. The audit committee must confer with the auditor to satisfy committee members that the financial affairs of a nonprofit organization are in order; review the audit and decide whether to accept it; and approve non-audit services by the independent CPA's accounting firm, and ensure such services conform to standards in the Yellow Book issued by the U.S. Comptroller General.

Charitable corporations must have their governing board or authorized board committee

review and approve the compensation of the chief executive officer or president, and the compensation of the chief financial officer or treasurer, to ensure that the payment is just and reasonable. Compensation includes benefits.

More information about the California Nonprofit Integrity Act of 2004 is available on the Attorney General's website at https://oag.ca.gov/sites/all/files/agweb/pdfs/charities/publications/nonprofit_integrity_act_nov04.pdf.

XII. COMMUNITY BENEFITS REQUIREMENTS

A. California Community Benefits Law

Background

In 1994, the California Legislature passed a law requiring nonprofit hospitals to annually prepare and file a community benefits report [Health and Safety Code Section 127340-127360]. The Legislature recognized that private nonprofit hospitals meet certain needs of their communities through the provision of essential health care and other services. The Legislature stated that public recognition of hospitals' unique status has led to favorable tax treatment by the government. The Legislature believed that in exchange, nonprofit hospitals assume a social obligation to provide community benefits in the public interest.

The Legislature noted that California's private nonprofit hospitals provide a wide range of benefits to their communities in addition to those reflected in the financial data that hospitals report to the Office of Statewide Health Planning and Development (OSHPD). The Legislature identified community benefits that are often provided but not publicly reported, including:

1. Community-oriented wellness and health promotion.
2. Prevention services, including, but not limited to, health screening, immunizations, school examinations, and disease counseling and education.
3. Adult day care.
4. Child care.
5. Medical research.
6. Medical education.
7. Nursing and other professional training.
8. Home-delivered meals to the homebound.
9. Sponsorship of free food, shelter, and clothing to the homeless.
10. Outreach clinics in socioeconomically-depressed areas.

The Legislature stated its intent that the direct provision of goods and services, as well as preventive programs, should be emphasized by hospitals in the development of their community benefits plans.

In 2019, AB 204 was passed to amend the California Community Benefits Law. The changes to the law made by AB 204 are described below.

Which Hospitals are Covered?

Not all California hospitals must undertake a needs assessment and prepare and file a community benefits report under this law. This law applies only to private (non-governmental)

nonprofit general acute care hospitals, acute psychiatric hospitals, and special hospitals if they are owned by a corporation that has been determined to be exempt from taxation under the U.S. Internal Revenue Code.

Hospitals that are dedicated to serving children and that do not receive direct payment for services to any patient, as well as small and rural hospitals as defined in Health and Safety Code Section 124840, unless the hospital is a part of a hospital system, are exempt from the requirements of this law. AB 204 expanded the excluded hospitals to include a district hospital organized and governed pursuant to the Local Health Care District Law (Division 23 (commencing with Section 32000)) or a nonprofit corporation that is affiliated with the health care district hospital owner by means of the district's status as the nonprofit corporation's sole corporate member pursuant to Section 14169.31(h) of the Welfare and Institutions Code.

However, every hospital that is tax-exempt under Section 501(c)(3) is required to complete a community health needs assessment as required by a separate, but similar, federal law *(see B. "Federal Community Benefits Law," page 9.53)*.

Annual Reporting Requirement

Each hospital covered by this law must do all of the following.

Community Needs Assessment

Each hospital must complete a community needs assessment evaluating the health needs of the community served by the hospital. This needs assessment may be completed by the hospital alone, in conjunction with other health care providers, or through other organizational arrangements.

The assessment must include, but is not limited to, a process for consulting with community groups and local government officials in the identification and prioritization of community needs that the hospital can address directly, in collaboration with others, or through other organizational arrangement. No specific format is required.

A hospital's community needs assessment must be updated at least once every three years.

Community Benefits Plan

Each hospital must annually update its community benefits plan for providing community benefits either alone, in conjunction with other health care providers, or through other organizational arrangements.

The community benefits plan must include all of the following elements:

1. Mechanisms to evaluate the plan's effectiveness including, but not limited to, a method for soliciting the views of the community served by the hospital and identification of community groups and local government officials consulted during the development of the plan.
2. Measurable objectives to be achieved within specified time frames.
3. Community benefits categorized into the following framework:
    a. Medical care services.
    b. Other benefits for vulnerable populations.

c. Other benefits for the broader community.

d. Health research, education, and training programs.

e. Non-quantifiable benefits.

Additionally, under AB 204, a hospital's community benefit report must contain an explanation of the methodology used to determine the hospital's costs, written in plain English. The community benefits plan must be annually posted on the hospital's website.

No specific format is required.

Plan Submission

Each hospital must annually submit its community benefits plan to OSHPD. The community benefits plan must include, but not be limited to, the activities that the hospital has undertaken to address community needs within its mission and financial capacity. The hospital must, to the extent practicable, assign and report the economic value of community benefits provided in furtherance of its plan.

The plan must be filed with OSHPD not later than 150 days after the hospital's fiscal year ends. OSHPD makes these reports available to the public on its website at https://data.chhs.ca.gov/dataset/community-benefit-plans.

Under AB 204, hospitals under the common control of a single corporation or another entity may file a consolidated report if the report includes each hospital's community benefit financial data and describes the benefits provided to the communities in the hospitals' geographic area. Hospitals on a consolidated license may file a consolidated community benefit plan report if they serve the same geographic area.

Under AB 204, OSHPD may now impose up to a $5,000 fine on hospitals for failure to adopt, update, or submit community benefit plans consistent with the law.

Mission Statement

Each hospital covered by this law was required, by July 1, 1995, to reaffirm in its mission statement that its policies integrate and reflect the public interest in meeting its responsibilities as a nonprofit organization.

Definitions

As used in this law, the following terms have the following meanings:

"Charity care" means free health services provided without expectation of payment to persons who meet the organization's criteria for financial assistance and are unable to pay for all or a portion of the services. Charity care shall be reported at cost, as reported to the Office of Statewide Health Planning and Development. Charity care does not include bad debt defined as uncollectible charges that the organization recorded as revenue but wrote off due to a patient's failure to pay.

"Community" means the service areas or patient populations for which the hospital provides health care services.

"Community benefit" means a hospital's activities that are intended to address community needs and priorities primarily through disease prevention and improvement of health status, including, but not limited to, any of the following:

1. Health care services rendered to vulnerable populations, including, but not limited to, charity care and the unreimbursed cost of providing services to the uninsured, underinsured, and those eligible for Medi-Cal, Medicare, California Children's Services Program, or county indigent programs.
2. The unreimbursed cost of services identified by the Legislature as community benefits that are often provided but not publicly reported. (These are listed under "Background," page .)
3. Financial or in-kind support of public health programs.
4. Donation of funds, property, or other resources that contribute to a community priority.
5. Health care cost containment.
6. Enhancement of access to health care or related services that contribute to a healthier community.
7. Services offered without regard to financial return because they meet a community need in the service area of the hospital, and other services including health promotion, health education, prevention and social services.
8. Food, shelter, clothing, education, transportation, and other goods or services that help maintain a person's health.

AB 204 excludes from the definition of "community benefit" any activities or programs provided primarily for marketing purposes or more beneficial to the organization than to the community.

"Community benefits plan" means the written document prepared for annual submission to OSHPD that must include, but not be limited to, a description of the activities that the hospital has undertaken in order to address identified community needs within its mission and financial capacity, and the process by which the hospital developed the plan in consultation with the community.

"Community needs" means those requisites for improvement or maintenance of health status in the community.

"Community needs assessment" means the process by which the hospital identifies, for its primary service area as determined by the hospital, unmet community needs.

"Mission statement" means a hospital's primary objectives for operation as adopted by its governing body.

"Vulnerable populations" means any population that is exposed to medical or financial risk by virtue of being uninsured, underinsured, or eligible for Medi-Cal, Medicare, California Children's Services Program, or county indigent programs. "Vulnerable populations" also includes both of the following:

1. Racial and ethnic groups experiencing disparate health outcomes, including Black/African American, American Indian, Alaska Native, Asian Indian, Cambodian, Chinese, Filipino, Hmong, Japanese, Korean, Laotian, Vietnamese, Native Hawaiian, Guamanian or Chamorro, Samoan, or other nonwhite racial groups, as well as individuals of Hispanic/Latino origin, including Mexicans, Mexican Americans, Chicanos, Salvadorans, Guatemalans, Cubans, and Puerto Ricans.

2. Socially disadvantaged groups, including all of the following:
    a. The unhoused.
    b. Communities with inadequate access to clean air and safe drinking water, as defined by an environmental California Healthy Places Index score of 50 percent or lower.
    c. People with disabilities.
    d. People identifying as lesbian, gay, bisexual, transgender, or queer.
    e. Individuals with limited English proficiency.

B. Federal Community Benefits Law

The ACA added a new subsection (r) to Internal Revenue Code Section 501 that imposes federal requirements to qualify as a Section 501(c)(3) charitable hospital organization. Many of these requirements are similar to the state community benefit law discussed in A. "California Community Benefits Law," page 9.49, and the Hospital Fair Pricing Policies Law described in chapter 8. Hospitals that are exempt from the state community benefit law, such as public hospitals and small and rural hospitals, are nevertheless required to comply with these federal requirements, if they are tax-exempt under Section 501(c)(3). In addition to meeting the requirements of Section 501(c)(3) and the community benefit standards described above, hospitals that are tax-exempt under Section 501(c)(3) must meet four additional requirements:

1. Conduct community health needs assessments (described on the following page).
2. Establish and communicate financial assistance policies.
3. Limit charges to indigent patients.
4. Establish certain billing and collection practices.

The requirements listed in 2., 3., and 4. are described in detail in V. "Federal Laws Regarding Financial Assistance Policies," page 8.31. This portion of the manual explains federal community benefit requirements.

The IRS published proposed regulations under Section 501(r) on June 26, 2012 and April 5, 2013 [77 Fed. Reg. 38148; 78 Fed. Reg. 20523]. In January 2014, the IRS issued Notice 2014-2, which confirmed that hospital organizations may continue to rely on these proposed regulations, pending the publication of final regulations or other applicable guidance. On Dec. 31, 2014, the IRS published final regulations (Final Regulations) that obsoleted IRS Notice 2014-2, but continue to allow reliance on both the 2012 and 2013 proposed regulations until a hospital organization's first taxable year beginning after Dec. 29, 2015 [Treasury Regulations Section 1.501(r)-7; Treasury Regulations Section 1.6033-2].

Community Health Needs Assessment

Hospitals that are tax-exempt under Section 501(c)(3) are required to conduct a community health needs assessment (CHNA) and adopt an implementation strategy to meet the needs identified by the assessment. The governing body of the hospital must adopt an implementation strategy to meet the community needs identified through the CHNA.

In completing its CHNA, a hospital must:

1. Define the community it serves,
2. Assess the health needs of that community,
3. Document the CHNA in a written report, and
4. Make the CHNA report widely available to the public.

These steps are described in more detail below.

Define the Community Served by the Hospital

In defining the community it serves, a hospital may take into account all of the relevant facts and circumstances, including the geographic area served by the hospital, target population(s) served (for example, children, women, or the aged), and principal functions (for example, focus on a particular specialty area or targeted disease). However, a hospital may not define its community to exclude medically underserved, low income, or minority populations who live in the geographic areas from which the hospital draws its patients (unless such populations are not part of the hospital's target patient population(s) or affected by its principal functions) or otherwise should be included based on the method the hospital uses to define its community.

In addition, a hospital must take into account all patients without regard to whether (or how much) they or their insurers pay for the care received or whether they are eligible for assistance under the hospital's financial assistance policy. In the case of a hospital consisting of multiple buildings that operate under a single state license and serve different geographic areas or populations, the community served by the hospital is the aggregate of these areas or populations.

Assess Community Health Needs

To assess the health needs of the community it serves, a hospital must:

1. Identify significant health needs of the community,
2. Prioritize those health needs, and
3. Identify resources (such as organizations, facilities, and programs in the community, including those of the hospital) potentially available to address those health needs.

For these purposes, the health needs of a community include requisites for the improvement or maintenance of health status both in the community at large and in particular parts of the community (such as particular neighborhoods or populations experiencing health disparities). These needs may include, for example, the need to address financial and other barriers to accessing care, to prevent illness, to ensure adequate nutrition, or to address social, behavioral, and environmental factors that influence health in the community.

A hospital may determine whether a health need is significant based on all of the facts and circumstances present in the community it serves. In addition, a hospital may use any criteria to prioritize the significant health needs it identifies, including, but not limited to, the burden, scope, severity, or urgency of the health need; the estimated feasibility and effectiveness of possible interventions; the health disparities associated with the need; or the importance the community places on addressing the need.

In assessing the community health needs, the hospital must solicit and take into account input received from persons who represent the broad interests of that community, including those with special knowledge of or expertise in public health. These persons must include, at a minimum:

1. At least one person representing a state, local, tribal, or regional governmental public health or equivalent department or agency, or a State Office of Rural Health, with knowledge, information, or expertise relevant to the health needs of the community served by the hospital.
2. Members of medically underserved, low-income, and minority populations in the community served by the hospital, or individuals or organizations serving or representing the interests of such populations. Medically underserved populations include populations experiencing health disparities or at risk of not receiving adequate medical care as a result of being uninsured or underinsured or due to geographic, language, financial, or other barriers.

Hospitals must also consider written comments received on the hospital's most recently conducted CHNA and most recently adopted implementation strategy.

In addition, hospitals may (but are not required to) solicit and take into account input received from a broad range of persons located in or serving its community, including, but not limited to, health care consumers and consumer advocates, nonprofit and community-based organizations, academic experts, local government officials, local school districts, health care providers and community health centers, health insurance and managed care organizations, private businesses, and labor and workforce representatives.

The American Hospital Association has a guide for hospitals to engage patients and community members in the CHNA. The Community Health Assessment and Implementation Pathway provides an eight-step approach to integrating community and patient engagement into the CHNA process. *(See www.hpoe.org/resources/hpoehretaha-guides/2846?utm_source=newsletter&utm_medium=email&utm_campaign=NewsNow.)*

Document the CHNA in a Written Report

The IRS requires that the written CHNA report include all of the following:

1. A definition of the community served by the hospital and a description of how the community was determined.
2. A description of the process and methods used to conduct the CHNA. The CHNA report will be considered to describe the process and methods used to conduct the CHNA if it describes the data and other information used in the assessment, as well as the methods of collecting and analyzing this data and information, and identifies any parties with whom the hospital collaborated, or with whom it contracted for assistance, in conducting the CHNA. In the case of data obtained from external source material (such as public health agency data), the CHNA report may cite the source material rather than describe the method of collecting the data.
3. A description of how the hospital solicited and took into account input received from persons who represent the broad interests of the community it serves. A hospital's CHNA report will be considered to describe how the hospital took into

account input received from persons who represent the broad interests of the community it serves if it summarizes, in general terms, any input provided by such persons and how and over what time period such input was provided (for example, whether through meetings, focus groups, interviews, surveys, or written comments and between what approximate dates); provides the names of any organizations providing input and summarizes the nature and extent of the organization's input; and describes the medically underserved, low-income, or minority populations being represented by organizations or individuals that provided input. A CHNA report does not need to name or otherwise identify any specific individual providing input on the CHNA. If a hospital solicits, but cannot obtain, input from a source described above, the CHNA report also must describe the hospital's efforts to solicit input from such source.

4. A prioritized description of the significant health needs of the community identified through the CHNA, along with a description of the process and criteria used in identifying certain health needs as significant and prioritizing those significant health needs.
5. A description of the resources potentially available to address the significant health needs identified through the CHNA.
6. An evaluation of the impact of any actions that were taken, since the hospital finished conducting its immediately preceding CHNA, to address the significant health needs identified in the hospital's prior CHNA(s).

Make the CHNA Report Widely Available

Hospitals must:

1. Make the final CHNA report widely available on its website. If the hospital does not have its own website separate from the organization that operates it, the report should be posted on the organization's website. The hospital could also post the report on the website of another entity, if the hospital includes a conspicuously-displayed link on its own website to the website where the document is posted, along with instructions regarding access. In all cases, the report must be accessible, downloadable and printable for free. Users must not be required to create an account, provide identifying information, or obtain special hardware or software (other than software readily available to the public at no cost) in order to access the report. Posting a draft (rather than the final version) of the CHNA report on a website is not sufficient. If an individual asks how to access the CHNA report online, the hospital must provide the direct website address of the page where the document is posted.
2. Make a paper copy of the CHNA report available for public inspection upon request and without charge at the hospital.

The report must be available by these two means at least until the date the hospital has made its two subsequent CHNA reports widely available to the public.

Separate CHNA Reports

With respect to hospital organizations operating with multiple facilities, the IRS requires such organizations to conduct a separate CHNA for each facility, unless it adopts a joint CHNA report as described below. However, if a hospital is collaborating with other facilities and organizations in conducting its needs assessment or if another organization (such as a state or local public health department) has conducted a CHNA for all or part of the hospital's community, portions of the hospital's CHNA report may be substantively identical to portions of a CHNA report of a collaborating hospital or other organization conducting a CHNA, if appropriate under the facts and circumstances.

For example, if two hospital facilities with overlapping, but not identical, communities are collaborating in conducting a CHNA, the portions of each hospital's CHNA report relevant to the shared areas of their communities might be identical. Similarly, if the state or local public health department with jurisdiction over the community served by a hospital conducts a CHNA for an area that includes the hospital's community, the hospital's CHNA report might include portions of the state or local public health department's CHNA report that are relevant to its community.

Joint CHNA Reports

A hospital that collaborates with other hospitals or other organizations (such as state or local public health departments) in conducting its CHNA satisfies its obligations if the governing body adopts a joint CHNA report produced for the facility and one or more of the collaborating facilities and organizations, provided that the following conditions are met:

1. The joint CHNA report meets the same requirements as apply to separate CHNA reports.
2. The joint CHNA report is clearly identified as applying to the hospital.
3. All of the collaborating hospitals and organizations included in the joint CHNA report define their community to be the same.

Timing

The CHNA must be conducted in the taxable year for which the exemption is claimed or either of the two taxable years immediately preceding such taxable year. Thus, a CHNA must be conducted at least once every three years. This requirement is separate from the state law requiring hospitals to conduct a community needs assessment. California's Community Benefits Law is discussed in detail under "Community Health Needs Assessment," page . (New, acquired and terminated hospitals should consult legal counsel regarding timing requirements.)

Implementation Strategy

The hospital governing body must adopt a written plan, called an "implementation strategy," to meet the community health needs identified through the CHNA. This must be adopted on or before the 15th day of the fifth month after the end of the taxable year in which the hospital completes the final step for the CHNA (that is, widely publicizing the final version of the CHNA), regardless of whether the hospital began working on the CHNA in a prior taxable year. This timing requirement for adoption of the implementation strategy is in line with the due date of the Form 990 filing, without extensions.

The written plan must, with respect to each significant health need identified through the CHNA, either:

1. Describe how the hospital plans to address the health need. The hospital must describe the actions the hospital intends to take to address the health need and the anticipated impact of these actions; identify the resources the hospital plans to commit to address the health need; and describe any planned collaboration between the hospital and other facilities or organizations in addressing the health need.

OR

2. Identify the health need as one the hospital does not intend to address and explain why the hospital does not intend to address the health need. In explaining why it does not intend to address a significant health need, it is sufficient to include a brief explanation of its reason for not addressing the health need. Such reasons may include, for example, resource constraints, other facilities or organizations in the community addressing the need, a relative lack of expertise or competency to effectively address the need, the need being a relatively low priority, and/or a lack of identified effective interventions to address the need.

Joint Implementation Strategies

A hospital may develop an implementation strategy in collaboration with other hospitals or other organizations, including, but not limited to, related and unrelated hospital organizations and facilities, for-profit and government hospitals, governmental departments, and nonprofit organizations. In general, a hospital that collaborates with other facilities or organizations in developing its implementation strategy must still document its implementation strategy in a separate written plan that is tailored to the particular hospital, taking into account its specific resources.

However, a hospital that adopts a joint CHNA report may also adopt a joint implementation strategy that, with respect to each significant health need identified through the joint CHNA, either describes how one or more of the collaborating facilities or organizations plan to address the health need or identifies the health need as one the collaborating facilities or organizations do not intend to address and explains why they do not intend to address the health need. Each collaborating hospital must ensure that the joint implementation strategy adopted:

1. Is clearly identified as applying to the hospital;
2. Clearly identifies the hospital's particular role and responsibilities in taking the actions described in the implementation strategy and the resources the hospital plans to commit to such actions; and
3. Includes a summary or other tool that helps the reader easily locate those portions of the joint implementation strategy that relate to the hospital.

Reporting

Section 6033(b)(15)(A) of the Internal Revenue Code, which was enacted pursuant to the ACA, requires a hospital organization to report annually on its IRS Form 990 a description of how the organization is addressing the needs identified in each CHNA and a description of

any needs that are not being addressed, together with the reasons why the needs are not being addressed.

Penalties

The IRS has the authority to audit nonprofit hospitals for compliance with federal community benefit laws. Subject to the discussion below, hospitals found out of compliance with the CHNA and implementation strategy requirements may face an excise tax of $50,000, income tax for any year(s) out of compliance, or loss of tax-exempt status. [Treasury Regulations Section 1.501(r)-2; Rev. Proc. 2015-21, 2015-13 I.R.B. 817 (Mar. 30, 2015); Internal Revenue Code Section 4959]

Minor Omissions and Errors Not Considered Failure to Comply

A minor omission or error will not be deemed failure to meet the requirements of IRC Section 501(r) if:

1. Either inadvertent or due to reasonable cause; and
2. The hospital corrects such omission or error as promptly after discovery as is reasonable. Correction must include the establishment (or review and, if necessary, revision) of formal or informal practices or procedures that are reasonably designed to promote compliance with the law.

Multiple omissions or errors are considered minor, only if minor in the aggregate.

Revenue Procedure 2015-21 (which updates and revises Notice 2014-3, a draft revenue procedure issued on Dec. 31, 2013) clarifies that minor omissions and errors, if corrected promptly after discovery, are not considered failures to comply and do not need to be disclosed to the IRS pursuant to the process described below.

Excuse of Other Omissions and Errors Neither Willful Nor Egregious

Other omissions and errors that may not be considered "minor," but are neither willful nor egregious, will be excused if the hospital corrects and discloses the omission or error in accordance with the procedures set forth in Revenue Procedure 2015-21, which includes specific disclosure requirements on the organization's Form 990 for the tax year in which the omission or error is discovered. However, even if such failure is excused the hospital will still be subject to an excise tax for failure to conduct a community health needs assessment as required by Section 501(r)(3).

C. Comparison of State and Federal Requirements for Community Health Needs Assessments and Plans

Appendix FAP 2, "Comparison of California and IRS Requirements for Community Health Needs Assessments and Plans," contains a side-by-side analysis and comparison of certain questions and issues under existing California and federal law related to community benefits.

XIII. TAX-EXEMPT FINANCING CONSIDERATIONS

A. Overview

Nonprofit corporations can borrow money from commercial lenders for corporate purposes just as business corporations do, subject only to any restrictions that may appear in their articles of incorporation or bylaws.

Unlike business corporations, however, nonprofit corporations may also borrow funds on a tax-exempt basis. In the typical hospital tax-exempt financing, a government entity acts as the issuer of the tax-exempt bonds, notes or other obligations and lends the proceeds raised by the sale of the bonds to a nonprofit hospital. The hospital uses the proceeds to acquire capital assets or for other approved purposes. The hospital's loan repayments to the issuer (or to a trustee acting on the issuer's behalf) coincide with the payments made to the holders of the bonds. The hospital may pledge the assets it acquires with the bond proceeds along with other hospital assets to secure the loan repayment obligations and the payment obligations owed to the bondholders. The interest earned on the bonds is generally not included in the bondholders' income for federal or state income tax purposes. As a result, the hospital can obtain financing at generally lower interest rates than it could with non-tax-exempt financing.

A private underwriter helps to structure the financing and, at the closing of the financing transaction, may purchase the bonds for its own interest or, more typically, resell the bonds to other investors. Because of the legal complexities of a tax-exempt financing, several sets of attorneys are usually involved in the transaction. Bond counsel typically drafts the legal documents for the issuer, structures the issuance to qualify for tax-exempt treatment under applicable tax law, and renders a legal opinion as to the tax-exempt status of the bonds.

The underwriter and the hospital usually each have their own legal counsel to represent them in the transaction. The underwriter's counsel oversees the securities law aspects of the transaction, while counsel for the hospital is generally asked to provide a legal opinion as to various organizational, due diligence and other legal matters on behalf of the hospital.

The issuer of the bonds and the trustee may also be represented by their own legal counsel.

Although attorneys with applicable expertise are involved when tax-exempt bonds are issued, there are numerous continuing requirements in connection with such bonds that a nonprofit hospital will need to monitor and consider after the bonds are issued, with the assistance of its professional advisors. The following discussion addresses many of the leading legal and tax issues connected with tax-exempt financing. However, a fundamental requirement for tax-exempt financing involves the continued tax-exempt status of the borrowing organization. Therefore, in addition to those key issues summarized below, the many issues addressed in this chapter relating to maintaining a nonprofit hospital's exempt status are equally applicable for compliance with requirements for tax-exempt bonds. In addition, the borrowing tax-exempt organization will be required to comply with various covenants and restrictions contained in the indenture and documents signed by the organization in connection with the bonds.

B. Continuing Federal Requirements

Limit on Private Business Use

Tax-exempt financing is available only to qualified tax-exempt organizations. Accordingly, financing will not qualify for tax-exempt treatment, or will lose such treatment, if the financing proceeds are used for an impermissible private use.

In order to avoid such adverse treatment, no more than 5 percent of the bond proceeds may be used for private, nonexempt business use.

Management or Service Contracts

Nonprofit hospitals often have contracts with private management companies, physicians or physician groups to provide management or physician services within the hospital. These contracts must be scrutinized to ensure they do not violate the restrictions on private use. Non-compliant contracts may need to be terminated or modified if they would otherwise disqualify a financing from tax-exempt treatment.

Safe harbor guidelines were released by the IRS on Aug. 22, 2016, and were amplified further by the IRS on Feb. 6, 2017 [Revenue Procedures 2016-44 and 2017-13]. The guidance in Revenue Procedure 2017-13 replaces the seven distinct safe harbors set forth by Revenue Procedure 97-13 almost 20 years ago with a single safe harbor encompassing eight criteria that must be satisfied. As with the prior safe harbors, the recent guidelines protect only management and service contracts and functionally related uses (e.g., storage of equipment) but not agreements that could result in private use (e.g., leases).

In the recent guidance, the IRS created a safe harbor for management or service contracts that meet all of the following requirements:

1. **Reasonable compensation.** As was the case under the prior guidance, all compensation must be reasonable for services rendered during the term of the contract. This safe harbor expressly includes reimbursement of expenses and overhead charges as part of a service provider's compensation.
2. **No net profits arrangements.** Contracts are also still subject to the requirement that they cannot award the service provider a share of the net profits from the operations of the property. Compensation will not be treated as a sharing of net profits if no element of the compensation accounts for or is contingent upon the net profits of the property or both revenues and expenses of the property for the same period. This provision continues the ability for qualified users to pay incentives based on metrics that measure quality, performance, or productivity as long as the amount and timing of compensation do not take into account and are not contingent upon the net profits or a combination of revenues and expenses of the property.
3. **No bearing of net operating losses.** Unlike earlier guidance, Revenue Procedures 2016-44 and 2017-13 prohibit the contract from having the substantive effect of shifting liability to the service provider for any portion of net losses from the operation of the property. To meet this safe harbor, the compensation and reimbursement for expenses cannot take into account either the net losses or both the revenues and expenses of the property, nor can the timing of payments be contingent upon the net losses from the property. A contractual reduction in compensation by a stated target dollar amount due to a provider's failure to contractually maintain expenses below a specific target is permitted.
4. **Types of Compensation.** Revenue Procedure 2017-13 specifically states that compensation for services will not be treated as providing a share of net profits or requiring the provider to bear a share of net losses if the compensation is:
    a. Based solely on a capitation fee, a periodic fixed fee, or a per unit fee;
    b. Incentive compensation for meeting metrics that measure quality, performance or productivity (see 2., above), or

c. A combination of the foregoing.

5. **Contract term and termination.** The term of the contract, including all renewal periods, may be no more than the lesser of 30 years or 80 percent of the weighted average reasonably expected economic life of the managed property, with economic life determined as of the beginning of the term of the contract. Note that there are no longer any required early termination provisions for contracts but rather termination may now be optional based on mutual agreement of the parties.

   Note, however, that regardless of this safe harbor guidance from the IRS, Section 1301(e) of Public Law 99-514, The Tax Reform Act of 1986, is an uncodified statute that creates a safe harbor for management contracts and provides that use of tax-exempt bond financed space pursuant to a management contract will not be treated as trade or business use so long as:

   a. The term of the contract, including renewal options, does not exceed five years,

   b. The tax-exempt entity has the option to cancel the contract at the end of any three-year period,

   c. The manager under the contract is not compensated in whole or in part based on net profits, and

   d. At least 50% of the annual compensation of the manager is based on a periodic fixed fee.

   Given that statutes have precedence over administrative guidance, and that only a subsequent act of Congress can alter this statutory safe harbor, a management contract that meets the statutory safe harbor will always be within the safe harbor from private business use, no matter how the IRS modifies its safe harbors.

6. **Control over use of the managed property.** Also new to the guidance is the requirement that the qualified user must be able to demonstrate that it exercises a significant degree of control over the property being used. The control requirement is met if the contract requires the exempt organization to approve the annual budget, capital expenditures, each disposition of related property, rates charged for uses, and the general nature and type of use of the property (e.g., type of services provided). Approval of rates may be shown by expressly approving such rates, or by a general description of the methodology for setting rates (such as requiring that the service provider charge rates that are reasonable and customary as specifically determined by or negotiated with an independent third party, such as an medical insurance company).

7. **Risk of loss of managed property.** The guidance also provides that the qualified user, and not the service provider, must bear the risk of damage or destruction of the property (e.g., loss caused by unforeseeable circumstances beyond the parties' control). The qualified user may insure against this loss and may also impose a penalty upon the service provider for a failure to operate the property according to contractual standards.

8. **Consistent tax positions.** Under the guidelines, the service provider may not take any tax position inconsistent with being a service provider for the property.

For example, the service provider must not take any deduction for depreciation or amortization, claim an investment tax credit, or deduct any payment with respect to the property as rent.

9. **Relationship between the parties.** As in previous guidance, Revenue Procedure 2016-44 restates that the service provider cannot have any role or relationship with the qualified user that would have the effect of substantially limiting the qualified user's ability to exercise its rights under the contract. To meet the safe harbor for this requirement:

    a. The service provider may not have more than 20 percent of the qualified user's board seats (by voting power);

    b. Overlapping board members cannot include the service provider's CEO or chairperson (or equivalent executives); and

    c. The parties cannot have the same CEO.

    The two changes of significance from the independence standard in the prior safe harbors are that the limitations apply not only to the service provider but also to related parties of the service provider, such as for-profit subsidiaries, and it no longer limits the representation of a qualified user on the board of the service provider.

In this guidance, the IRS also recognized a safe harbor for eligible expense reimbursement arrangements. For these purposes, an **"eligible expense reimbursement arrangement"** means a management contract under which the only compensation to the service provider consists of reimbursement of actual and direct expenses paid by the service provider to unrelated parties and reasonable related administrative overhead expenses of the service provider.

Revenue Procedure 2017-13 applies to contracts entered into on or after Jan. 17, 2017, and may be applied to a contract entered into before that date. Prior safe harbors under Revenue Procedure 97-13 as modified by Rev. Proc. 2001-39 and amplified by Notice 2014-67 may be applied to management contracts entered into before Aug. 18, 2017 and that are not materially modified or extended on or after Aug. 18, 2017.

Typically, the legal review of hospital management and service contracts is performed by bond counsel. The review usually takes place in the early stages of the financing transaction so that any necessary remedial action can be taken in timely fashion. However, the hospital must ensure that contracts entered into after the financing transaction has concluded are also compliant.

A copy of Revenue Procedure 2017-13 can be obtained at www.irs.gov/pub/irs-drop/rp-17-13.pdf.

Partnerships

In final regulations issued on Oct. 27, 2015, the IRS included a new rule with respect to the private business use test applied to partnerships, with the intent to "provide flexibility to accommodate public-private partnerships, and to remove barriers to tax-exempt financing of the government's (or 501(c)(3) organization's) portion of the benefit of property used in joint ventures ..." [80 Fed. Reg. 65637, 65641 (Oct. 27, 2015); Treasury Regulations 1.141-1(e), 1.141-3(g)(2)(v)]. Pursuant to the new regulations, a partnership is treated as an aggregate

of its partners, rather than as a separate entity. The amount of private business use by a "nongovernmental person" (or a for-profit entity in a partnership with a 501(c)(3) organization) resulting from the use of property by a partnership is that person's greatest percentage share of any partnership item of income, gain, loss, deduction or credit attributable to the period that the partnership uses the property. As an example, the regulations provide that "if a partnership has a nongovernmental partner and that partner's share of partnership items varies, with the greatest share being 25 percent, then that nongovernmental partner's share of the partnership's use of the property is 25 percent." The regulations thus provide for the possibility of use of tax-exempt financing, to a certain extent, in partnerships.

Limit on Changed Use

When tax-exempt bonds are issued, bond holders typically expect the bonds to retain their tax-exempt status for the life of the bonds.

However, the bonds' exempt status can be adversely affected or lost altogether if there is a change in use of the facilities or other assets financed with the proceeds of the bonds.

For example, if a nonprofit hospital sold its facility to a for-profit owner, any outstanding tax-exempt bonds used to finance the facility would lose their tax-exempt status unless remedial action is promptly taken, including, as of Oct. 27, 2015, remedial action in anticipation of the changed use [80 Fed. Reg. 65637, 65641-42 (Oct. 27, 2015)].

Remedial action may include redemption of the bonds or the prepayment and replacement of the borrower's payments and obligations with a government security or other instrument with the same yield (i.e., defeasance). Typically, a defeasance is a more costly method of prepayment of the bonds within a required time period, spending cash proceeds resulting from the change in use within two years following the sale in a manner consistent with tax-exempt bond uses, or agreeing with the IRS to make a payment to the federal government.

Any proposed or anticipated change in the use of facilities or other assets financed with tax-exempt bonds should be planned well in advance with bond counsel in order to avoid potentially serious problems.

Arbitrage and Related Reporting Requirements

The basic purpose of tax-exempt financing is to give exempt organizations an attractive means of financing their capital needs. The purpose is not to provide such organizations with a vehicle to arbitrage the financial markets; that is, to borrow money at lower tax-exempt interest rates and invest the money in higher yielding non-exempt obligations. Accordingly, bonds characterized as arbitrage bonds do not qualify for tax-exempt status.

An **"arbitrage bond"** is any bond that is issued as part of a bond issue, any portion of the proceeds of which are reasonably expected, at the time of the issuance of the bond, to be used, directly or indirectly, to acquire higher yielding investments or to replace funds which were used directly or indirectly to acquire higher yielding investments. [Internal Revenue Code Section 148(a)]

The arbitrage rules and calculations are complex. Generally, at the time of issuance of tax-exempt bonds the borrowing hospital must represent and promise that it will not engage in arbitrage. The borrower is typically subject to ongoing arbitrage reporting requirements to the IRS and the bond trustee, providing calculations demonstrating that no arbitrage profit has been earned or, if such profit has been earned, the amount of such profit. The borrower must generally rebate to the federal government any arbitrage profit earned.

Document Retention

The IRS has issued an informational paper addressing document retention and guidance on other topics related to tax-exempt financing. The paper, entitled "After the Bonds Are Issued: Then What," is available on the IRS website at www.irs.gov/pub/irs-tege/bonds_act_0607.pdf.

The guidance notes that Section 1.6001-1(e) of the Treasury Regulations provides that records should be retained for as long as the contents are material to the administration of any internal revenue law.

With respect to a tax-exempt bond transaction, the information contained in certain records support the exclusion from gross income taken at the bondholder level for both past and future tax years. Therefore, as long as the bondholders are excluding from gross income the interest received on account of their ownership of the tax-exempt bonds, certain bond records will be material. Similarly, in a financing arrangement involving the use of a government or other qualified agency to issue bonds, in its name, for the benefit of the nonprofit organization (as the ultimate borrower) (i.e., conduit financing), the information contained in the bond records is necessary to support the interest deduction taken by the conduit borrower for both past and future tax years for its payment of interest on the bonds.

To support these tax positions, material records should generally be kept for as long as the bonds are outstanding, plus three years after the final redemption date of the bonds. This rule is consistent with the specific record retention requirements under Section 1.148-5(d)(6)(iii)(E) of the Treasury Regulations concerning arbitrage.

C. California Requirements

California law may also affect hospital tax-exempt bond financing. For example, Government Code Sections 15459-15459.4 require that, as a condition of the issuance of revenue bonds to finance a health facility by the California Health Facilities Financing Authority (CHFFA), or any local governmental agency, the borrower must give reasonable assurance to CHFFA that the services of the health facility will be made available to all persons residing or employed in the area served by the facility.

As part of this assurance, the borrower must agree to take certain actions, including:

1. Advising patients of their potential eligibility for Medi-Cal and Medicare benefits or benefits from other governmental third-party payers;
2. Making available to CHFFA and the public a list of physicians with staff privileges at the borrower's facility which includes each physician's name, specialty, language spoken, business address and phone number and whether the physician takes Medi-Cal and Medicare patients;
3. Periodically informing practitioners with staff privileges, in writing, of the facility's community service obligation in a prescribed form; and
4. Posting appropriately multilingual notices in a prescribed form in appropriate areas within the facility, including without limitation admissions offices, emergency rooms, and business offices (with copies for posting in the county welfare office) advising of the facility's agreement to make its services available to all persons residing or employed in the facility's service area.

The hospital must make available to CHFFA, and to the public upon request, an annual report substantiating compliance with these requirements. The annual report must include by category for inpatient and emergency admissions and for any separate identifiable outpatient service:

1. The total number of Medicare, Medi-Cal and all patients receiving services;
2. The dollar volume of services provided to each such patient category; and
3. The total number of patients who had no financial sponsor at the time of service.

The report must also include any other information CHFFA may reasonably require.

Among other remedies, CHFFA may refer a violation of these requirements to the California Attorney General for appropriate legal action.

D. Common Continuing Contractual Restrictions

A tax-exempt financing will typically obligate the borrower to both affirmative and negative covenants.

On the affirmative side, a borrower will typically be obligated, among other things, to maintain its legal existence in good standing, its properties and assets, and its operating licenses and permits and payment eligibility under government reimbursement programs. It must also promise to make payments in accordance with the bond payment schedule, to pledge specified assets as security for performance of its payment and other obligations, to maintain appropriate records and make required reports, and to comply with required debt ratios and other financial tests.

On the negative side, a borrower will typically be required, among other things, not to transfer or encumber assets or incur indebtedness beyond specified limits, not to merge with, or be acquired by, another entity without consent and an approving opinion of bond counsel, and not to take any actions that might jeopardize the tax-exempt status of the bonds.

XIV. CALIFORNIA PROPERTY TAX EXEMPTION

A. Overview

California exempts from property taxation certain property used exclusively for hospital and other specific purposes (the "Welfare Exemption"). The Welfare Exemption exempts eligible property from property taxes only; it does not exempt eligible property from special assessments for local improvements. If the owner of the property meets the requirements discussed below, the property may be exempt from property taxes under the Welfare Exemption. The Welfare Exemption is co-administered by the county assessor and the California State Board of Equalization. [Revenue and Taxation Code Section 214]

B. Welfare Exemption Requirements

Qualifying Organization

The owner of the property cannot be organized or operated for profit and must be qualified as a tax-exempt organization under Revenue and Taxation Code Section 23701(d) or Internal Revenue Code Section 501(c)(3) [Revenue and Taxation Code Section 214]. Property owned by a qualifying hospital but leased to a taxable party will not qualify for tax exemption.

No part of the net earnings of the owner may inure to the benefit of any private shareholder or individual. However, in the case of a hospital, the organization shall not be deemed to be organized or operated for profit if, during the immediately preceding fiscal year, operating revenues, exclusive of gifts, endowments and grants-in-aid, did not exceed the operating expenses by an amount equivalent to 10 percent of those operating expenses. Operating expenses include depreciation based on cost of replacement and amortization of, and interest on, indebtedness [Revenue and Taxation Code Section 214].

Qualifying Purpose

The property must be irrevocably dedicated to hospital, religious, charitable, or scientific purposes. Upon the liquidation, dissolution or abandonment of the owner, the property may not inure to the benefit of any private person except a fund, foundation or corporation organized and operated for hospital, religious, scientific or charitable purposes.

A proper statement of irrevocable dedication to hospital, religious, charitable, or scientific purposes must be included in the organization's articles of incorporation to qualify for the Welfare Exemption. In addition, the organization's articles must contain a "dissolution clause" stating that upon dissolution of the organization, its property will be distributed to an organization organized and operated exclusively for hospital, religious, charitable, or scientific purposes within the meaning of Revenue and Taxation Code Section 214. In the case of any other fund, foundation, limited liability company or corporation chartered by an act of Congress, the irrevocable dedication clause and dissolution clause must be contained in the bylaws, articles of association, articles of organization, constitution or regulations of the organization.

Exclusive Use

The property must be used for the actual operation of the exempt activity, and cannot exceed an amount of property reasonably necessary to accomplish the exempt purpose. It is not sufficient for the property to be intended to be used for the exempt purpose, it must actually be used for such purpose. The property cannot be used or operated by the owner or any other person so as to benefit any officer, trustee, director, shareholder, member, employee, contributor, or bondholder of the owner or operator, or any other person, through the distribution of profits, payment of excessive charges or compensations or the more advantageous pursuit of their business or profession.

The nonprofit hospital property must be used exclusively for hospital purposes to qualify for the Welfare Exemption. It has been held, however, that property used exclusively for hospital purposes should include any property used exclusively for any facility that is incidental to, or reasonably necessary for, the accomplishment of the hospital purposes. In addition, certain occasional uses for non-qualifying purposes may be permitted without compromising the property tax exemption.

The fact that licensed physicians use the hospital to practice their profession or receive fees or other lawful compensation to practice their profession in the hospital does not disqualify the hospital from the Welfare Exemption. However, the Welfare Exemption is not available to any portion of the hospital that is leased to a physician for his or her use as an office for general practice. [Revenue and Taxation Code Sections 214.7-9]

C. Filing Requirements

A nonprofit hospital must file claims for the Welfare Exemption by February 15 of each year with the assessor. The assessor reviews all claims for the Welfare Exemption to ascertain whether the requirements of Revenue and Taxation Code Section 214 are met. [Revenue and Taxation Code Section 254.5(b)(1)] The forms for claiming the Welfare Exemption should be available on each county assessor's website or by calling the county assessor's office.

In addition, the qualifying organization must file with the Board of Equalization a claim for an organizational clearance certificate. The assessor may not approve a Welfare Exemption claim until the claimant has been issued a valid organizational clearance certificate from the Board of Equalization. The forms to request an organization clearance certificate are available on the Board of Equalization's website at www.boe.ca.gov/proptaxes/welfareorgreq.htm.

An initial claim for an organizational clearance certificate under the Welfare Exemption can be filed on a Form BOE-277. In addition, a first-time claim must be accompanied by a description of the activities conducted by the organization, as well as the following documents:

1. A certified copy of the financial statements of the organization.
2. A certified copy of the articles of organization and any amendment thereto (including the irrevocable dedication clause and the dissolution clause), or in the case of any noncorporate fund or foundation, its bylaws, articles of association, constitution, or regulations and any amendments thereto.
3. A copy of a valid, unrevoked letter or ruling from the California Franchise Tax Board or the Internal Revenue Service stating that the organization qualifies as an exempt organization.

In addition to the initial request for an organization clearance certificate, the organization is required to complete BOE-278-OCC upon request of the Board of Equalization, to verify whether the organization continues to qualify for exemption. The Board of Equalization has developed guidance regarding completion of the forms for the Welfare Exemption. The guidance is available at https://www.boe.ca.gov/proptaxes/pdf/pub149.pdf.

APPENDIX HC 9-B

Summary of Significant Factors Determining the Permissibility of Participation in Partnership

ISSUES	POSITIVE FACTORS	NEGATIVE FACTORS
Purpose of the Partnership Does the partnership agreement expressly state that the partnership has a charitable purpose and that the charitable purpose will take precedence over all other concerns, including profit motives, where conflicting interests arise?	Express charitable purpose and charitable override in the partnership agreement.	No express charitable purpose and no charitable override in the partnership agreement.
Voting Power Does the partnership agreement give a nonprofit or the for-profit a majority vote in the partnership's board of directors?	A nonprofit controls a majority of the votes on the board.	The for-profit controls a majority of the votes on the board, or alternatively, there is a 50-50 split of nonprofit and for-profit controlled votes on the board.

(over)

ISSUES	POSITIVE FACTORS	NEGATIVE FACTORS
Other Assurances or Indicia of Control Which partner can initiate significant actions? Which partner can block such actions? What are those actions from the standpoint of advancing nonprofit or for-profit interests? Which partner has the right to select the chairman of the board and to set the board's agenda? Does the chair have the power to break a tie vote? Are there clauses in the foundational documents providing for dilution of nonprofit control if a nonprofit's shares of ownership fall below a certain share? Is there evidence that partnership decisions are being referred to the for-profit partners for approval?	A nonprofit can initiate actions in furtherance of its charitable purpose and can block actions in furtherance of any for-profit purpose or actions with any potential for private inurement or private benefit; A nonprofit has the right to select the chairman of the board and to set the board agenda; A nonprofit-appointed chair has the power to break a tie vote; A nonprofit retains its control despite any possible dilution of its ownership share; The partnership is independent of any informal control by the for-profit partner.	A nonprofit cannot initiate actions in furtherance of its charitable purpose and cannot block actions in furtherance of any for-profit purpose or actions with any potential for private inurement or private benefit; A nonprofit does not have the right to select the chairman of the board and to set the board agenda; The chair is appointed by the for-profit, or is appointed by a nonprofit but has no right to break a tie vote; A nonprofit loses control with dilution of its ownership share; There is evidence that partnership decisions are being referred to the for-profit partner for approval.
Influence of and Control Over the Manager and Executives Is the partnership managed by a company that is owned or affiliated with the for-profit or nonprofit partner? Is the entity employing the executives of a company which is owned or affiliated with the for-profit or nonprofit partner?	The management company is affiliated with a nonprofit partner or is an independent nonprofit; The entity employing the executives is affiliated with a nonprofit partner or is an independent nonprofit.	The management company is affiliated with the for-profit partner or is an independent for-profit; The entity employing the executives is affiliated with the for-profit partner or is an independent for-profit.

ISSUES	POSITIVE FACTORS	NEGATIVE FACTORS
Right to Terminate Manager or Executives for Violation of Non-Profit Duties Does a nonprofit have the right to unilaterally terminate the manager or the executives if the manager or executives default on their nonprofit duties?	A nonprofit has the right to unilaterally terminate the manager or the executives if the manager or executives default on their nonprofit duties.	A nonprofit does not have the right to unilaterally terminate the manager or the executives if the manager or executives default on their nonprofit duties.
Right of Dissolution Does a nonprofit have the right to dissolve the partnership if participation in the partnership will hinder its tax-exempt status?	A nonprofit has the right to dissolve the partnership if participation in the partnership will hinder its tax-exempt status.	A nonprofit does not have the right to dissolve the partnership if participation in the partnership will hinder its tax-exempt status.
Alternative Dispute Resolution Clause Do the conflict resolution provisions of the partnership agreement require precedence of exempt purposes over business purposes in any mediation or arbitration?	The conflict resolution provisions of the partnership agreement requires precedence of exempt purposes over business purposes in any mediation or arbitration.	The conflict resolution provisions of the partnership agreement does not require precedence of exempt purposes over business purposes in any mediation or arbitration.
Duties of Manager Does the management agreement expressly bind the manager to a charitable purpose duty?	The management agreement binds the manager to an express duty to serve the charitable purpose.	The management agreement does not bind the manager to an express duty to serve the charitable purpose; There is such a clause, but the manager appears to primarily serve a for-profit purpose.

ISSUES	POSITIVE FACTORS	NEGATIVE FACTORS
Control Over Partnership Distributions Are distributions expressly or effectively controlled by the for-profit or nonprofit partner? Is a preference given to distributions to cover the tax liabilities of the for-profit partners?	Decisions over distributions are either joint or are expressly or effectively controlled by a nonprofit partner; There is no preference given to distributions to cover the tax liabilities of the for-profit partners.	Decisions over distributions are expressly or effectively controlled by the for-profit partner; There is a preference given to distributions to cover the tax liabilities of the for-profit partners.
Capital Contributions Does a nonprofit partner (or its subsidiary) or the for-profit partner (or its subsidiary) have the right to request that all of the partners make additional capital contributions? Do the for-profit partners have the right to make capital contributions when nonprofit partners do not, thereby diluting nonprofit partners' share percentage?	A nonprofit partner or its subsidiary has the right to request that all of the partners make additional capital contributions. The for-profit partners do not have the right to make capital contributions and dilute nonprofit partner's share when nonprofit partners do not.	The for-profit partner or its subsidiary has the right to request that all of the partners make additional capital contributions. The for-profit partners have the right to make capital contributions and dilute a nonprofit partner's share when a nonprofit partners do not.
Individual Ownership Interests Do the foundational documents permit ownership interest to be sold to individuals, including physicians and management-level employees?	Individual ownership of interest by physicians and management-level employees is permitted.	Individual ownership of interest by physicians and management-level employees is not permitted.

ISSUES	POSITIVE FACTORS	NEGATIVE FACTORS
Employees Are the executives employed by the for-profit partner (or its subsidiary) or a nonprofit partner (or its subsidiary)? Are said executives provided with an incentive compensation plan based on profitability? Are the remaining employees of the partnership employed by the for-profit or nonprofit partner, and is there proper distinction, accounting and reimbursement of hours worked on behalf of the for-profit and the partnership?	The executives are employed by a nonprofit partner, its subsidiary or an independent nonprofit; The executives have no incentive compensation plan based on profitability; The remaining employees are employed by a nonprofit, its subsidiary or an independent nonprofit; There is proper distinction, accounting and reimbursement of hours worked on behalf of the for-profit and the partnership.	The executives are employed by the for-profit partner, its subsidiary or an independent for-profit; The executives have an incentive compensation plan based on profitability; The remaining employees are employed by the for-profit; there is no proper distinction, accounting and reimbursement of hours worked on behalf of the for-profit and the partnership.
Symmetry or Asymmetry of Non-Compete Clauses Do the non-competition clauses create equal barriers to competition by the parties? If they do not, are the nonprofit or the for-profit activities advantaged?	The non-competition clauses are equally restrictive on the partners or are less restrictive of competing activities by a nonprofit partner.	The non-competition clauses are less restrictive of competing activities by the for-profit partner.
Branding Campaign Does the partnership involve a for-profit brand-name recognition campaign paid for by the partnership?	There is no for-profit brand name recognition campaign; if there is a campaign, it is financed strictly by the for-profit partners.	There is a for-profit brand name recognition campaign financed by the partnership.
Business Plans Do the partnership's business plans adopt a nonprofit partner's or the for-profit partner's goals and strategies, and with what apparent intent?	Business plans adopt nonprofit partner's goals and strategies, apparently with a nonprofit intent.	Business plans adopt for-profit partner's goals and strategies, apparently with a for-profit intent.

ISSUES	POSITIVE FACTORS	NEGATIVE FACTORS
Partnership Law Conflict Is there a conflict or a potential conflict between the charitable purpose provision of the foundational documents and state law, which may or may not define a partnership as a "for-profit" entity?	There is no conflict between the charitable purpose provision of the foundational documents and state law.	There is a conflict or a potential conflict between the charitable purpose provision of the foundational documents and state law.
State Law Override Does the confluence of applicable state law and the presence or absence of a particular charitable override provision increase or decrease the likelihood that a charitable purpose provision of the foundational documents would be enforced over any duties (especially fiduciary duties to the for-profit partners) imposed by state law?	There is a high likelihood that a charitable purpose provision of the foundational documents would be enforced over any duties imposed by state law.	There is a low likelihood that a charitable purpose provision of the foundational documents would be enforced over any duties imposed by state law.

ISSUES	POSITIVE FACTORS	NEGATIVE FACTORS
Charity Care Is there sufficient tracking and accounting of indigent care after the formation of the partnership? Are there structural incentives for limiting charity care (i.e. executive compensation plans mandating that debts and charity care must be maintained with less than 1% negative variance from budget)? Is the net effect of the partnership or joint venture the increase or the reduction or elimination of certain charity and community services previously provided by a nonprofit?	There is sufficient tracking and accounting of indigent care after the formation of the partnership; There are no structural incentives for limiting charity care; and The net effect of the partnership or joint venture is the increase of charity and community services from those previously provided by a nonprofit.	There is insufficient tracking and accounting of indigent care after the formation of the partnership; There are structural incentives for limiting charity care; and the net effect of the partnership or joint venture is the reduction or elimination of charity and community services from those previously provided by a nonprofit.

APPENDIX FAP 2

Comparison of California and IRS Requirements for Community Health Needs Assessments and Plans

(1) What should be included in community benefit plans?

CALIFORNIA	IRS
The community benefit plan report must include, but need not be limited to, the following: • A description of the activities that the hospital has undertaken to address the identified community needs within its mission and financial capacity; • The process by which the hospital developed the plan in consultation with the community. Health and Safety Code Section 127345(a) **"Community benefit"** means a hospital's activities that are intended to address community needs and priorities primarily through prevention and improvement of health status, including, without limitation, the following: • Health care services, rendered to vulnerable populations, including, but not limited to, charity care and the unreimbursed cost of providing services to the uninsured, underinsured, and those eligible under state health programs, or county indigent programs. • Unreimbursed cost for certain community health services. • Financial or in-kind support of public health programs. • Donation of funds, property, or other resources that contribute to a community priority. • Health care cost containment. • Enhancement of access to health care or related services that contribute to a healthier community. • Services offered without regard to financial return because they meet a community need in the service area of the hospital, and other services including health promotion, health education, prevention, and social services. • Food, shelter, clothing, education, transportation, and other goods or services that help maintain a person's health. "Community benefit" does not mean activities or programs that are provided primarily for marketing purposes or are more beneficial to the organization than to the community. Health and Safety Code Section 127345(d) *(continued on next page)*	Internal Revenue Code Section 501(r) does not have specific requirements regarding preparation of a "community benefit plan." Although a specific community benefit plan is not required, final regulations published on December 31, 2014 [79 Fed. Red. 78954 (Dec. 31, 2014] (the Final Regulations) require the hospital to adopt a written "implementation strategy" to meet the community health needs identified in the Community Health Needs Assessment (CHNA). The differences between the two are described in this chart and in the manual. Section 1.501(r)–3(c) (all references are to Title 26 of the Code of Federal Regulations, unless otherwise stated)

(1) What should be included in community benefit plans? *(continued)*

CALIFORNIA	IRS
Community benefit plans should include the following: 1. Mechanisms to evaluate the plan's effectiveness including, but not limited to, a method for soliciting the views of the community served by the hospital and identification of community groups and local government officials consulted during the development of the plan. 2. Measurable objectives to be achieved within specified time frames. 3. Community benefits categorized into the following framework: a. Medical care services. b. Other benefits for vulnerable populations. c. Other benefits for the broader community. d. Health research, education, and training programs. e. Nonquantifiable benefits. Health and Safety Code Section 127355. The community benefit plan must assign and report the economic value of community benefits provided in furtherance of its plan, and include a description of how needs identified in the assessment are being addressed and which needs are not being addressed, and why. Health and Safety Code Section 127350(d)	

(2) What is required of a community health needs assessment?

CALIFORNIA	IRS
The community needs assessment is the process by which the hospital identifies, for its service area, unmet community needs for improvement and maintenance of health status of the community. Health and Safety Code Section 127345(d)-(e)	In completing its CHNA, the hospital must complete the following steps: • Define the community it serves; • Assess the health needs of that community; • In assessing the health needs of the community, solicit and take into account input received from persons who represent the broad interests of that community, including those with special knowledge of or expertise in public health; • Document the CHNA in a written report ("CHNA report") that is adopted for the hospital facility by an authorized body of the hospital facility; and • Make the CHNA report widely available to the public. Section 1.501(r)–3(b)(1)(i)-(v) To assess the health needs of the community a hospital serves, a hospital must identify significant health needs of the community, prioritize those health needs, and identify resources (such as organizations, facilities, and programs in the community) potentially available to address those health needs. The health needs of a community should include requisites for the improvement or maintenance of health status in both the community at large and in particular parts of the community (such as particular neighborhoods or populations experiencing health disparities). In determining whether a health need is significant, the hospital facility may consider all of the facts and circumstances present in the community it serves. A hospital facility may use any criteria to prioritize the significant health needs it identifies, including, but not limited to, the burden, scope, severity, or urgency of the health need; the estimated feasibility and effectiveness of possible interventions; the health disparities associated with the need; or the importance the community places on addressing the need. Section 1.501(r)–3(b)(4) *(continued on next page)*

(2) What is required of a community health needs assessment? *(continued)*

CALIFORNIA	IRS
	In order to be considered to take into account the broad interests of the community it serves (including those with special knowledge of or expertise in public health), the hospital must solicit and take into account input received from all of the following: • At least one state, local, tribal, or regional governmental public health department (or equivalent department or agency), or a State Office of Rural Health, with knowledge, information, or expertise relevant to the health needs of that community; • Members of medically underserved, low-income, and minority populations in the community served by the hospital facility, or individuals or organizations serving or representing the interests of such populations • Written comments received on the hospital facility's most recently conducted CHNA and most recently adopted implementation strategy; and • The hospital facility may also solicit and take into account input received from a broad range of other persons located in or serving its community. Section 1.501(r)–3(b)(5) The CHNA report must include the following: • A definition of the community served by the hospital facility and a description of how it was determined; • A description of the process and methods used to conduct the CHNA; • A description of how the hospital facility solicited and took into account input received from persons who represent the broad interests of the community it serves; • A prioritized description of the significant identified health needs of the community identified through the CHNA, along with a description of the process and criteria used in identifying certain health needs as significant and prioritizing those significant health needs; • A description of the resources potentially available to address the significant health needs identified through the CHNA; and • An evaluation of the impact of any actions that were taken, since the hospital facility finished conducting its immediately preceding CHNA, to address the significant health needs identified in the hospital facility's prior CHNA(s). Section 1.501(r)–3(b)(6)(i)(A)-(F)

(3) How often must community benefit plans and community health needs assessments be updated?

CALIFORNIA	IRS
Community benefit plans must be adopted and updated on an annual basis. Health and Safety Code Section 127350(c) The community needs assessment must be updated at least once every three years. Health and Safety Code Section 127350(b) OSHPD may grant an automatic 60-day extension to a hospital. Health and Safety Code Section 127346(b)	A CHNA will meet applicable timing requirements if it is conducted in the current taxable year or in either of two taxable years immediately preceding such taxable year (i.e., the CHNA must be conducted once every three years). Section 1.501(r)–3(a)(1)

(4) May the hospital complete its community health needs assessment in conjunction with other organizations?

CALIFORNIA	IRS
Yes. A hospital may complete its community health needs assessment either alone, or in conjunction with other health care providers, or through other organizational arrangements. Health and Safety Code Section 127350(b)	Yes, under limited circumstances. • A hospital facility that collaborates with other hospital facilities or other organizations (such as state or local public health departments) in conducting its CHNA will satisfy the applicable requirements if an authorized body of the hospital facility adopts for the hospital facility a joint CHNA report produced for the hospital facility and one or more of the collaborating facilities and organizations, provided that the joint CHNA report has all required contents of a separate CHNA report, is clearly identified as applying to the hospital facility, and all of the collaborating hospital facilities and organizations included in the joint CHNA report define their community to be the same. Section 1.501(r)–3(b)(6)(v) In addition, portions of separate CHNA reports may be substantively identical to portions of a collaborating hospital facility or other organization conducting a CHNA, if appropriate under the facts and circumstances. Section 1.501(r)-3(b)(6)(iv)

(5) Are updates of the community health needs assessment sufficient or is an entirely new community health needs assessment required?

CALIFORNIA	IRS
Yes. Health and Safety Code Section 127350(b) provides that the "community needs assessment shall be updated at least once every three years."	No. The Final Regulations do not provide for updated CHNAs. However, the IRS expects that, in conducting CHNAs, hospital facilities will build upon previously-conducted CHNAs. 79 Fed. Reg. 78954, 78962 (Dec. 31, 2014)

(6) What are the requirements for approving the report?

CALIFORNIA	IRS
There are no specific requirements for approving the reports.	An authorized body of the hospital must adopt the CHNA and the implementation strategy. Sections 1.501(r)–3(a)(2) and 1.501(r)–3(b)(1)(iv) **"Authorized body"** is defined to include: • The governing body (that is, the board of directors, board of trustees, or equivalent controlling body) of the hospital organization that operates the hospital facility, or a committee of, or other party authorized by, that governing body to the extent such committee or other party is permitted under state law to act on behalf of the governing body; or • Is the governing body of an entity that is disregarded or treated as a partnership for federal tax purposes that operates the hospital facility or a committee of, or other party authorized by, that governing body to the extent such committee or other party is permitted under state law to act on behalf of the governing body. Section 1.501(r)–1(b)(4)(i)-(ii)

(7) What are the implementation requirements?

CALIFORNIA	IRS
There are no specific implementation requirements, but the community benefits plan should include mechanisms to evaluate the plan's effectiveness and measurable objectives within specific time frames. Health and Safety Code Section 127355(a)-(b) The community benefits plan must also include a report of activities that the hospital has taken to meet community needs. The community benefits plan must be posted on the hospital's internet website annually. Health and Safety Code Section 127350(d)	The implementation strategy should describe how the hospital plans to address the health need or identify the health need as one that the hospital does not intend to address and explain why not. Section 1.501(r)–3(c)(1)(i)-(ii) In describing how a hospital plans to address an identified significant health need, the implementation strategy must describe the actions the hospital intends to take to address the health need and the anticipated impact of these actions. The implementation strategy must also identify the resources the hospital plans to commit to address the health need and must describe any planned collaboration between the hospital facility and other facilities or organizations in addressing the health need. Section 1.501(r)–3(c)(2) In explaining why a hospital facility does not intend to address a significant health need, a brief explanation of the reason is sufficient. For example, reasons could include resource constraints or lack of expertise to effectively address the need. Section 1.501(r)-(3)(c)(3)

(8) How is the relevant community defined?

CALIFORNIA	IRS
"Community" is not precisely defined and provides latitude to the hospital in setting the relevant community. In particular, under Health and Safety Code Section 127345(b), "**'Community'** means the service areas or patient populations for which the hospital provides health care services."	The Final Regulations provide a somewhat complex, nuanced definition for "community." • In defining the community a hospital serves, a hospital may take into account all of the relevant facts and circumstances, including the geographic area served by the hospital, target population(s) served (for example, children, women, or the aged), and principal functions (for example, focus on a particular specialty area or targeted disease). However, a hospital facility may not define its community to exclude medically underserved, low-income, or minority populations live in geographic areas from which the hospital facility draws its patients (unless such populations are not part of the hospital facility's target patient population(s) or affected by its principal functions) or otherwise should be included based on the method the hospital facility uses to define its community. In addition, in determining its patient populations for purposes of defining its community, the hospital facility must take into account all patients without regard to whether (or how much) they or their insurers pay for the care received or whether they are eligible for assistance under the hospital facility's financial assistance policy. • Also, if a hospital facility consists of multiple buildings that operate under a single state license and serve different geographic areas or populations, the community served by the hospital facility is the aggregate of such areas or populations. Section 1.501(r)–3(b)(3)

(9) Are any tax-exempt private nonprofit hospitals exempt from these requirements?

CALIFORNIA	IRS
Yes. The following tax-exempt hospitals are exempt from the requirements: • Hospitals that are dedicated to serving children and that do not receive direct payment for services to any patient. • Certain small and rural hospitals, unless the hospital is part of a hospital system. • District hospitals or nonprofit corporations affiliated with a district hospital owner by means of the district's status as the nonprofit corporation's sole corporate member. Health and Safety Code Section 127345(f)(1)-(2) Public hospitals, including county, health care districts and University of California hospitals are also exempt, as are chemical dependency recovery hospitals.	As a general matter, no. All hospitals exempt from taxation under Section 501(c)(3) that are required to be licensed by the state or similarly recognized must comply with the CHNA requirements. Multiple buildings operated under a single state license are considered to be a single hospital facility. Section 1.501(r)–1(b)(17)

(10) Are systemwide reports permitted?

CALIFORNIA	IRS
Yes. Hospitals under common control of a single entity may file a consolidated report if the report includes each hospital's community benefit financial data and describes the benefits provided to the communities in the hospitals' geographic area. Health and Safety Code Section 127350(d)	Generally, each hospital facility must prepare its own CHNA report, although joint reports are permitted under certain circumstances. *(See answer to question number 5.)*

(11) What are the requirements for making the reports and related information publicly available?

CALIFORNIA	IRS
Hospitals are required to post their community benefit plans annually on their website. Health and Safety Code Section 127350(e) In addition, OSHPD makes the reports available to the public on its website.	A hospital must make its CHNA report widely available on a website that meets certain specifications, at least until the date the hospital facility has made widely available on a website its two subsequent CHNA reports; and make a paper copy of the CHNA report available for public inspection upon request and without charge at the hospital for the same timeframe. Section 1.501(r)–3(b)(7)(i)(A)-(B)

(12) What are the requirements for reporting to an agency?

CALIFORNIA	IRS
The community benefit plan must be filed with OSHPD within 150 days after the end of the hospital's fiscal year. Health and Safety Code Section 127350(d)	With respect to the hospital's IRS Form 990 (Return for Organization Exempt from Income Tax), the hospital organization must include either a copy of the most recently adopted implementation strategy for each hospital facility it operates, or the URL of each web page on which it has made each such implementation strategy available along with (or as part of) the CHNA to which the implementation strategy relates; for each hospital facility it operates, a description of the actions taken during the taxable year to address the significant health needs identified through its most recently conducted CHNA, or, if no actions were taken with respect to one or more of these health needs, the reason(s) why no actions were taken; and the amount of the excise tax imposed on the organization under IRS Section 4959 during the taxable year. Section 1.6033–2(a)(2)(ii)(l)(2)-(4)

(13) What are the penalties for failure to satisfy the requirements of each applicable law?

CALIFORNIA	IRS
OSHPD may impose a fine of up to $5000 for failure to adopt, update, or submit a community benefit plan. Health and Safety Code Section 127346(a)	Failure to meet the obligations under Internal Revenue Code Section 501(r) may result in revocation of tax exempt status or imposition of taxes on income for the taxable year or years when the hospital facility was a non-compliant facility. Section 1.501(r)-2(a)-(d)) In determining whether revocation of exemption is appropriate, the IRS will consider all relevant facts and circumstances, including, but not limited to the following: • Whether the organization has previously failed to meet the requirements of Section 501(r), and, if so, whether the same type of failure previously occurred; • The size, scope, nature, and significance of the organization's failure(s); • In the case of an organization that operates more than one hospital facility, the number, size, and significance of the facilities that have failed to meet the applicable requirements relative to those that have complied with these requirements; • The reason for the failure(s); • Whether the organization had, prior to the failure(s), established practices and procedures (formal or informal) reasonably designed to promote and facilitate overall compliance with the requirements; • Whether the practices or procedures had been routinely followed and the failure(s) occurred through an oversight or mistake in applying them; • Whether the organization has implemented safeguards that are reasonably calculated to prevent similar failures from occurring in the future; • Whether the organization corrected the failure(s) as promptly after discovery as is reasonable given the nature of the failure(s); and • Whether the organization took measures to implement safeguards to prevent similar failures and correct the failures promptly after discovery and before the IRS discovered the failure(s). Section 1.501(r)–2(a)(1)-(9) The Final Regulations also provide latitude for certain minor or inadvertent omissions and errors that are corrected and allows certain failures to be excused if the hospital corrects and discloses the failures, provided the failures are not willful or egregious. Section 1.501(r)–2(b)-(c); Rev. Proc. 2015-21 *(continued on next page)*

(13) What are the penalties for failure to satisfy the requirements of each applicable law? *(continued)*

CALIFORNIA	IRS
	In addition to the penalties discussed above, if a hospital organization fails to meet the CHNA requirements separately with respect to a hospital facility it operates in any taxable year, the IRS will impose a tax of $50,000. If a hospital organization operates multiple hospital facilities and fails to meet the CHNA with respect to more than one facility it operates, the $50,000 tax is imposed for each hospital facility's failure. The tax is imposed for each taxable year that a hospital facility fails to meet the requirements of Section 501(r)(3). Section 53.4959–1(a)

(14) Law and guidance regarding impact of state laws

CALIFORNIA	IRS
	Although the IRS has recognized that similar state law analogs exist to which a hospital may wish to draw upon, the Final Regulations do not contain any provisions equating compliance with one or more requirements in applicable state law to compliance with one or more of the requirements of the Final Regulations. Moreover, the IRS explained that the Final Regulations are not intended to preempt any state laws or regulations, and that it expects that any additional or stricter requirements under a state's laws or regulations will continue to apply to hospital facilities licensed in that state. 79 Fed. Reg. 78954, 78994 (Dec. 31, 2014)

(15) Effective dates for each applicable law

CALIFORNIA	IRS
The law was effective Jan. 1, 1995. Hospitals had to conduct a community needs assessment every three years, beginning in 1995, and develop and adopt a community benefits plan by April 1996.	Hospital organizations should note that the statutory effective date for the CHNA requirements is a hospital organization's first taxable year beginning after March 23, 2012. However, the Final Regulations apply to a hospital facility's taxable years beginning after Dec. 29, 2015. For taxable years prior to Dec. 29, 2015, a hospital facility may rely on a reasonable, good faith interpretation of Section 501(r). A hospital facility will be deemed to have operated in accordance with a reasonable, good faith interpretation of Section 501(r) if it has complied with the provisions of proposed regulations published on June 26, 2012 [77 Fed. Reg. 38148 (June 26, 2012)] and/or the proposed regulations published on April 5, 2013 [78 Fed. Reg. 20523 (April 5, 2013)] or the Final Regulations. 79 Fed. Reg. 78954, 78956, 78996 (Dec. 31, 2014) The Final Regulations state that an authorized body of the hospital facility must adopt the implementation strategy on or before the 15th day of the fifth month after the taxable year in which the hospital facility conducts a CHNA. Section 1.501(r)-3(c)(5)(i) The Final Regulations also include a transitional rule pertaining to the first adoption and implementation of the CHNA, where it was conducted in a taxable year before March 23, 2012: • The hospital does not need to meet the requirements of Section 501(r)(3) again until the third taxable year following the taxable year in which the hospital facility previously conducted a CHNA, provided that the hospital facility adopted an implementation strategy to meet the community health needs identified through that CHNA on or before the 15th day of the fifth calendar month following the close of its first taxable year beginning after March 23, 2012. Section 1.501(r)-3(e)(1)

10 Fundamentals of Hospital Licensing and Certification

I. Introduction 10.1

II. Definitions 10.1

III. Hospital Licensure 10.3

A. General Information 10.3

Program Flexibility 10.3

B. Basic Services 10.4

C. Supplemental Services 10.4

D. Contracted Services 10.5

E. CDPH Authority to Deny License 10.5

F. Other Required Licenses and Permits 10.6

G. Web Resources 10.6

IV. Changes to the License or the Licensee 10.7

A. General Information 10.7

B. Voluntary Cancellation or Suspension of License 10.8

Cancellation 10.8

Suspension 10.9

C. Changes in Hospital Beds 10.9

Voluntary Suspension of Licensed Bed Capacity 10.9

Voluntary Cancellation or Suspension of Special Permit 10.10

Reclassification of Beds 10.10

Conversion of Beds 10.11

D. Changes of Ownership 10.11

Consolidating Hospitals 10.13

V. Public Notice Regarding Service Changes 10.13

A. General Requirement Regarding Service Downgrade or Change 10.13

B. Emergency Service Reduction or Elimination 10.14

C. Closing a Health Facility or Eliminating/Relocating a Supplemental Service 10.14

VI. Enforcement and Penalties for Noncompliance With State Licensing or Federal Certification Requirements 10.15

A. General Information 10.15

B. Survey Preparedness 10.16

C. Resources 10.16

VII. COVID-19 and Hospital Licensing 10.16

VIII. Medicare Enrollment and Certification 10.17

A. Enrollment 10.17

When All Health and Safety Standards are Met on the Date of Survey 10.18

When All Health and Safety Standards are Not Met on the Date of Survey 10.19

Enrollment Revalidation 10.19

Patient Protection and Affordable Care Act 10.20

Provider-Based Physicians 10.25

B. Denial of Enrollment and Loss of Ability to Bill 10.25

Denial of Enrollment 10.25

Revocation of Enrollment and Billing Privileges 10.26

Deactivation of Billing Privileges 10.27

Revocation Versus Deactivation 10.28

C. Changes of Ownership 10.28

Automatic Assignment of Medicare Agreement 10.29

Rejection of Automatic Assignment of Medicare Agreement 10.29

Acquisition and Merger of Hospitals 10.30

D. Provider-Based Rules 10.31

E. PPS-Exempt Units 10.33

Basics 10.33

Changes in Status 10.34

Changes in Size 10.35

F. COVID and Hospital Medicare Certification Waivers 10.35

IX. Medi-Cal Enrollment and Certification 10.36

X. The Patient Protection and Affordable Care Act (ACA) as Applied to Medicaid 10.38

A. Generally 10.38

B. Order/Referring Provider Enrollment 10.38

C. Notification of Terminations from Medicare and/or Medicaid 10.38

D. Terminations from Medicaid 10.38

XI. Open Issues Currently Under Review at CDPH 10.39

A. Revisions to Hospital Licensing Regulations 10.39

B. Potential Change of Ownership Regulations 10.39

C. Hospital Within a Hospital Requirements/Co-Location Requirements 10.39

FORMS & APPENDICES

HC 10-B List of Miscellaneous Licenses

Form 20-1 Adverse Event Report Form — *Sample*

10 Fundamentals of Hospital Licensing and Certification

I. INTRODUCTION

Health facilities in California are licensed, regulated, inspected, and/or certified by a number of public and private agencies at the state and federal levels. The California Department of Public Health (CDPH) Licensing and Certification (L&C) Program is responsible for ensuring that health facilities comply with state statutes and regulations. In addition, L&C has a contract with the Centers for Medicare & Medicaid Services (CMS) to ensure that California health facilities that participate in the Medicare and Medicaid programs meet federal requirements.

CDPH and the California Legislature have been increasingly active in issues related to hospital operations and transparency. Legislation regarding adverse event reporting, privacy breach notification, expanded public notice and other requirements for the reduction or elimination of hospital services, and fair pricing (charity care) requirements are recent examples of the changing requirements affecting hospitals.

This chapter provides information and guidance focused specifically on the state licensing and Medicare certification issues faced by hospitals, including general acute care hospital licensure, Medicare and Medi-Cal enrollment and certification, the CDPH administrative penalty system for hospitals, adverse event reporting requirements, and public notice and other requirements for hospital services reduction or elimination.

II. DEFINITIONS

"Accreditation" is a means of obtaining certification from an approved national accreditation program, such as The Joint Commission, The American Osteopathic Association or DNV Healthcare, Inc., rather than undergoing a certification survey by CDPH (a separate licensing survey by CDPH is still required). Providers accredited by one of the national accreditation programs are "deemed" to meet all of the Medicare Conditions of Participation (CoP) [42 C.F.R. Section 488.5].

Compliance Tip: Accrediting agencies offer both simple accreditation and "deemed" status accreditation options. A provider must apply for a "deemed" status accreditation to obtain Medicare certification based on the accreditation decision.

"Certification" is the recommendation made by the state survey agency that a provider is in compliance with the CoP [42 C.F.R. Section 488.1]. For example, hospitals wishing to participate in Medicare or Medicaid must meet the specified CoPs found at 42 C.F.R. Part 482.

"Conditions of Participation" are the requirements providers other than skilled nursing facilities must meet to participate in the Medicare program and includes conditions of certification for rural health clinics. [42 C.F.R. Section 488.1]

"Enrollment" is the process by which a provider requests participation in the Medicare program by submitting the CMS 855A enrollment application to the Medicare Administrative Contractor (MAC). Once the enrollment application is approved and the provider is determined to meet all CoPs, the provider is then eligible to receive reimbursement for services provided to Medicare beneficiaries.

"Licensure" means the process of obtaining the basic license necessary to operate a health facility. Licenses list the authorized number and classification of beds for a facility and are issued by CDPH [Health and Safety Code Section 1251].

A **"Medicare Administrative Contractor"** or **"MAC"** is an entity that has a contract with CMS to enroll providers, determine and make payments for Part A and Part B benefits, and to perform other related functions. [42 U.S.C. Section 1395kk-1(a)(3)]

A **"National Provider Identifier"** or **"NPI"** is the 10-digit standard unique identifier for health care providers and health plans mandated by the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act (HIPAA) of 1996. CMS developed the National Plan and Provider Enumeration System (NPPES) to assign these unique identifiers. Effective May 23, 2008, the NPI replaced the Provider Number or Legacy Number previously used by providers to submit claims to Medicare, Medi-Cal and other payers [69 Fed. Reg. 3434 (Jan. 23, 2004)].

A **"provider"** is a hospital, transplant center, critical access hospital, skilled nursing facility, nursing facility, home health agency, hospice, comprehensive outpatient rehabilitation facility, religious nonmedical health care institution, or a clinic, rehabilitation agency or public health agency that furnishes outpatient physical therapy or speech pathology services [42 C.F.R. Sections 400.202, 488.1 and 498.2].

A **"special permit"** is a permit issued in addition to a license, authorizing a health facility to offer one or more special services once CDPH has determined that the health facility meets the standards of quality of care required for such services. Special permits are issued by CDPH [Health and Safety Code Section 1251.5].

A **"supplier"** is an independent laboratory, supplier of durable medical equipment or supplies, ambulance, independent diagnostic testing facility, portable X-ray services, physical therapist in independent practice, End-Stage Renal Disease facility, rural health clinic, federally-qualified health center, ambulatory surgical center, physician or chiropractor [42 C.F.R. Sections 400.202, 488.1 and 498.2].

"Title 22" refers to Title 22 of the California Code of Regulations. The hospital licensing regulations can be found in Division 5, Licensing and Certification of Health Facilities, Home Health Agencies, Clinics, and Referral Agencies. Chapter 1 covers General Acute Care Hospitals [Sections 70001-70960]. Chapter 2 covers Acute Psychiatric Hospitals [Sections 71001-71703]. Chapter 3 covers Skilled Nursing Facilities [Sections 72001-72713]. Other chapters cover other types of facilities and clinics.

III. HOSPITAL LICENSURE

A. General Information

"Health facilities" are facilities, places, or buildings that are organized, maintained and operated for the diagnosis, care, prevention, and treatment of human illness, physical or mental, including convalescence and rehabilitation and including care during and after pregnancy, or for any one or more of these purposes, for one or more persons, to which the persons are admitted for a 24-hour stay or longer [Health and Safety Code Section 1250]. In order to operate as a health facility, a facility must submit an application to CDPH and obtain and maintain a license issued by CDPH covering all of the services rendered at the facility [Title 22, California Code of Regulations, Sections 70041 and 70103].

The hospital license identifies the total number of licensed beds as well as a breakdown of the types of beds the hospital maintains and the number of beds in each category (burn, coronary care, intensive care, medical-surgical, pediatric, perinatal, rehabilitation, acute respiratory or tuberculosis patients receiving 24-hour medical care). [Title 22, California Code of Regulations, Section 70034]

In addition, CDPH is required to separately identify on the license each supplemental service, including the address of where each outpatient services is provided and the type of services provided at each outpatient location [Health and Safety Code Section 1253.5]. (A supplemental service is an organized inpatient or outpatient service which a hospital is not required by law to provide [Title 22, California Code of Regulations, Section 70067]. Additional information regarding supplemental services is provided in C. "Supplemental Services," page .

A copy of the hospital license and any special permits must be posted conspicuously in a prominent location in the hospital accessible to public view [Title 22, California Code of Regulations, Sections 70123 and 70359].

Program Flexibility

While hospitals generally must maintain continuous compliance with licensing requirements, the law contemplates hospitals using alternative concepts, methods, procedures and approaches to satisfying these requirements [Health and Safety Code Section 1276; Title 22, California Code of Regulations, Sections 70129, 70307 and 70363]. A hospital seeking flexibility in one or more Title 22 requirements should discuss with its local CDPH district office how its facts or circumstances support an alternative method of compliance with the licensing requirements. Following these discussions, the hospital should seek written "program flexibility" from the CDPH district office, explaining why a variance of one or more of the licensing requirements is appropriate under the circumstances. CDPH typically replies to such requests in writing, outlining any terms and conditions under which the exception or flexibility is granted. While CDPH may provide flexibility in how licensing regulations are applied, it does not typically provide hospitals with flexibility in satisfying statutory requirements.

B. Basic Services

There are eight basic services that a general acute care hospital must provide in order to obtain and maintain a license:

1. Medical
2. Nursing
3. Surgical
4. Anesthesia
5. Clinical laboratory
6. Radiology
7. Pharmacy
8. Dietary services

[Health and Safety Code Section 1250; Title 22, California Code of Regulations, Section 70011]

Definitions and the specific requirements applicable to each basic service are found in Title 22, California Code of Regulations, Sections 70201-70279.

General acute care hospitals include "rural general acute care hospitals." However, unlike other general acute care hospitals, a "rural general acute care hospital" is not required to provide surgery and anesthesia services [Health and Safety Code Section 1250(a)]. In addition, a general acute care hospital that exclusively provides acute medical rehabilitation center services may also provide surgical and anesthesia services through a contract with another acute care hospital. [Health and Safety Code Section 1250(a)]

C. Supplemental Services

In addition to providing the required eight basic services, a hospital may elect to provide supplemental services. A supplemental service is an organized inpatient or outpatient service that is not required to be provided by law or regulation [Title 22, California Code of Regulations, Section 70067]. A hospital must obtain prior approval from CDPH if it chooses to provide supplemental services [Title 22, California Code of Regulations, Section 70301]. Supplemental services include acute respiratory care, basic emergency, burn center, cardiovascular surgery, cardiac catheterization laboratory, chronic dialysis unit, comprehensive emergency, coronary care, dental care, intensive care, intensive care newborn nursery, intermediate care, nuclear medicine, occupational therapy, outpatient services, pediatric, perinatal, physical therapy, podiatric, psychiatric, radiation therapy, rehabilitation center, renal transplant center, respiratory care, skilled nursing, social services, and speech pathology. Definitions and the specific requirements that must be met for each supplemental service are found in Title 22, California Code of Regulations, Sections 70401-70657.

The supplemental services that are underlined above are considered **"special services"** and require a special permit issued by CDPH [Health and Safety Code Sections 1251.5, 1253, 1255, and 1277(c); Title 22, California Code of Regulations, Sections 70061 and 70351]. If a hospital desires to provide any of the supplemental services that require a special permit, it must submit an application to CDPH and have the supplemental service inspected, approved and added to the hospital license before it can begin providing any of these services.

Supplemental services that do not require a special permit should also be listed by CDPH on the hospital license [Title 22, California Code of Regulations, Section 70305].

California law authorizes hospitals to establish one or more observation units, defined as areas within a hospital in which observation services are provided and that are not part of an emergency department and are outside of an inpatient unit. Observation units must have signage identifying the unit as an outpatient area of the hospital and must comply with the nurse-to-patient ratios required for emergency services (maximum of four patients per nurse; fewer depending on patient severity of illness). An observation unit must also comply with building standards enforced by the California Department of Health Care Access and Information (HCAI) (formerly known as the Office of Statewide Health Planning and Development (OSHPD)). Further, hospitals are required to provide written notice of observation status to each patient receiving observation services in an inpatient or observation unit "as soon as practicable." The notice must provide, among other things, that the patient is receiving an outpatient level of care and that this may affect health care coverage, reimbursement and eligibility for certain post-hospitalization services [Health & Safety Code Section 1253.7]. This state notice requirement is separate from the federal requirement established by the NOTICE Act, which requires Medicare-participating hospitals to provide the Medical Outpatient Observation Services Notice (MOON) to all Medicare beneficiaries receiving observation services for more than 24 hours. The federal statute and the state statute apply to different patient populations and have different requirements for when the notice must be provided. Details of these requirements are included in chapter 12 of CHA's *Consent Manual*.

D. Contracted Services

CDPH interprets Health and Safety Code Section 1250 to require general acute care hospitals to provide all eight basic hospital services directly. CDPH does not believe that a hospital can outsource an entire basic service. However, a hospital may supplement its provision of these basic hospital services or provide additional services pursuant to a contractual relationship with an outside provider or contractor. Examples of such services would include advanced imaging services or dialysis services. A hospital's use of an "outside resource" is contemplated in Section 70713 of Title 22 of the California Code of Regulations, as well as in the Medicare Conditions of Participation at Title 42 of the Code of Federal Regulations, Section 482.12. A hospital's arrangement with a third party to provide services to hospital patients should be in writing and specify that the hospital retains professional and administrative responsibility for the services provided by the third party. Hospitals that contract with third parties should ensure that the arrangement is documented in writing and can be provided to a surveyor or regulator upon request; that they have the proper systems in place to monitor and review those services provided by outside resources in accordance with the hospital's Quality Assurance Performance Improvement Program; and that these services are provided in accordance with the standards that apply when a hospital provides these services directly.

E. CDPH Authority to Deny License

CDPH can deny a license application for the following reasons:

1. The applicant fails to meet state and/or local regulations for fire or safety clearance, health and sanitation requirements, or Title 22 regulations.

2. The applicant's owners have been convicted of a crime defined in Section 1265.2 of the Health and Safety Code, or have knowingly made a false statement of fact or information in the license application.

3. The applicant's owners were owners or officers of another licensee, or a management company under contract with a licensee at a time when the licensee's license was suspended or the licensee was decertified.

[Health and Safety Code Section 1265.1; *Licensing and Certification Policy and Procedure Manual* Section 202.40]

F. Other Required Licenses and Permits

In addition to the acute care hospital license issued by CDPH, a hospital must maintain numerous other licenses, permits, certifications, accreditations and approvals necessary to provide several of the basic services required to maintain a hospital license as well as other health care services a hospital may elect to provide. For example, in order to maintain a hospital license, a hospital must provide laboratory services and pharmacy services. Each hospital laboratory must maintain both a laboratory license issued by CDPH Laboratory Field Services and a Clinical Laboratory Improvement Amendments (CLIA) certificate issued by CMS. A hospital pharmacy must have a pharmacy permit issued by the California State Board of Pharmacy as well as a registration certificate issued by the U.S. Drug Enforcement Administration. Each license, permit, certification and approval maintained by a hospital is governed by its own sets of rules and regulations regarding applications, notices and operations. *(See CHA Appendix HC 10-B, "List of Miscellaneous Licenses," for more examples of the different types of licenses and permits a hospital may hold.)*

G. Web Resources

CDPH maintains a helpful website at https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/HealthCareFacilities.aspx. This website includes, among other information:

1. A link to CDPH's Licensing and Certification Application page, which provides an overview of the licensing application process and a link to the online application portal.

2. CDPH's "All Facility Letters," which provide information regarding changes or clarifications in licensing requirements, enforcement, new technologies, or other information.

3. Information about how to contact CDPH, including all district offices throughout the state.

4. Basic licensing information about different categories of health facilities licensed by CDPH.

5. A link to CalHealthFind, a searchable database of health facilities licensed by CDPH.

6. Compliance information on state enforcement actions and penalties.

IV. CHANGES TO THE LICENSE OR THE LICENSEE

A. General Information

Most changes in the services rendered by a hospital, or the entity licensed to operate the hospital, trigger the need for some sort of notice or filing to CDPH. It is important to determine whether a specific change triggers a simple notice or whether a more complex application filing, and approval of the change, will be required before the change can occur. In addition, some changes in services require public notice or other action.

Compliance Tip: Effective July 2, 2020, with limited exceptions, CDPH accepts general acute care hospital and acute psychiatric hospital initial, change of ownership, and report of change filings only via electronic submission through its online portal: https://eforms.cdph.ca.gov/. A user must be registered with the portal and must be granted specific access to a facility within the portal in order to access that facility's record and submit applications on its behalf.

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1. The following types of changes typically require an informational filing with CDPH but do not require advance approval from CDPH:
2. Change of licensee mailing address (must report 10 days prior to change).
3. Change of persons with a stock ownership interest of 10 percent or more in the licensee .
4. Change of principal officers of the licensee (must report within 10 days of change). This includes a change in the hospital CEO.

[Title 22, California Code of Regulations, Section 70127]

In contrast, the following types of changes require a more complex application filing that CDPH must approve in advance of the change.

1. Change of hospital name (legal and/or dba).
2. Increase/decrease of licensed bed capacity *(see also C. "Changes in Hospital Beds," page 10.9)*.
3. Change of license category.
4. Change of location.
5. Change of bed classification.
6. Change of ownership *(see also D. "Changes of Ownership," page 10.11)*.
7. Changes in hospital units or services.
    a. Written notice must be given to CDPH not later than 10 days after the date when construction involving an increase in bed capacity or change of services of an existing hospital is commenced [Title 22, California Code of Regulations, Section 70807]. Hospitals will need to comply with the requirements of the HCAI prior to and during construction. Typically, CDPH requires approval or sign-off from HCAI before CDPH will approve any corresponding licensing changes.

b. Adding/closing units.

c. Adding/closing outpatient departments.

d. Converting space. Note that space approved for a specific use cannot be converted to other uses without the written approval of CDPH [Title 22, California Code of Regulations, Section 70805]. Such changes in the use of hospital space may also require approval from HCAI.

e. *Voluntarily canceling or suspending a special permit (see page 10.10)*.

(See Title 22, California Code of Regulations, Section 70105.)

In 2018, the California Legislature passed a law that prescribes timelines for CDPH to approve a general acute care hospital or acute psychiatric hospital's written application to, among other things, modify, add, or expand a service or program. Specifically, statute now requires CPDH to complete its review, including a site visit, if applicable, and approve or deny an application within 100 days of receipt of the application. It also requires CDPH to approve an application to expand an existing service within 30 business days of receipt of the completed application, unless the hospital is out of compliance with laws governing that service. [Health and Safety Code Section 1272]

Finally, California law prescribes specific requirements for downgrading, reducing, or eliminating a service. While these requirements are sometimes redundant, overlapping or inconsistent, hospitals must comply with all of the requirements that apply to a specific action. For example, if a hospital chooses to close its emergency department, it must comply with all the requirements described in the following sections of this chapter as well as any additional requirements established at the local or county level:

1. "Voluntary Cancellation or Suspension of Special Permit," page 10.10.
2. A. "General Requirement Regarding Service Downgrade or Change," page 10.13.
3. B. "Emergency Service Reduction or Elimination," page 10.14.
4. C. "Closing a Health Facility or Eliminating/Relocating a Supplemental Service," page 10.14.

B. Voluntary Cancellation or Suspension of License

Cancellation

A hospital may voluntarily cancel its license by notifying CDPH in writing as soon as possible, and in all cases at least 30 days prior to the desired effective date. Any license voluntarily cancelled may be reinstated by CDPH within 12 months of the date of voluntary cancellation upon receipt of an application along with evidence showing compliance with current operational and construction licensing requirements and the application filing requirements of Health and Safety Code Section 1265. [Health and Safety Code Section 1300(a); Title 22, California Code of Regulations, Section 70133] In other words, when a hospital license is voluntarily cancelled, any HCAI grandfathering it previously enjoyed is typically lost.

Further, depending on the nature of the services provided, a hospital that seeks to voluntarily cancel its license may be required to comply with other requirements in addition to the 30-day notice requirement. For example, a hospital that has an emergency room must also comply with the requirements described in B. "Emergency Service Reduction or Elimination," page 10.14.

Suspension

A hospital may request that its license or all of its licensed beds be temporarily put in suspense. CDPH may approve the request for a period not to exceed 12 months. Any license or portion thereof that has been temporarily placed in suspense is subject to all renewal requirements of an active license, including payment of renewal fees, during the period of temporary suspension. The license may be reinstated by CDPH during the period the license is in suspense upon receipt of an application and evidence showing compliance with current operational requirements and with the application filing requirements of Health and Safety Code Section 1265. If the license is not reinstated within the 12-month period, the license expires automatically and is not subject to reinstatement. [Health and Safety Code Section 1300(a); Title 22, California Code of Regulations, Section 70131]

Compliance Tip: As a practical matter, CDPH has historically permitted hospital licenses and hospital beds to remain in suspense longer than 12 months if the hospital makes a timely request for extension(s) of the suspension.

A hospital that has an emergency room must also comply with the requirements described in B. "Emergency Service Reduction or Elimination," page 10.14.

C. Changes in Hospital Beds

Voluntary Suspension of Licensed Bed Capacity

A health facility may place up to 50 percent of its licensed bed capacity in voluntary suspense for a period not exceeding three years by submitting written notification to CDPH and HCAI. However, this provision does not authorize a facility to suspend *all* beds utilized for the provision of a basic service or *all* beds utilized for a special service or other supplemental service for which the facility holds a special permit or licensure approval. [Health and Safety Code Section 1271.1(a)] Beds that are placed in voluntary suspension are not considered permanently converted to other than patient use, and may be converted back to patient use at a later time [Health and Safety Code Section 1271.1(c)].

Prior to the expiration of the voluntary suspension, the facility may request an extension. The extension may be granted by CDPH if it finds, after consultation with HCAI, that there is no identified need for additional beds in the service area. If, during a period of voluntary suspension pursuant to this provision, OSHPD identifies a need for additional beds (of the category suspended) in the service area, HCAI may require the facility to terminate the voluntary suspension and exercise one of the following options:

1. Place some or all of the suspended beds in operation within one year; or
2. Have the beds deemed permanently converted to other than patient use.

[Health and Safety Code Section 1271.1(a)]

A health facility may remove some or all of its voluntarily suspended beds from voluntary suspension by written request to CDPH. CDPH must grant the request unless the areas housing the suspended beds fail to meet applicable operational or construction requirements. [Health and Safety Code Section 1271.1(b)]

Regulations regarding suspending beds state that CDPH shall not approve a suspension request for a period of more than 12 months [Title 22, California Code of Regulations, Section 70131]. However, as a legal matter, the statute provides the controlling authority, not the regulations. In practice, CDPH has allowed hospitals to maintain beds and services in suspense for periods greater than 12 months.

Any beds placed in suspense will be decertified from participation in the Medicare and Medi-Cal programs. Note that placing beds in suspense may have an impact on a hospital's number of "available beds." This can have important payment consequences.

(See also Licensing and Certification Policy and Procedure Manual *Section 207.00)*

Voluntary Cancellation or Suspension of Special Permit

Cancellation

A hospital must notify CDPH in writing as soon as possible and in all cases at least 30 days prior to the effective date of cancellation of a special permit [Health and Safety Code Section 1300(a); Title 22, California Code of Regulations, Section 70367].

If the cancellation involves a reduction in emergency services, the hospital must also comply with the requirements described in B. "Emergency Service Reduction or Elimination," page 10.14.

Suspension

Upon written request and good cause, a hospital may request to suspend a special permit. CDPH may approve the request for a period not to exceed 12 months. Any special permit that has been temporarily suspended remains subject to all renewal requirements of an active special permit, including the payment of renewal fees, during the period of suspension. [Health and Safety Code Section 1300(a); Title 22, California Code of Regulations, Section 70365] Examples of good cause include closure for renovation, closure for repairs, closure due to unavailability of required staff in an isolated area, and closure due to disasters or emergencies that make continuing operation unfeasible.

A special permit that is not reinstated within the 12-month period expires automatically.

If the suspension involved the emergency department, the hospital must also comply with the requirements described in B. "Emergency Service Reduction or Elimination," page 10.14.

Reinstatement

A special permit canceled or suspended pursuant to this provision may be reinstated by CDPH after it receives an application from the licensee along with evidence showing compliance with supplemental service requirements and the application filing requirements of Health and Safety Code Section 1265. [Health and Safety Code Section 1300(a); Title 22, California Code of Regulations, Sections 70365 and 70367].

Reclassification of Beds

A hospital license provides the licensee the authority to operate as a hospital and a summary of the number of beds and types of services it can provide. Hospital licenses identify the total number of licensed beds that a particular hospital has, as well as a more detailed breakdown of the types of beds the hospital maintains and the number of beds in each category.

There are a number of different types of beds that can be identified on a hospital license. A **"general acute care bed"** is a bed designated for burn, coronary care, intensive care,

medical-surgical, pediatric, perinatal, rehabilitation, acute respiratory or tuberculosis patients receiving 24-hour medical care [Title 22, California Code of Regulations, Section 70034]. A hospital license lists both a hospital's total number of general acute care beds as well as the number of beds for each general acute and other service provided by the hospital. An **"intermediate care bed"** is a bed designated for patients requiring skilled nursing and supportive care on less than a continuous basis, as compared to a **"skilled nursing care bed,"** which is a bed designated for patients requiring skilled nursing care on a continuous and extended basis [Title 22, California Code of Regulations, Sections 70038 and 70060].

CDPH recognizes that a hospital's approved capacity by license category is a guide for how a hospital utilizes its licensed bed space, although it is not an absolute rule. The hospital licensing regulations provide that 5 percent of a hospital's total licensed bed capacity may be used by a licensee for a classification other than that designated on the hospital license [Title 22, California Code of Regulations, Section 70809(b)]. On its face, this provision does not appear to require prior approval from, or notice to, CDPH before a hospital utilizes this 5 percent flexibility.

In addition, upon application to CDPH and a showing that seasonal fluctuations justify the different use, a hospital can use an additional 5 percent of its total licensed bed capacity for other than the classified use, upon approval from CDPH [Title 22, California Code of Regulations, Section 70809(b)].

Even though the hospital licensing regulations provide a hospital some flexibility to use beds in a manner other than how they are licensed, it is important to keep in mind that such an alternative use, although permissible from a licensing perspective, could have certification and payment implications. Moreover, despite this flexibility to use a certain number of beds other than how they are licensed, a hospital is not permitted to utilize more beds for inpatient services than its total licensed bed capacity except in case of a "justified" emergency when temporary permission is granted by CDPH [Title 22, California Code of Regulations, Section 70809(a)].

Conversion of Beds

If a hospital converts patient accommodation space to some other use (including, for example, physician sleep room or medical director office space), and this space cannot be converted back to patient accommodation within 24 hours, this space and any licensed beds will be considered "permanently converted" [Title 22, California Code of Regulations, Section 70054]. If a hospital has beds that have been permanently converted, this will have an impact on the hospital's licensed bed capacity, its number of beds certified by the Medicare and Medi-Cal programs, and its available bed count for Medicare's Indirect Medical Education and Disproportionate Share Hospital purposes.

D. Changes of Ownership

In general, licenses are site specific and entity specific. Licenses are not transferable without the prior approval of CDPH [Health and Safety Code Section 1251]. Regulations require that a licensee notify CDPH in writing at least 30 days prior to the effective date of any change of ownership, and a new application for a license must be submitted by the prospective new owner [Title 22, California Code of Regulations, Section 70125]. In practice, however, this notice should be submitted much earlier. If there is a change of ownership, the new owner must submit a complete license application to the CAB, have the application package reviewed and approved and have the new license issued on the day the ownership changes.

Compliance Tip: CAB should be consulted in the early stages of a possible CHOW transaction to get an estimate of the processing timeline. This information should be used as a guide for determining how far in advance of a target closing date the CHOW application should be submitted.

(See also VIII. "Medicare Enrollment and Certification," page 10.17, for additional and important timing considerations.)

In order to avoid operating without a license, it is important to understand specifically what types of changes are considered a change of ownership and what changes may only constitute a change of information. This is an important distinction because a change of ownership requires a new license to be issued by CDPH before the change can occur, while a change of information only requires a post-change notice filing that typically does not require any approval from CDPH. Generally a **"change of ownership"** means a transfer of the control of the physical facility and of the legal and financial responsibility to provide care to patients in the facility [*Licensing and Certification Policy and Procedure Manual* Section 209.00 *et seq.*].

The following is a list of transactions that constitute changes of ownership and, therefore, require the submission of a new license application to CDPH and the issuance of a new hospital license:

1. **Partnership.** The removal, addition, or substitution of a partner unless otherwise specified in the partnership agreement.
2. **Unincorporated or sole proprietorship.** The transfer of title and property to another party.
3. **Corporation.** The merger of the provider corporation into another corporation, or the consolidation of two or more corporations resulting in the creation of a new corporation.
4. **Leasing.** The lease of all or part of a provider facility constitutes a change of ownership for the leased portion. While leasing is not included in the *Licensing and Certification Policy and Procedure Manual* as an example of a change of ownership, CDPH generally follows the Medicare definition of a change of ownership found at 42 C.F.R. Section 489.18, which does list leasing as an example of a change of ownership. *(See D. "Changes of Ownership," page 10.11, regarding related Medicare requirements.)*

Compliance Tip: A good rule of thumb is that if the federal tax ID number of the current licensee changes, it probably constitutes a change of ownership.

In contrast, the following is a list of changes that require informational notices to CDPH but do not require prior approval or the issuance of a new license:

1. **Partnership.** The change of limited partners (provided such a change does not result in a dissolution of the partnership).

2. **Corporation.** The transfer of corporate stock (except for HHAs), change of corporate officers, change of directors, or merger of another corporation into the provider corporation (where the provider corporation remains the surviving entity).
3. **Limited Liability Company.** The change of members.

Consolidating Hospitals

A single consolidated hospital license may be issued to a general acute care hospital that includes more than one physical plant maintained and operated on separate premises or that has multiple licenses for a single health facility on the same premises. In order to be issued a single, consolidated hospital license, all of the facilities must have a single governing body, a single administration and a single medical staff with a single set of bylaws, rules, regulations and committee structure. In addition, each of the physical plants must be located within 15 miles of each other (with specified exceptions) and, according to CDPH, each hospital campus must provide all eight basic hospital services. A single consolidated license will not be issued where the separate freestanding physical plant is a skilled nursing facility or an intermediate care facility. [Health and Safety Code Section 1250.8; *Licensing and Certification Policy and Procedure Manual* Section 211.00]

A general acute care hospital with a single consolidated license may, at its option, maintain a single Medi-Cal provider number or separate provider numbers for each of the physical plants subject to the consolidated license. Further, a hospital with a consolidated license, at its election, can either maintain separate Medicare provider numbers for each campus or a single Medicare provider number for both sites. In order to maintain a single Medicare provider number for both sites, it must generally satisfy Medicare's provider-based rules *(see discussion below)* and designate one campus the "main campus" and the other campus the "remote location" or "provider-based campus." [*Licensing and Certification Policy and Procedure Manual* Section 211.00] Additionally, based on the National Provider Identifier regulations, the regulators have stated that the same decision must be made for both the Medi-Cal and Medicare programs. So, for example, a provider could not maintain a single Medicare enrollment for both of its sites and at the same time maintain a different Medi-Cal enrollment for each site.

V. PUBLIC NOTICE REGARDING SERVICE CHANGES

A. General Requirement Regarding Service Downgrade or Change

Health and Safety Code Section 1255.2 states that a "health facility implementing a downgrade or change shall make reasonable efforts to ensure that the community served by its facility is informed of the downgrade or closure." This requirement is not limited to closing the entire hospital or closing the emergency department. It is unclear which types of service downgrades, changes or closures trigger this requirement. It is also unclear whether an upgrade or expansion would be considered a "change" that triggers this requirement.

The law states that reasonable efforts may include, but are not limited to, advertising the change in terms likely to be understood by a layperson, soliciting media coverage regarding the change, informing patients of the impending change, and notifying contracting health care service plans [Health and Safety Code Section 1255.2].

B. Emergency Service Reduction or Elimination

Before a reduction or elimination of the level of emergency medical services, a hospital must provide at least 180 days prior written notice to:

1. CDPH;
2. The local governmental entity responsible for health services; and
3. All health care service plans or other entities that contract with the hospital to provide services to enrollees of the plan or other entity.

In addition, the hospital must notify the public of the intended change in a manner that is likely to reach a significant number of residents of the community served by the hospital. The law provides that the mandatory public notice must include, but is not limited to:

1. Written notice to the city council of the city in which the hospital is located.
2. Continuous notice posted in a conspicuous location on the home page of the hospital's internet website.
3. Notice published in a conspicuous location within a newspaper of general circulation serving the local geographical area in which the hospital is located.
4. Continuous notice posted in a conspicuous location within the internet website of a newspaper of a general circulation serving the local geographical area in which the hospital is located; and
5. Notice posted at the entrance of every community clinic within the affected county in which the hospital is located that grants voluntary permission for posting.

The notice requirements do not apply if CDPH determines that the use of resources to keep the emergency department open substantially threatens the stability of the hospital as a whole, or if CDPH cites the emergency department for unsafe staffing practices.

[Health and Safety Code Section 1255.1]

Before approving a downgrade or closure of emergency services pursuant to a voluntary suspension or cancellation of a hospital license or special permit, CDPH must receive from the county, through its emergency medical services agency, an impact evaluation of the downgrade or closure upon the community, including community access to emergency care, and how that downgrade or closure will affect emergency services provided by other entities. The county must incorporate at least one public hearing in its impact evaluation. The complete list of requirements that counties must follow in preparing these reports may be found in Health and Safety Code Section 1300.

The hospital should also notify CalTrans (if removal of any highway signs directing motorists to the hospital is necessary), local law enforcement and ambulance companies, and its accrediting organization, if any.

C. Closing a Health Facility or Eliminating/Relocating a Supplemental Service

Not less than 120 days prior to closing a general acute care hospital or acute psychiatric hospital, or 90 days prior to eliminating or relocating (to a different campus) a supplemental service, the facility must:

1. Provide public notice of the proposed closure, or the proposed elimination or relocation of the supplemental service, including a notice posted at the entrance to all affected facilities.
2. Provide notice to CDPH.
3. Provide notice to the Board of Supervisors of the county in which the health facility is located.

The required notice must include all of the following:

1. A description of the proposed closure, elimination, or relocation. The description shall be limited to:
    a. Publicly available data, including the number of beds eliminated, if any,
    b. The probable decrease in the number of personnel, and
    c. A summary of any service that is being eliminated, if applicable.
2. A description of the three nearest available comparable services in the community. If the health facility providing the notice serves Medi-Cal or Medicare patients, the notice must specify if the providers of the nearest available comparable services serve these patients.
3. A telephone number and address for each of the following, where interested parties may offer comments:
    a. The health facility.
    b. The parent entity, if any, or contracted company, if any, that acts as the corporate administrator of the health facility.
    c. The chief executive officer.

The public notice required for closure of a facility or elimination of a supplemental service must be delivered, at a minimum, in the same manner as required for the public notice required for the elimination or reduction of an emergency service, as described above.

County facilities need not comply with this requirement; they are instead subject to Health and Safety Code Section 1442.5. Further, the notice requirements do not apply in the event a health facility is forced to close or eliminate a service due to a natural disaster or state of emergency that prevents it from being able to operate at its current level. [Health and Safety Code Section 1255.25]

VI. ENFORCEMENT AND PENALTIES FOR NONCOMPLIANCE WITH STATE LICENSING OR FEDERAL CERTIFICATION REQUIREMENTS

A. General Information

The CDPH Licensing and Certification (L&C) Field Operations Branch has more than 500 surveyors located in several district offices around the state. These employees conduct facility surveys and complaint investigations, and may visit a hospital at any time to determine whether it is in compliance with state licensing requirements. Visits may result from a complaint from a patient, employee or other third party; a newspaper article; or a report by the hospital itself regarding an unusual occurrence, privacy breach or adverse event.

L&C also has a contract with CMS to ensure that California health facilities that participate in the Medicare and Medicaid programs meet federal requirements. CDPH uses the same surveyors for both state and federal surveys. When a surveyor employed by L&C visits a hospital, it is sometimes difficult to determine whether the surveyor is acting on behalf of the state or on behalf of CMS. At times, a surveyor may be representing both. If in doubt, hospitals should seek clarification from the surveyor regarding the nature of the survey.

In addition to the general licensing and Medicare and Medicaid related surveys, L&C also surveys other more specific aspects of hospital operations, such as hospitals' compliance with patient safety law requirements and hospitals' efforts to reduce medication errors.

B. Survey Preparedness

A hospital should be prepared for a survey at all times. This should include having a team ready to meet the surveyors when they enter the building, a mechanism for alerting personnel that surveyors are in the building, training on how to respond to surveyors, a checklist for a quick review of the department prior to the surveyors' visit, and a system to effectuate communication among the hospital leadership throughout the survey process. In addition, the hospital should conduct mock surveys and training to address survey readiness. Policies, procedures and other key documents should be readily accessible.

C. Resources

The California Hospital Association has developed a guide to the licensing and certification survey process, the *California Hospital Survey Manual*. This guide explains who the surveyors are, which laws they assess compliance with and how they conduct a survey. It also explains the different types of surveys and possible outcomes of a survey: the statement of deficiencies, immediate jeopardy, fines and the Medicare/Medicaid termination process. Included are tips on how to prepare for surveys, how to interact with the surveyors, how to write plans of correction and how to appeal adverse actions. For more information about the manual or to order, visit www.calhospital.org/publications/california-hospital-survey-manual-2.

VII. COVID-19 AND HOSPITAL LICENSING

In March 2020, following the Secretary of the U.S. Department of Health and Human Service's declaration of a nationwide public health emergency in response to the spread of the COVID-19 virus, the governor proclaimed a state of emergency for the state of California. The proclamation paved the way for a series of Executive Orders and CDPH All Facilities Letters offering flexibilities and waivers regarding various hospital (and other provider) licensing requirements. Of particular note, CDPH All Facilities Letter 20-26, as originally issued, suspended CDPH's enforcement of certain hospital licensing requirements, and in doing so, offered hospitals the ability to begin providing new and expanded services upon application to CDPH without pre-approval from CDPH; the opportunity to repurpose existing physical space to accommodate COVID-19 mitigation strategies; flexibility in the notification procedures normally required when downgrading, eliminating or changing a supplemental service; and a limited ability for to seek staffing waivers when experiencing a COVID-19 related surge of patients or staffing shortages resulting from COVID-19 impacts. Since it was originally issued, AFL 20-26 has been revised numerous times to address hospitals' evolving

needs for flexibility during the course of the pandemic. The current version, which is limited to offering flexibilities relating to certain Title 22 requirements regarding physical space to accommodate patient surge, patient cohorting, and other COVID-19 mitigation strategies, is due to expire June 30, 2022. The AFL expressly provides, however, that hospitals can submit an emergency program flexibility request if they have continued need for flexibility beyond that date.

Hospitals opting to operate under these waivers and flexibilities should understand (1) that these waivers and flexibilities are constantly being adjusted to account for changes in circumstances throughout the duration of the state of emergency, and (2) the waivers and flexibilities are time-limited, in that they are connected to the state of emergency. Upon the expiration of the state of emergency, hospitals that relied on the waivers and flexibilities should be prepared to promptly unwind any changes that were made in reliance on those flexibilities or to follow any specifically-prescribed processes for unwinding such changes. For more information on the specific waivers and flexibilities, visit https://www.gov.ca.gov/category/executive-orders/ (Executive Orders) and https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/LNCAFL20.aspx (CDPH 2020 All Facilities Letters).

VIII. MEDICARE ENROLLMENT AND CERTIFICATION

A. Enrollment

To receive payment for covered Medicare items or services provided to a Medicare beneficiary, a provider must be enrolled in the Medicare program [42 C.F.R. Section 424.505]. In order to become enrolled in the Medicare program, a provider must submit a CMS 855A enrollment application to its Medicare Administrative Contractor (MAC). Once the enrollment process is successfully completed, including, if applicable, a state survey and certification or accreditation process, CMS enrolls the provider in the Medicare program by issuing a provider participation agreement and authorizing the Provider's NPI to be used as a Medicare billing number. [42 C.F.R. Section 489.11]

To date, CMS has approved four accrediting organizations to provide deemed status to hospitals: the Accreditation Commission for Health Care (ACHC), The Joint Commission (TJC), DNV-Healthcare (DNV) and Center for Improvement of Healthcare Quality (CIHQ) [42 C.F.R. Section 488.5]. *(See https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Accrediting-Organization-Contacts-for-Prospective-Clients-.pdf.)* Only TJC and DNV have been granted deeming authority for psychiatric hospitals, including the special staffing and medical records requirements that are considered necessary for the provision of active treatment in psychiatric hospitals. **"Deemed status"** means that CMS has certified a hospital for Medicare participation, based on accreditation by one of these organizations and CMS "deems" the provider or supplier to be in compliance with the applicable Medicare Conditions of Participation [42 C.F.R. Sections 488.4 and 488.1]. A deemed status hospital is subject to validation surveys as provided under 42 C.F.R. Section 488.9.

Historically, the effective date of enrollment in the Medicare program depended, in part, on whether the provider was surveyed by the state agency (in California, CDPH) for certification purposes or by a private accrediting organization. This changed with the amendments to the federal regulation [42 CFR Section 489.13] governing the "effective date of agreement or

approval" as published on Aug. 16, 2010 [75 Fed. Reg. 50042 (Aug. 16, 2010)]. There are no longer different rules governing the effective date when a provider is accredited by a CMS-approved accrediting organization as opposed to the state agency. Instead, the effective date of enrollment depends upon when all health and safety standards are met, as described below.

When All Health and Safety Standards are Met on the Date of Survey

Pursuant to the revised Medicare regulation, the Medicare provider agreement is effective on the date the state agency, CMS, or CMS contractor survey is completed, or on the effective date of the accreditation decision, as applicable, if on that date, the provider or supplier meets all applicable federal requirements. Importantly, in revising the governing regulation, CMS has clarified that the effective date of the provider agreement may not be earlier than the latest of the dates on which CMS determines that each applicable federal requirement is met.

The regulation does not specify each and every federal requirement that must be met in order for a provider to become Medicare certified. Instead, the regulation identifies, by way of example, the federal requirements that could impact the effective date of Medicare certification, including, but not limited to:

1. The enrollment requirements established in 42 C.F.R. Part 424, the conditions for Medicare payment;
2. The requirements identified in 42 C.F.R. Sections 489.10 and 489.12 (the basic requirements for provider agreements, including compliance with civil rights laws, disability rights laws, age discrimination laws, etc.); and
3. The applicable Medicare health and safety standards, including the applicable Conditions of Participation, the requirements for participation, the conditions for coverage, or the conditions for certification.

[42 C.F.R. Section 489.13]

One of the federal requirements that may impact the effective date of a provider agreement or supplier approval is verification of Office for Civil Rights (OCR) compliance. The Aug. 16, 2010, final rule clarifies that CMS is not changing its current policy relating to OCR compliance. The transmittal letter sent to a prospective provider informing it that a provider agreement is being issued and identifying its effective date still states that the applicant's Medicare participation is contingent upon compliance with all civil rights requirements as determined by OCR. This is true even though compliance with the OCR requirements may not be established until after a provider agreement has been issued. [75 Fed. Reg. 50042, 50403-404 (Aug. 16, 2010)]

The commentary accompanying the Aug. 16, 2010, final rule also specifically contemplates a CMS contractor performing ongoing enrollment verification activities after it has issued a recommendation for approval of an enrollment application. This means that if a second contractor review occurs after a survey, it may delay the effective date of a provider agreement if, during this review, the contractor identifies that the provider is not in compliance with all applicable federal requirements. [75 Fed. Reg. 50042, 50401 (Aug. 16, 2010)]

When All Health and Safety Standards are Not Met on the Date of Survey

If, on the date the survey is completed, the provider has failed to meet any one of the applicable health and safety standards, and no other federal requirements remain to be satisfied, the effective date of the agreement for a hospital is the earlier of:

1. The date on which the provider meets all applicable Conditions of Participation or, if applicable, the date the CMS-approved accrediting organization has issued a positive accreditation decision, after the accreditation organization has determined that the provider meets all applicable conditions; or
2. The date on which a provider is found to meet all Conditions of Participation, despite the fact that there are outstanding lower-level deficiencies, and:
    a. CMS or the state survey agency receives an acceptable plan of correction for the lower-level deficiencies or a CMS-approved accreditation organization issues a positive accreditation decision after receiving an acceptable plan of correction for the lower-level deficiencies; or
    b. CMS receives an approved waiver request (with the date of receipt as the effective date, regardless of when CMS approves the waiver request).

If a hospital has been found to meet all Conditions of Participation, but has lower-level deficiencies and has submitted an approved plan of correction or received a positive accreditation decision and has an approved waiver request, the effective date of Medicare certification is the later of the dates outlined above in (2)(a) and (2)(b).

If, on the date the survey is completed, the provider has failed to meet any one of the applicable health and safety standards and has also not satisfied other federal requirements, the effective date of the provider agreement may not be earlier than the latest of the dates on which CMS determines that each applicable federal requirement is met.

[42 C.F.R. Section 489.13(c)(2) and (3)]

For a skilled nursing facility (SNF) that has not met all of the applicable federal requirements for participation on the date of its survey, the effective date of enrollment in the Medicare program is the date on which the SNF is in substantial compliance, as defined in 42 C.F.R. Section 488.301, and the SNF has submitted, if applicable, an approvable waiver request [42 C.F.R. Section 489.13(c)(1)].

Enrollment Revalidation

While providers are already required to resubmit and recertify the accuracy of their enrollment information every five years [42 C.F.R. Section 424.515], in June of 2010, CMS directed Medicare contractors to begin a provider enrollment revalidation initiative focusing on all hospitals which are not already entered into the Provider Enrollment Chain and Ownership System (PECOS). Hospitals that initially enrolled prior to 2003 are probably not in PECOS and should receive revalidation request letters instructing them to submit a revalidation application within 90 days of the date of the request letter. *(See CMS Revalidations page at www.cms.gov/Medicare/Provider-Enrollment-and-Certification/medicareprovidersupenroll/revalidations.html for more information.)*

Hospitals should not submit a CMS 855A enrollment form or the internet-based PECOS enrollment application and supporting documentation before receiving a formal revalidation

request, confirming an approaching revalidation deadline through the CMS Revalidation Look Up Tool, or speaking with their Medicare contractor. *(See CMS Revalidation Look Up Tool at https://data.cms.gov/revalidation for current due dates.)* CMS now encourages providers to submit a revalidation if they are within three months of the listed due date but have not received a formal notice from their MAC.

Patient Protection and Affordable Care Act

The Patient Protection and Affordable Care Act (ACA) of 2010, signed by President Obama on March 23, 2010, contained several provisions related to changes in the provider enrollment process. These provisions expand the Medicare disclosure and collateral sanctions rules in ways that will have a serious and significant impact on all providers.

Below is a brief summary of some of the important enrollment-related provisions contained in ACA and the final regulations. The final regulations were published on Feb. 2, 2011 [76 Fed. Reg. 5862]. Most provisions went into effect March 23, 2011, one year after enactment of ACA.

On Sept. 29, 2012, Governor Brown signed SB 1529, which added and revised provisions of the California Welfare and Institutions Code to comply with the requirements of ACA. The corresponding Welfare and Institutions Code sections are provided after each applicable ACA provision below.

Enhanced Disclosures

Pursuant to ACA, providers submitting Medicare enrollment or revalidation applications are required to disclose all current or previous affiliations, directly or indirectly, with a provider or supplier that has:

1. Uncollected debt;
2. Been suspended;
3. Been excluded from participating in a federal health care program; or
4. Had its billing privileges denied or revoked.

If the U.S. Department of Health and Human Services determines that such affiliation poses an undue risk of fraud, waste or abuse, the enrollment application may be denied.

[42 U.S.C. Section 1395cc(j)(5)]

Depending on how “affiliation” is defined, this provision could have wide-ranging and serious negative impacts on large provider systems with multiple provider subsidiaries. On Sept. 10, 2019, CMS published the Program Integrity Enhancements to the Provider Enrollment Process final rule with comment period. The final rule adopted very broad definitions of “affiliation” and what constitutes a “disclosable event.” The breadth of the definitions makes appropriate compliance burdensome for providers. Although a comment period was included, the final rule is in effect now.

Under the final rule, the requirements will be phased-in. At first, only initially enrolling and revalidating providers will be required to disclose reportable affiliation information when CMS, after determining that the provider may have at least one reportable affiliation, requests the disclosure. However, CMS indicates that these disclosures will eventually be extended beyond those initial scenarios. Given the complications involved in adhering to these new

requirements, it is recommended that hospitals contact experienced legal counsel to discuss the ramifications of the final rule.

Enhanced Screening

Effective March 25, 2011, for new enrollees, and March 23, 2012, for current and revalidating providers, providers were subject to enhanced screening measures including:

1. License checks
2. Database checks
3. Unannounced site visits
4. Criminal background checks
5. Fingerprinting
6. Application screening fees

[42 U.S.C. Section 1395cc(j)(2)]

The final regulations state that providers will be categorized into the following three risk groups, upon which one of three different levels of screening processes will be imposed:

1. **Limited:** physicians, non-physician practitioners (including nurse practitioners, CRNAs, occupational therapists, speech/language pathologists, and audiologists), medical groups, clinics, ambulatory surgery centers, Competitive Acquisition Program/Part B vendors, end-stage renal disease facilities, federally-qualified health centers, histocompatibility labs, home infusion therapy suppliers, hospitals (including critical access hospitals, Department of Veterans Affairs hospitals, and other federally owned facilities), Indian Health facilities, mammography screening centers, pharmacies newly enrolling or revalidating via the CMS-855B application, organ procurement organizations, mass immunization roster billers, opioid treatment programs (if 42 C.F.R. Section 424.67(b)(3)(ii) applies), rural health clinics, radiation therapy centers, religious non-medical health care institutions, and skilled nursing facilities.
2. **Moderate:** community mental health centers, comprehensive outpatient rehabilitation facilities, hospices, independent diagnostic testing facilities, independent clinical labs, portable X-ray suppliers, ambulance service suppliers, physical therapists and groups, revalidating home health agencies (HHAs), revalidating Medicare Diabetes Prevention Program (MDPP) suppliers, revalidating durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) suppliers, prospective (newly enrolling) opioid treatment programs that have been fully and continuously certified by the Substance Abuse and Mental Health Services Administration (SAMHSA) since Oct. 23, 2018, and revalidating opioid treatment programs.
3. **High:** newly enrolling HHAs, MDPP suppliers, DMEPOS suppliers, and opioid treatment programs that have not been fully and continuously certified by SAMHSA since Oct. 23, 2018, providers or suppliers who have had a payment suspension or final adverse action within the last 10 years, providers or suppliers who have been

excluded from Medicare by the OIG, had billing privileges revoked within the last 10 years, have been terminated or otherwise precluded from billing Medicaid, have been excluded from any federal health care program, have been subject to any final adverse action within the last 10 years, and providers or suppliers who apply for enrollment within six months of the lifting of a temporary moratorium for such a provider or supplier type.

[42 C.F.R. Sections 424.518 and 455.450]

Effective Oct. 11, 2014, an applicant or provider is subject to the "high" risk level of screening if the provider category is designated by the DHCS as "high risk." Additionally, any applicant can be subject to the high risk level of screening if any of the following applies:

1. A payment suspension was imposed on the applicant based on a credible allegation of fraud, waste, or abuse.
2. The applicant has an existing Medicaid overpayment based on fraud, waste or abuse.
3. The applicant has been excluded by the federal Office of Inspector General or another state's Medicaid program within the previous 10 years.
4. CMS within the last six months has lifted a temporary moratorium on the particular provider type that the applicant is applying as.

[Welfare and Institutions Code Section 14043.38]

Since Jan. 1, 2013, all providers categorized as high risk have been required to submit fingerprints for criminal background checks within 30 days of a request by the department [Welfare and Institutions Code Section 14043.38]. The requirement also applies to individuals who hold a five percent or more direct or indirect ownership interest in a high-risk provider but not the officers, directors or managing employees of such providers, except that if the provider is a non-profit Drug Medi-Cal Provider, the officers and executive director of the applicant will be subject to the requirement.

Effective Oct. 11, 2014, all applications submitted by an applicant categorized as high risk must include proof that fingerprints for all required individuals have been submitted by attaching a copy of a prefilled DOJ Request for Live Scan Service (BCIA 8016) form for each required individual [Welfare and Institutions Code Section 14043.38].

Provider types currently designated as high risk include newly enrolling home health agencies; newly enrolling Medicare diabetes prevention program suppliers; newly enrolling durable medical equipment suppliers; and newly enrolling opioid treatment programs that have not been fully and continuously certified by SAMHSA since Oct. 23, 2018 [42 C.F.R. 424.518(c)].

Providers who do not cooperate with the new screening procedures or pay the applicable screening fees will be denied enrollment or have their existing enrollment terminated [Welfare and Institutions Code Section 14043.26].

Application Fees

Beginning March 25, 2011, providers and suppliers were required to submit an application fee ($631 for 2022) or request a hardship exception with every Medicare application for initial enrollment, revalidation, addition of new practice locations or change of ownership where the

new provider is not accepting assignment of the current provider agreement. Applications will not be processed until the fee has been paid or a hardship exception has been granted. Failure to pay the fee or obtain a hardship exception will result in rejection of the application and, in the case of a revalidation application, revocation of existing billing privileges. The fee must be paid electronically at *https://pecos.cms.hhs.gov/pecos/feePaymentWelcome.do*.

The fee requirement does not apply to physician and non-physician practitioners unless they are enrolling as another type of supplier such as a DMEPOS vendor. [42 C.F.R. Section 424.514].

Welfare and Institutions Code Section 14043.25 will, effective upon approval of the applicable State Plan Amendment, require providers and suppliers to submit this fee along with any Medi-Cal enrollment applications. As of this printing, Medi-Cal will accept only a cashier's check to pay the fee when the application is submitted in paper or will accept electronic funds transfers if the application is submitted through the Provider Application and Validation for Enrollment (PAVE) system. However, the application fee will not be collected from individual physicians or non-physician practitioners or from providers that already submitted the fee along with another Medicare or state Medicaid application. If the fee was already paid with another application, Medi-Cal will require proof of payment [Welfare and Institutions Code Section 14043.25].

Enhanced Oversight/Provisional Period

Under ACA, new providers are supposed to be subject to a period of enhanced oversight for 30 days to one year. This period of enhanced oversight will include prepayment reviews and/or payment caps. The final regulations did not address this provision in ACA.

Temporary Moratoriums

ACA authorizes CMS to impose temporary moratoria on the enrollment of new Medicare, Medicaid or Children's Health Insurance Program (CHIP) providers and suppliers or new locations for these providers in six-month increments based on any of the following:

1. Data that identify a trend associated with a high risk of fraud, waste or abuse;
2. A state Medicaid program has imposed a moratorium on a particular group of providers/suppliers;
3. A state Medicaid program has imposed a moratorium on a particular geographic area or provider type; or
4. CMS and the OIG or DOJ identifies a geographic area or provider type as having a significant potential for fraud, waste or abuse.

[42 C.F.R. Section 424.570]

The moratoriums will not apply to relocations, changes of ownership, mergers or consolidations. While there will be no judicial review of the creation of moratoriums, an administrative appeal will be available for adverse determinations based on the imposition of the moratoriums. Implementation of moratoriums will be announced in the Federal Register but there will not be an opportunity for public comment. State Medicaid programs must establish corresponding moratoriums. [Welfare and Institutions Code Section 14043.55]

Payment Suspensions

CMS may suspend payments to a provider pending an investigation of a credible allegation of fraud unless the Secretary determines that there is good cause not to suspend payments [Health and Safety Code Section 100185.5, Welfare and Institutions Code Section 14107.11].

The final regulations define "**credible allegation of fraud**" to include an allegation from any source, including, but not limited to, fraud hotline complaints, claims data mining, patterns identified through provider audits, civil false claims cases, and law enforcement investigations that have an "indicia of reliability." [76 Fed. Reg. 5862, 5929 (Feb. 2, 2011) (amending 42 C.F.R. Section 405.370)]

Additionally, states will not receive matching Federal Financial Participation (FFP) payments if they fail to suspend payments to providers when there is a pending investigation of a credible allegation of fraud and no good cause exception applies [76 Fed. Reg. 5862, 5932 (Feb. 2, 2011)].

Compliance Programs

As a new condition of enrollment under ACA, providers will be required to implement a compliance program containing the core elements established by the Secretary in consultation with OIG. Although the Secretary has not published mandatory compliance program regulations for health care providers, OIG has issued a series of voluntary compliance program guidance documents for various health care organizations at https://oig.hhs.gov/compliance/compliance-guidance/index.asp. *(See also chapters 1 and 2 regarding elements of a compliance program and board responsibilities for compliance.)*

Ordering/Referring Provider Enrollment

Effective July 6, 2010, physicians who refer or order certain Part B items or services for Medicare beneficiaries are required to enroll in Medicare.

The interim final rule was published on May 5, 2010, at 75 Fed. Reg. 24437. A final rule finalizing several provisions implemented in the interim final rule was published on April 27, 2012, at 77 Fed. Reg. 25284. The enrollment requirement applies to Part B DMEPOS, Part A and Part B HHA services and Part B laboratory and imaging supplier services, but provides an exception for physicians and non-physician practitioners who opt out of Medicare if specific requirements are met. This requirement was also to be applied to prescribers of Part D Drugs and providers of Part C services but now is no longer the case as the enrollment requirement has been replaced by a preclusion list. [83 Fed. Reg. 16440 (April 16, 2018)] *(For more information, see MLN Resource — Medicare Provider Enrollment; Providers who Solely Order or Certify, https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/EnrollmentResources/provider-resources/Med-Prov-Enroll-MLN9658742.html)*

CMS implemented this requirement in two phases. Initially, when a claim was submitted with missing, incomplete or invalid information, or when the ordering/referring provider was not eligible to order or refer, the billing provider received an information message on an adjusted claim indicating that the claim did not pass the edits. In the second phase of implementation, beginning in 2014, CMS turned on the edits and began denying Part B clinical laboratory and imaging, DME and Part A HHA claims when the claims failed the order/referring edit — that is, when the ordering/referring provider was not enrolled in Medicare.

The Medicare enrollment application for ordering/referring providers is CMS 855O.

Terminations from Medicare and/or Medicaid

CMS allows contractors to revoke a provider's Medicare billing privileges when any state Medicaid agency terminates, revokes, or suspends the provider's Medicaid enrollment or billing privileges. [42 C.F.R. Section 424.535]

Misrepresentations

Effective March 23, 2010, the Secretary has been given the authority to exclude providers from participating in any federal health care program if they knowingly make false statements, omissions, or misrepresentations of a material fact in any contract or bid regarding, or on any application to enroll or participate in, any federal health care program, including Medicaid. [42 U.S.C. Section 1320a-7(b)(16)]

On Dec. 5, 2014, CMS issued a Final Rule [79 Fed. Reg. 72500] that implemented provider enrollment provisions giving CMS the following additional enforcement tools:

1. Ability to deny enrollment to a provider, supplier or owner with an unpaid Medicare debt, or one who previously had an ownership interest in a provider or supplier with an unpaid Medicare debt based on certain factors listed in the regulation.
2. Ability to deny enrollment or revoke billing privileges of a provider or supplier if a "managing employee" has been convicted within the previous 10 years of a felony offense that CMS determines is detrimental to the best interests of the Medicare program and its beneficiaries.
3. Ability to revoke billing privileges of providers or suppliers that have a pattern or practice of billing for services that do not meet Medicare requirements.

Provider-Based Physicians

Physician billing privileges are effective the later of either:

1. The date of filing of a Medicare enrollment application that was subsequently approved by a Medicare contractor; or
2. The date that the supplier first began furnishing services at a new practice location.

[42 C.F.R. Section 424.520]

B. Denial of Enrollment and Loss of Ability to Bill

Denial of Enrollment

CMS may deny a provider's enrollment application for any of the following reasons:

1. **Noncompliance.** The provider is found out of compliance with the applicable Medicare enrollment requirements and has not submitted a plan of correction.
2. **Provider or supplier conduct.** The provider or supplier, or any owner, managing employee, authorized or delegated official, medical director, supervising physician, or other health care or administrative or management services personnel furnishing services payable by a Federal health care program, of the provider or supplier is excluded from the Medicare, Medicaid or any other federal health care program, debarred, suspended or otherwise excluded from participating in any other federal procurement or nonprocurement activity.
3. **Felonies.** Within the 10 years preceding the provider's enrollment or revalidation of enrollment, the provider or any of its owners was convicted of a federal or state

felony considered to be detrimental to the best interests of the Medicare program (which include, for example, violent felonies, extortion, embezzlement, fraud or criminal neglect or misconduct). This section was revised in December of 2014 to include felony convictions of "managing employees."

4. **False information.** The provider submitted false or misleading information on the enrollment application or failed to disclose ownership and control interests.
5. **On-site review.** Upon an on-site review or other reliable evidence, CMS determines that the provider is either not operational, or is not meeting the enrollment or participation requirements (including compliance with civil rights requirements).
6. **Medicare debt.** The enrolling provider, supplier, or owner (as defined in 42 C.F.R. Section 424.502), has an existing Medicare debt at the time of filing of an enrollment application that has not been paid in full. In MLN Matters, Article MM8039, dated Oct. 17, 2013, CMS clarified that denials will not be issued to individuals or entities on a Medicare-approved repayment plan or whose overpayments are currently being offset or appealed. This section was revised in December of 2014 to include debts owed by providers or suppliers previously owned by the enrollee based on specific criteria listed in the regulation.
7. **Payment suspension**. The provider or supplier, or any owning or managing employee or organization of the provider or supplier has been placed under a Medicare or Medicaid payment suspension as defined in 42 C.F.R. Sections 405.370-405.372 or in 455.23.
8. Insufficient initial reserve operating funds for HHAs as required by 42 C.F.R. Section 489.28(a).
9. Failure to submit application fee or be granted a hardship exception.
10. Temporary moratorium imposed by CMS for specific geographic area.
11. Prescription authority has been suspended or revoked by DEA.
12. Provider is currently revoked under a different name, numerical identifier, or business identity and the reenrollment bar period has not expired.
13. Affiliation under 42 C.F.R. Section 424.519 that poses undue risk of fraud, waste, or abuse to the Medicare program.
14. Other program termination or suspension in a state Medicaid program or any other federal health care program, or the provider's license is currently revoked or suspended in a different state than the one that the provider is currently attempting to enroll.
15. Patient harm (not directly applicable to hospitals).

[42 C.F.R. Sections 424.530 and 489.12]

Revocation of Enrollment and Billing Privileges

CMS may revoke a currently enrolled provider's billing privileges and corresponding enrollment agreement for any of the following reasons:

1. The same first five reasons listed above for denial of an enrollment application.

2. **Failure to submit application fee.** An institutional provider does not submit an application fee or is not granted a hardship exception with its Medicare revalidation application.
3. **Misuse of billing number.** The provider knowingly sells, or allows another person or entity to use, its provider number.
4. **Abuse of billing privileges.** The provider submits a claim or claims for services that could not have been furnished to a specific individual on the date of service. This section was revised in December of 2014 to include providers that have a pattern or practice of submitting claims that fail to meet Medicare requirements.
5. **Failure to report.** The provider did not comply with the reporting requirements specified in 42 C.F.R. Section 424.516(d)(1)(ii) and (iii).
6. **Failure to document.** The provider did not comply with the documentation requirements specified in 42 C.F.R. Section 424.516(f).
7. **Failure by a Home Health Agency (HHA) to meet the initial reserve operating funds requirements.** The HHA provider cannot furnish supporting documentation verifying that it meets the initial reserve operating funds requirement found in 42 C.F.R. Section 489.28(a) within 30 days of a CMS or Medicare contractor request.
8. **Medicaid Termination.** The provider's Medicaid billing privileges are terminated or revoked by a state Medicaid agency.
9. Prescribing authority suspended or revoked by DEA.
10. **Improper prescribing practices.** CMS determines that there has been a pattern or practice of prescribing Part B or D drugs that either:
    a. Is abuse or represents a threat to the health and safety of Medicare beneficiaries or both, or
    b. Fails to meet Medicare requirements.
11. Existing debt referred to the US Department of Treasury.
12. Provider is currently revoked under a different name, numerical identifier, or business identity and the re-enrollment bar period has not expired.
13. Affiliation under 42 C.F.R. Section 424.519 that poses undue risk of fraud, waste, or abuse to the Medicare program.
14. Billing from non-compliant location.
15. Abusive ordering, certifying, referring, or prescribing of Part A or B services, items or drugs.
16. Patient harm (not directly applicable to hospitals).

[42 C.F.R. Section 424.535]

Deactivation of Billing Privileges

CMS may deactivate a provider's billing privileges for any of the following reasons:

1. **Claims.** The provider does not submit any claims for 12 consecutive calendar months.

2. **Information changes.** The provider does not report changes to the previously supplied information on the enrollment application within the required time period. For example, changes in practice location, managing employee, or billing service must be reported within 90 calendar days and changes in ownership or control must be reported within 30 calendar days.
3. Incomplete or inaccurate information. The provider does not furnish complete and accurate Information and all supporting documentation within 90 calendar days of receipt of notification from CMS to submit an enrollment application and supporting documentation, or resubmit and certify to the accuracy of Its enrollment Information.
4. Not in compliance. The provider Is not In compliance with all enrollment requirements.
5. Non-operational practice location. Provider's practice location is non-operational or otherwise invalid.
6. Deceased. The provider Is deceased.
7. Voluntary withdraw. The provider Is voluntarily withdrawing from Medicare.
8. HHA Seller. The provider Is the seller In an HHA change of ownership under 424.550(b)(1).

[42 C.F.R. Section 424.540]

Revocation Versus Deactivation

When a provider's billing privileges are revoked, any participation agreement in effect at the time of revocation is terminated effective on the date of revocation [42 C.F.R. Section 424.535(b)]. If the provider elects to re-establish enrollment, it must re-enroll by submitting a new complete enrollment application. In this context, the provider must be resurveyed and recertified by the state survey agency or a private accrediting organization as a new provider and will be required to enter into a new participation agreement with CMS [42 C.F.R. Section 424.535(d)].

If, in contrast, a provider's provider number and billing privileges are deactivated (as distinct from revoked), the provider can seek reactivation of its billing privileges by submitting a new enrollment application to reactivate its billing privileges or, at a minimum, to recertify that the enrollment information on file is correct. In this context, the provider (except for an HHA) is not required to obtain a new certification or enter into a new participation agreement with CMS. However, an HHA must obtain an initial state survey or accreditation by an approved accreditation organization before its Medicare billing privileges can be reactivated. [42 C.F.R. Section 424.540]

C. Changes of Ownership

Medicare billing numbers (also referred to as provider numbers) are not transferable without the prior approval of CMS [42 C.F.R. Section 424.550(a)]. Providers are prohibited from selling their billing numbers or privileges and/or allowing another individual or entity to use their Medicare billing numbers. When a hospital undergoes a change of ownership for Medicare certification purposes, the current owner and the prospective new owner must submit the appropriate CMS 855A applications to the MAC before the change of ownership

occurs [42 C.F.R. Section 424.550(b)]. CMS has instructed CDPH to not issue a new hospital license to a prospective new owner of a hospital until the MAC has reviewed and recommended approval of the CMS 855A change of ownership application. As a result, the CMS 855A change of ownership application should be sent to the MAC at least 60-90 days before the proposed effective date of the change in ownership. Moreover, under 42 C.F.R. Section 424.516(e)(1), notification must be given to CMS within 30 days of a change of ownership or control.

As with licensing, there is a distinction between a change of ownership and a change of information. CMS defines a **"change of ownership"** at 42 C.F.R. Section 489.18 as:

1. **Partnership.** In the case of a partnership, the removal, addition, or substitution of a partner, unless the partners expressly agree otherwise, as permitted by state law.
2. **Unincorporated sole proprietorship.** The transfer of title and property to another party.
3. **Corporation.** The merger of the provider corporation into another corporation, or the consolidation of two or more corporations, resulting in the creation of a new corporation. The transfer of corporate stock or the merger of another corporation into the provider corporation does not constitute change of ownership.
4. **Leasing.** The lease of all or part of a provider facility constitutes change of ownership of the leased portion.

Medicare's change of ownership requirements are also outlined in the instructions to the applicable CMS 855A application.

Automatic Assignment of Medicare Agreement

Under 42 C.F.R. Section 489.18(c), when an enrolled provider is acquired, CMS automatically assigns the current Medicare provider agreement to a new owner, unless the new owner rejects automatic assignment. Assignment of the Medicare agreement results in uninterrupted participation of the acquired provider or supplier in the Medicare program and extension of the deemed status from the accrediting body until it decides whether a resurvey is necessary.

While automatic assignment allows an acquiring provider to continue to bill for services uninterrupted with the target's existing enrollment numbers, it also subjects the acquiring provider to potential overpayments, underpayments and civil monetary penalties, even when related to periods of time prior to the acquisition [Sept. 6, 2013, CMS policy memorandum to State Survey Agency Directors (Ref: S&C: 13-60-ALL)].

Rejection of Automatic Assignment of Medicare Agreement

Rejection of assignment results in a termination of the prior Medicare agreement, in accordance with 42 C.F.R. Section 489.52, and as a result the acquired facility will be treated as an initial applicant when it seeks to participate in the Medicare program. Initial applicants are not eligible for Medicare reimbursement unless and until they are determined to be in compliance with all federal requirements. This policy applies equally to a hospital that is acquired by another hospital and made a provider-based facility to the acquiring facility. Therefore, once the acquiring owner rejects assignment of an agreement, the effective date for the new Medicare participation (and therefore, eligibility for reimbursement) will be the date the facility under the new ownership is determined to meet all applicable federal requirements, not the date of acquisition. [Ref: S&C: 13-60-ALL]

While rejection of automatic assignment and voluntary termination will generally protect the buyer from assuming successor liability for Medicare overpayments or civil monetary penalties, it also subjects the acquiring provider to significant delays in enrollment and eligibility for reimbursement.

The most significant negative consequences of rejecting assignment is that the CMS approved Medicare accreditation program may not "extend" prior accreditation to the new owner. Instead, the provider must undergo a full unannounced initial accreditation or certification survey in accordance with 42 C.F.R. Section 489.10. Additionally, in the Sept. 6, 2013, CMS policy memorandum to State Survey Agency Directors (Ref: S&C: 13-60-ALL), CMS listed several survey timing requirements that will greatly increase the period of time a buyer of a provider would not be able to obtain reimbursement for Medicare services. Specifically:

1. An initial survey may not be performed until after the applicable MAC has issued its recommendation for approval of the new owner's 855 enrollment application.
2. The MAC has been instructed to not review the new owner's 855 enrollment application until after the acquisition has occurred. (This instruction directly contradicts prior policy, which allowed for the submission and processing of both initial and CHOW applications prior to the effective date of a sale transaction.)
3. Any survey performed within two weeks or less following the acquisition date may not be considered by CMS to be unannounced and may, therefore, not be accepted as evidence of deemed status or compliance with the Medicare conditions of participation.
4. CMS also expects that the workload priorities set forth in its Nov. 5, 2007 policy memorandum to State Survey Agency Directors (Ref: S&C-08-03) be followed. Pursuant to such guidance, initial surveys are generally the lowest workload priority.

[Ref: S&C: 13-60-ALL]

Acquisition and Merger of Hospitals

An owner of an existing Medicare-participating hospital (Hospital A) may acquire another Medicare-participating hospital (Hospital B) and make Hospital B a remote location or second campus of Hospital A, effectively treating Hospital B as a Campus (Campus) of Hospital A following the acquisition. In this situation, Hospital A has two options:

1. Hospital A may accept assignment of Hospital B's Medicare provider agreement and either continue to bill for services at that location with Campus's provider number or treat Campus as a provider-based location and hold claims until approved to bill for services rendered at Campus under the Hospital A certification. By accepting assignment of the Hospital B provider agreement, there should be no interruption in the Medicare participation of Campus, although as outlined above, there will be a delay in payment to Hospital A for services rendered at the Campus post-closing that are billed under the Hospital A provider number.
2. Hospital A could reject assignment and instead add Campus to Hospital A's existing provider agreement. However, this would require following the same process used for initial applicants and Hospital A would not be eligible to bill or be reimbursed for services rendered at Campus until completion of a full certification survey and enrollment process for the additional Campus.

[Ref: S&C: 13-60-ALL]

CMS has clarified its policy regarding how Medicare uncompensated care payments are handled when two Medicare participating hospitals are merged. Specifically, when there is a hospital merger and the surviving hospital accepts assignment of the provider agreement of the merging or disappearing hospital, the historic data associated with the merging hospital will be transferred over and brought under the provider agreement of the surviving hospital such that the post-merger hospital gets the benefit of the historic data of both merged hospitals. This is important because Medicare uncompensated care payments are based on historical data. If the surviving hospital in the merger context does not accept assignment of the provider agreement of the merging hospital, then the merging hospital is essentially treated as a new hospital (or hospital campus) and its historic uncompensated care data is lost. Depending on the data associated with the merging hospital, this could serve to reduce the total uncompensated care payments available to the surviving hospital for several years.

Compliance Tip: It is important for hospitals to consider the impact of all possible changes of ownership, including, but not limited to mergers, on Graduate Medical Education (GME) payments and on DSH payments. *See Chapter 5 for more information about these issues.*

D. Provider-Based Rules

Hospitals often purchase or establish services at locations outside the main hospital and sometimes beyond the hospital campus. For Medicare purposes, such hospitals can elect for these additional services or locations to either be freestanding or treated as part of the Medicare certified hospital. In order for the services and/or locations to be treated as part of the Medicare certified hospital, they must satisfy Medicare's provider-based rule and be operated as provider-based services or locations. Examples of provider-based services include departments of a hospital that furnish specialty services (for example, diagnostic or therapeutic radiology services). Provider-based sites can take a number of different forms, including remote inpatient hospital locations, satellite facilities or hospital outpatient departments. A hospital typically receives greater reimbursement for a provider-based service or location than if such services or locations were operated as freestanding.

Because provider-based facilities often receive higher reimbursement, CMS requires that a provider-based facility meet certain standards to establish that it is an integral and subordinate part of the main hospital such that services rendered at the provider-based location can be billed using the main hospital's Medicare provider number. To obtain provider-based status, a hospital department or remote location must:

1. Meet certain licensure requirements;
2. Be under the ownership and control of the main provider;
3. Have a specified reporting relationship with the main provider;
4. Share integrated clinical services;
5. Be fully financially integrated within the main provider's financial system; and
6. Be held out to the public as a single entity with the main provider.

In addition, if the provider-based facility is not located on the main hospital's campus or if it is operated as a joint venture or pursuant to a management agreement, additional requirements must be satisfied. The requirements that provider-based entities must meet are found at 42 C.F.R. Section 413.65.

In the Bipartisan Budget Act of 2015, enacted on Nov. 2, 2015, Congress established a new payment policy to reduce reimbursement at certain off-campus hospital outpatient departments. Specifically, Section 603 provides that off-campus hospital outpatient departments that do not fit within Medicare's definition of a dedicated emergency department and that were not billing Medicare under the outpatient prospective payment system (OPPS) prior to Nov. 2, 2015, are no longer be eligible for reimbursement under OPPS beginning Jan. 1, 2017, and instead are only eligible for a percentage of the OPPS reimbursement that otherwise would be available in an excepted or grandfathered provider-based department. Currently, such non-excepted, off-campus hospital outpatient departments are eligible for payment at approximately 40 percent of the OPPS rate.

On Nov. 2, 2016, CMS released its interim final rule implementing Section 603 as part of the 2017 OPPS final rule. Pursuant to this rule, when a hospital undergoes a CHOW, the Section 603 grandfathering of its outpatient off-campus clinics will survive only if the buyer accepts assignment of the hospital provider agreement. Further, the exception for off-campus, outpatient departments can survive a change of ownership only if both the hospital and its outpatient departments are transferred together; excepted or grandfathered clinics spun-off from a hospital and acquired by another hospital will lose their grandfathering. The final rule also clarified that an outpatient, off-campus department's excepted status is limited to the physical location of the clinic as of Nov. 2, 2015. While the exemption is generally limited to the grandfathered physical location, the final OPPS rule for CY 2017 permits the Section 603 exception to remain for an off-campus outpatient department that must relocate because of "extraordinary circumstances" that are beyond the hospital's control, such as natural disasters, seismic building code requirements or significant public health or safety issues. CMS has indicated that hospitals with pending requests for a relocating exception should use the PN modifier for non-excepted services as of Jan. 1, 2017, and if such requests are ultimately approved, work with the Medicare contractor to re-bill for these services. For relocations that occur after Jan. 1, 2017, hospitals are instructed to submit a relocation exception request no later than 30 days after the extraordinary circumstance occurred. If approved, the regional office will determine the effective date, which, pursuant to guidance from CMS, will be the later of the date of the relocation or the date of the request. As such, whenever possible, relocation requests should be submitted and received by CMS on or before the actual relocation date. At a minimum, the relocation exception request should include basic information about the hospital including its name, CMS certification number, provider contact, excepted and new addresses, the type of department that has relocated, where the department is relocating, and a detailed explanation of the rare and unusual circumstance that gave rise to the need to relocate. CMS has stated that the hospital can submit additional or supplemental information with the request. The relocation exception request must also be signed and certified as accurate, complete and current by the chief executive officer, administrator or other authorized person on behalf of the provider. CMS has indicated that relocation exception requested will be granted only in "limited and rare" circumstances.

Lastly, sections 16001 and 16002 of, the 21st Century Cures Act, enacted into law on Dec. 13, 2016, amended Section 1833(t)(21) of the Social Security Act to except certain mid-build, off-campus provider-based departments and certain cancer hospitals from Section 603. Of note, Section 16001 contemplates continuing Medicare payment under OPPS for services furnished by "mid-build" off-campus outpatient departments of providers. The mid-build requirement is defined at Social Security Act Section 1833(t)(21)(B)(v) and requires that a main provider had a binding written agreement in place with an outside unrelated party for the actual construction of an off-campus outpatient department before Nov. 2, 2015. A hospital that met this mid-build requirement must have submitted to its Medicare Administrative Contractor, no later than Feb. 13, 2017, a prover-based attestation that the off-campus department meets the requirements of 42 C.F.R. Section 413.65 and a written certification signed by the chief executive officer or chief operating officer of the main provider (or equivalent if different titles are used) that the department met the mid-build requirements. In addition, the provider must include this department as part of its enrollment file.

Effective Jan. 1, 2017, hospitals will continue to be able to bill and be paid for the technical component of services rendered at non-exempt off-campus outpatient departments using a newly established "PN" modifier. Pursuant to the final OPPS rule for 2019, payment for these claims will be made approximately 40 percent of the full OPPS rate.

E. PPS-Exempt Units

Basics

Hospitals are reimbursed for inpatient services rendered to Medicare beneficiaries based on the Inpatient Prospective Payment System (IPPS). The IPPS rate represents the average cost, nationwide, of treating a Medicare beneficiary according to his or her medical condition. The basis of payment under IPPS is classification of a patient's case into a Medicare Severity-Diagnosis Related Group (MS-DRG). The amount of reimbursement a hospital receives under the IPPS is generally calculated by multiplying the MS-DRG weight by a "standardized amount."

Payment under IPPS may also be adjusted if the hospital:

1. Serves a high percentage of low-income patients, known as the "disproportionate share hospital (DSH) adjustment";
2. Is an approved teaching hospital, known as the "indirect medical education (IME) adjustment"; and/or
3. Has actual costs for caring for a patient that exceed the total payment received by Medicare plus a fixed dollar amount (outlier cases).

(See chapter 5 for details about DSH, IME and outlier payments.)

"PPS-exempt units" are psychiatric units or rehabilitation units that are excluded from reimbursement under the inpatient hospital prospective payment system. They are paid under either the inpatient psychiatric facility prospective payment system or the inpatient rehabilitation facility prospective payment system [42 C.F.R. Section 412.25(a)]. A hospital may have only one PPS-exempt psychiatric unit and one PPS-exempt rehabilitation unit [42 C.F.R. Section 412.25(d)].

In order to be certified as a PPS-exempt psychiatric or rehabilitation unit, the unit must:

1. Be part of a hospital that:
    a. Participates in the Medicare program,
    b. Prior to Oct. 1, 2019, was not excluded in its entirety from the prospective payment system, and
    c. Has enough beds that are not excluded from the prospective payment system that it can maintain adequate cost information;
2. Have written admission criteria that apply uniformly to both Medicare and non-Medicare patients;
3. Have admission and discharge records that are readily available and separately identified from those of the hospital;
4. Have policies specifying that necessary clinical information is transferred to the unit when a patient of the hospital is transferred to the unit;
5. Meet applicable state licensure laws;
6. Have utilization review standards applicable for the type of care offered in the unit;
7. Have beds physically separate from the hospital's other beds;
8. Have the same fiscal intermediary or MAC as the hospital;
9. Be treated as a separate cost center for cost finding and apportionment purposes;
10. Use an accounting system that properly allocates costs;
11. Maintain adequate statistical data to support the basis of allocation;
12. Report its costs in the hospital's cost report covering the same fiscal period and using the same method of apportionment as the hospital; and
13. As of the first day of the first cost reporting period for which all other exclusion requirements are met, be fully equipped, staffed and capable of providing hospital inpatient psychiatric or rehabilitation care.

[42 C.F.R. Section 412.25(a)]

While outside the scope of this chapter, it is important to note that the following specific types of hospitals may also qualify for PPS-exempt status: psychiatric hospitals, rehabilitation hospitals, children's hospitals, long-term care hospitals, cancer hospitals, hospitals outside the 50 states, the District of Columbia or Puerto Rico and hospitals reimbursed under special arrangements [42 C.F.R. Section 412.23(a)-(h)].

Changes in Status

The status of a hospital unit may be changed from "not exempt" to "exempt" only at the start of a cost reporting period. If a unit is added to a hospital after the start of a cost reporting period, it cannot be changed to exempt from inpatient PPS until the start of the hospital's next cost reporting period.

The status of a hospital unit may be changed from "exempt" to "not exempt" at any time during a cost reporting period if the hospital notifies the MAC and the CMS Regional Office in writing of the change at least 30 days *before* the date of the change. A change in the status

of a unit from "exempt" to "not exempt" that is made during a cost reporting period must remain in effect for the remainder of that cost reporting period. [42 C.F.R. Section 412.25(c)]

Changes in Size

Changes in the number of beds or square footage of an excluded unit can be made one time at any time during a cost reporting period if the hospital notifies its MAC and the CMS Regional Office in writing of the planned change at least 30 days before the date of the change. The hospital must maintain the information needed to accurately determine costs that are attributable to the excluded unit, and any such change in bed size or square footage must remain in effect for the rest of that cost reporting period.

Changes in bed size or square footage may be made at any time if these changes are made necessary by relocation of a unit:

1. To permit construction or renovation necessary for compliance with changes in federal, state or local law affecting the physical facility; or
2. Because of catastrophic events such as fires, floods, earthquakes, or tornadoes.

[42 C.F.R. Section 412.25(b)]

F. COVID and Hospital Medicare Certification Waivers

Following the Secretary of the U.S. Department of Health and Human Service's declaration of a nationwide public health emergency (PHE) in response to the spread of the COVID-19 virus, and pursuant to its Section 1135 waiver authority, CMS issued numerous COVID-19 blanket waivers with retroactive effect of March 1, 2020. *(See https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf.)* The purpose of the blanket waivers was to provide regulatory flexibilities to help healthcare providers limit the spread of COVID.

Of particular note for hospitals, the COVID waivers allow hospitals to: provide care in temporary expansion sites, such as in the home; use provider-based departments as temporary expansion sites (as the provider-based department requirements are temporarily waived) to expand capacity and flexibility for relocating existing or creating new provider-based departments; and numerous provider enrollment requirements have been waived. For example, CMS has waived certain enrollment screening requirements (i.e., application fee, criminal background checks associated with fingerprint-based criminal background checks, and site visits), postponed all revalidation actions, and expedited pending or new application from providers.

Hospitals opting to operate under these waivers and flexibilities should understand:

1. That these waivers and flexibilities are constantly being adjusted to account for changes in circumstances throughout the duration of the PHE, and
2. The waivers and flexibilities are time-limited, in that they are connected to the federal declaration of the PHE.

Upon the expiration of the PHE, hospitals that relied on the waivers and flexibilities should be prepared to unwind any changes that were made in reliance on those flexibilities or to follow any specifically-prescribed processes for unwinding such changes. The Secretary of HHS has stated that he expects the waivers to continue through the some portion if

not all of 2021, and he will provide 60 days' notice of termination. For more information on the specific waivers and flexibilities relevant to hospitals, visit https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers.

IX. MEDI-CAL ENROLLMENT AND CERTIFICATION

Medi-Cal enrollment and certification for hospitals is generally processed by, and tracks the process of, CDPH licensing and Medicare enrollment. The enrollment and certification forms that must be completed and submitted to start the process are included as part of the CDPH licensing application and certification package. Medi-Cal certification generally follows the Medicare certification process and is based on the CMS Medicare certification Tie-In Notice (Form CMS-2007).

Historically, for hospitals, Medi-Cal followed the Medicare rules regarding changes of ownership. When undergoing a change of ownership, a hospital that had a Medi-Cal contract under the Medi-Cal Selective Provider Contracting Program (SPCP) was required to review the provisions of the seller's existing contract to ensure that timely and appropriate notice of the change of ownership was given to the California Medical Assistance Commission (CMAC). CMAC was dissolved and its powers, duties and responsibilities transferred to DHCS. The Medi-Cal DRG system went into effect for private hospitals on July 1, 2013, and for non-designated public hospitals on Jan. 1, 2014, replacing the SPCP and the cost-based reimbursement system for noncontract hospitals. [Welfare and Institutions Code Section 14165(b)(3)]

The impact of a change of ownership and the buyer's willingness to accept responsibility for a seller's Medi-Cal liabilities continues to be relevant for purposes of California's Hospital Quality Assurance Fee (QAF). In a hospital sale transaction, if the seller has an outstanding monetary obligation owed to the state in connection with the Medi-Cal program, and the buyer does not agree to be financially responsible to the state for this obligation, the buyer will be considered a "new hospital" under the QAF program and will not be eligible to participate in the QAF program immediately following the hospital acquisition. Instead, the "new hospital" will have to wait several years until it can establish participation in the QAF program based on its own data source from a period when it operated the hospital. Depending on when a transaction occurs, whether the buyer has a "days data source" during a time when it owned the hospital could impact multiple QAF program periods. Ultimately, a buyer that desires to participate in the QAF program and avoid being treated as a "new hospital" should affirm and document with DHCS that it is agreeing to be financially responsible to the state for any seller outstanding monetary liability in connection with the Medi-Cal program.

In a provider bulletin dated May 13, 2016, which supplements and modifies a prior bulletin issued on Aug. 26, 2014, DHCS set forth a process that a prospective new hospital owner can use in order to assume financial responsibility for the seller's Medi-Cal obligations so as to avoid being treated as a "new hospital" for QAF purposes. Specifically, for changes of ownership that occurred after publication of the May 13, 2016, bulletin, a new hospital owner that would like to continue to receive QAF payments and pay fees based on data from when the hospital was operated by the prior owner must submit a signed, complete and correct Financial Responsibility Agreement to DHCS within 30 days of the date of the

letter from the state granting the new owner Medi-Cal certification. If this is done in a timely manner, the hospital will be able to continue to participate in the QAF program under its new ownership without interruption. If the new owner does not submit a Financial Responsibility Agreement within this 30 day period, it will not be eligible to receive and retain any QAF supplemental payments retroactive to the change of ownership date and instead, it will be eligible to continue to participate in the QAF program and receive supplemental QAF payments only from the date DHCS receives a complete and correct Financial Responsibility Agreement. According to the bulletin, even though a new owner will be eligible to receive supplemental QAF payments only from the date DHCS receives the complete and correct Financial Responsibility Agreement, the new owner will still be required to continue to pay QAF fees retroactively to the CHOW date. This is a significant penalty for the late submission of the Financial Responsibility Agreement. Hospitals undergoing CHOWs should be vigilant in watching out for the Medi-Cal certification letter from the state, often sent many months after a CHOW has occurred, to avoid missing this important deadline.

A new owner of a hospital that underwent a CHOW before the publication of the May 13, 2016, provider bulletin had a one-time ability to submit a Financial Responsibility Agreement on or before Sept. 30, 2016, in order to continue to participate in QAF program. Pursuant to the May 2016 bulletin, a prospective buyer is no longer required to provide notice to DHCS at least 60 days in advance of the CHOW date or to submit a Public Records Act request to DHCS as originally contemplated in the Aug. 26, 2014, bulletin.

The 2016 DHCS bulletin also outlines a process by which a new owner can seek to designate itself a new hospital for QAF purposes. A hospital that is a "new hospital" does not participate in the QAF program under the statute, such that it does not pay QAF fees to the state nor is it eligible to receive supplemental Medi-Cal payments. A new owner that wishes to be treated as a new hospital must submit an attestation to DHCS, attesting that it meets the definition of a new hospital and signed under penalty of perjury, within 30 days of the date of the letter from the state notifying the new owner of its Medi-Cal certification.

Additionally, CDPH now requires all institutional providers, including hospitals, to enter into and sign a new Medi-Cal provider agreement (form DHCS 9098). In response to concerns raised by CHA and others, DHCS revised the provider agreement, effective June 2010. The DHCS 9098 has been further revised as of July 2017.

For purposes of this chapter, we used Medicare's definition of providers and suppliers but it is worth noting that a **"provider"** for Medi-Cal purposes includes all types of participants (not just providers as defined under Medicare) and Medi-Cal does not use the term "supplier."

The Medi-Cal program's process and requirements for enrolling various types of noninstitutional providers that hospitals may operate, including, for example, clinics, pharmacies and laboratories, are complex and often are different from the Medicare process and requirements. A failure to comply strictly with the Medi-Cal program's enrollment rules, including Medi-Cal's change of ownership provisions, may have significant adverse consequences. A discussion of the Medi-Cal programs enrollment process for providers that are not enrolled in Medi-Cal as part of an enrolled hospital (but instead are separately enrolled) is beyond the scope of this chapter.

X. THE PATIENT PROTECTION AND AFFORDABLE CARE ACT (ACA) AS APPLIED TO MEDICAID

A. Generally

ACA requires all state Medicaid programs to comply with and impose the same screening processes, enhanced oversight, disclosure requirements, temporary moratoriums, and compliance program requirements on providers as Medicare. *(For more information, see IX. "Medi-Cal Enrollment and Certification," page 10.36. See also Welfare and Institutions Code Section 14043.38.)*

B. Order/Referring Provider Enrollment

ACA requires states to amend their state Medicaid plans to impose an enrollment requirement on all ordering or referring physicians or other professionals. In response, Medi-Cal has posted a new enrollment application form for ordering/referring/prescribing providers on its enrollment website. Prior to this ACA provision, California did not require ordering or referring providers to be enrolled as Medi-Cal providers, and downstream providers or suppliers were reimbursed by Medi-Cal for items or services that had been ordered or prescribed by the non-enrolled provider. The final regulations clarified that this requirement does not apply to managed care providers in risk-based plans. *(See www.medicaid.gov/Federal-Policy-Guidance/downloads/CIB-12-23-11.pdf; see also Welfare and Institutions Code Sections 14043.1 and 14043.15.)*

C. Notification of Terminations from Medicare and/or Medicaid

Effective Sept. 5, 2010, CMS established a process for providing each state Medicaid agency with a list including the name, NPI and other identifying information of all providers that have been terminated from participation from Medicare or the CHIP program. Contractors are required to notify CMS no later than the 5th of each month of all revocations/terminations and CMS will then notify the states.

D. Terminations from Medicaid

Effective Jan. 2, 2011, states are required to terminate the participation of any individual or entity who has been terminated from Medicare, or been terminated or had its billing privileges revoked under any other state Medicaid program. The final regulations stated that the terminations will apply to ALL enrollments held by a terminated provider but will not apply to the owners, controllers or managers of the terminated provider.

[42 C.F.R. Section 455.416(c)]

This requirement applies only when providers/suppliers have had their billing privileges revoked for cause, not when revocation was based solely on the failure to submit claims over a 12-month period or any other voluntary action taken by the provider to end its participation (unless voluntary action was taken to avoid a sanction). When the termination is based on another state's action, the termination can be imposed only after all available appeal rights have been exhausted in the originating state.

XI. OPEN ISSUES CURRENTLY UNDER REVIEW AT CDPH

A. Revisions to Hospital Licensing Regulations

CDPH is currently working to revise the regulations governing GACHs under Title 22. In 2018 and continuing in 2019 and 2020, as part of its efforts, the agency began actively seeking input from interested stakeholders to ensure that its proposed regulations are consistent with other laws and regulations, modern hospital practices, and other relevant standards. Interested stakeholders should monitor CDPH All Facilities Letters to learn about forthcoming opportunities to contribute to this process.

B. Potential Change of Ownership Regulations

CDPH has been considering whether to draft Change of Ownership regulations. CDPH held stakeholder meetings on Oct. 30, 2018 [AFL-18-42] and Nov. 15, 2019 [AFL-19-35]. This is a space to watch in the future.

C. Hospital Within a Hospital Requirements/Co-Location Requirements

CDPH has previously, and may again evaluate the licensing standards that apply to hospitals that are co-located within other hospitals. While Medicare has clear rules that govern PPS-exempt hospitals that are co-located with general acute care hospitals (referred to as hospitals-within-hospitals (HwHs) by Medicare), there are no corresponding California state laws. As a result, CDPH currently expects that when two hospitals are co-located, each hospital will independently satisfy the applicable licensing requirements, including the independent provision of all basic services required within the scope of licensure for that hospital. This is the case even if it will result in some duplication of basic services (like dietary) within the same building.

Beyond HwHs, in November 2021, CMS updated its guidance regarding the requirements that apply when two hospitals are co-located, even if both hospitals are regular acute care hospitals reimbursed under PPS [QSO-19-13-Hospitals-Revised]. . CMS has historically indicated that all co-located hospitals must independently satisfy the Medicare conditions of participation with all hospital certified space occupied by and under the control of the hospital certified entity 24 hours a day, 7 days a week, 365 days a year. The guidance recognizes that space, may be shared between the co-located providers, but notes that any non-compliance in that space could be problematic for both hospitals. CMS is also supportive of co-located providers sharing certain personnel and services, but maintains that each provider must independently meet minimum staffing requirements at all times. CMS has indicated that it will revise its State Operations Manual to address co-location directly, but no revisions have been issued at the date of publication of this manual.

APPENDIX HC 10-B

List of Miscellaneous Licenses

The list below reflects some of the various licenses, permits, and approvals commonly held by California hospitals.

Facility License
Program Flexibility Approval
Medicare Provider Number
Medi-Cal Provider Number
Pharmacy Permit
DEA Registration
Clinical Lab License
CLIA Certificate
Radioactive Material License
Radiation Machine Registration
Mammography X-Ray Equipment and Facility Accreditation
Mammography Accreditation
EPA ID
Large Quantity Medical Waste Generator Certificate
Medical Waste Common Storage Facility Permit
Flammable and Hazardous Materials Permit
Industrial Users Wastewater Discharge Permit
Permits to Operate Air Pressure Tank, Steam Boilers and Liquefied Petroleum Gas Tank
Business License (aka business tax certificate)
Sellers Permit
Accreditation Certificate
Underground Storage Tank Operating Permit
Application for Fuel Fee Tax Account Number
Fire Permit
Alarm Permit
Elevator Permit
Radio Station Authorization
Heliport Permit
Permit to Operate Food Facility
Weights and Measures Device Registration Certificate

FORM 20-1

Adverse Event Report Form — *Sample*

[HOSPITAL LETTERHEAD]

(Must include hospital name and address elsewhere if this form is not reproduced on hospital letterhead)

[Date of report]

State of California, Department of Public Health
Licensing and Certification District Office
[Street Address]
[City], CA [ZIP]

To Whom It May Concern:

This hospital believes it may have detected the adverse event indicated below as defined in Health and Safety Code Section 1279.1, and is hereby reporting pursuant to Health and Safety Code Section 1279.1.

Due to the short time frame required for reporting in the law, the information this hospital has may be incomplete. If further investigation shows that no adverse event as defined in this law took place, you will be notified. However, in order to comply with the law's short time frame, this hospital is taking a precautionary measure and reporting accordingly.

This hospital may have detected the adverse event checked below:

- ☐ 1. Surgery performed on a wrong body part that is inconsistent with the documented informed consent for that patient. This does not include a situation requiring prompt action that occurs in the course of surgery or a situation that is so urgent as to preclude obtaining informed consent.
- ☐ 2. Surgery performed on the wrong patient.
- ☐ 3. The wrong surgical procedure performed on a patient, which is a surgical procedure performed on a patient that is inconsistent with the documented informed consent for that patient. This does not include a situation requiring prompt action that occurs in the course of surgery or a situation that is so urgent as to preclude obtaining informed consent.
- ☐ 4. Retention of a foreign object in a patient after surgery or other procedure, excluding objects intentionally implanted as part of a planned intervention and objects present prior to surgery that are intentionally retained.
- ☐ 5. Death during or up to 24 hours after induction of anesthesia after surgery of a normal, healthy patient who has no organic, physiologic, biochemical, or psychiatric disturbance and for whom the pathologic processes for which the operation is to be performed are localized and do not entail a systemic disturbance.

☐ 6. Patient death or serious disability associated with the use of a contaminated drug, device, or biologic provided by the health facility when the contamination is the result of generally detectable contaminants in the drug, device, or biologic, regardless of the source of the contamination or the product.

☐ 7. Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended. For purposes of this subparagraph, "device" includes, but it not limited to, a catheter, drain, or other specialized tube, infusion pump, or ventilator.

☐ 8. Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a facility, excluding deaths associated with neurosurgical procedures known to present a high risk of intravascular air embolism.

☐ 9. An infant discharged to the wrong person.

☐ 10. Patient death or serious disability associated with patient disappearance for more than four hours, excluding events involving adults who have competency or decision making capacity.

☐ 11. A patient suicide or attempted suicide resulting in serious disability while being cared for in a health facility due to patient actions after admission to the health facility, excluding deaths resulting from self-inflicted injuries that were the reason for the admission to the health facility.

☐ 12. A patient death or serious disability associated with a medication error, including, but not limited to, an error involving the wrong drug, the wrong dose, the wrong patient, the wrong time, the wrong rate, the wrong preparation, or the wrong route of administration, excluding reasonable differences in clinical judgment on drug selection and dose.

☐ 13. A patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products.

☐ 14. A maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a facility, including events that occur within 42 days postdelivery and excluding deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy, or cardiomyopathy.

☐ 15. Patient death or serious disability directly related to hypoglycemia, the onset of which occurs while the patient is being cared for in a health facility.

☐ 16. Death or serious disability, including kernicterus, associated with failure to identify and treat hyperbilirubinemia in neonates during the first 28 days of life. For purposes of this subparagraph, "hyperbilirubinemia" means bilirubin levels greater than 30 miligrams per deciliter.

☐ 17. A Stage 3 or 4 ulcer, acquired after admission to a health facility, excluding progression from Stage 2 to Stage 3 if Stage 2 was recognized upon admission.

☐ 18. A patient death or serious disability due to spinal manipulative therapy performed at the health facility.

☐ 19. A patient death or serious disability associated with an electric shock while being cared for in a health facility, excluding events involving planned treatments, such as electric countershock.

☐ 20. Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by a toxic substance.

☐ 21. A patient death or serious disability associated with a burn incurred from any source while being cared for in a health facility.

☐ 22. A patient death associated with a fall while being cared for in a health facility.

☐ 23. A patient death or serious disability associated with the use of restraints or bedrails while being cared for in a health facility.

☐ 24. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider.

☐ 25. The abduction of a patient of any age.

☐ 26. The sexual assault of a patient within or on the grounds of a health facility.

☐ 27. The death or significant injury of a patient or staff member resulting from a physical assault that occurs within or on the grounds of a facility. [Note: if this item is checked because a staff member suffered death or significant injury due to a physical assault on the grounds of the facility, please indicate the staff member's name at the bottom of the form, rather than a patient's name.]

☐ 28. An adverse event or series of adverse events that cause the death or serious disability of a patient, personnel, or visitor. [Note: An "adverse event" is defined as the incidents described in items 1. through 27., above. Thus, this category probably does not capture any additional adverse events not described in items 1. through 27. above. If for some reason an adverse event report is made about an event not listed in items 1. through 27. above, a brief description of the event should be included on this form. If a hospital has an adverse event that causes the death or serious disability of a patient, personnel, or visitor but is not listed above in items 1. through 27., legal counsel should be consulted to determine whether it should be reported. A different reporting requirement may apply.]

Hospital's code to link this report to its file regarding this potential adverse event:

_____

_____

_____

Date hospital detected the adverse event: _____

Please contact me at [insert phone number] or at [insert fax number] if you require further information.

Sincerely,

[Name]

[Title]

(over)

NOTE: "Serious disability" means:

a. A physical or mental impairment that substantially limits one or more of the major life activities of an individual, if the impairment lasts more than seven days or is still present at the time of discharge from an inpatient health care facility, or

b. The loss of bodily function, if the loss lasts more than seven days or is still present at the time of discharge from an inpatient health care facility, or

c. The loss of a body part.

**Generally, this report must be made within five days of detection. However, if the adverse event is an ongoing or urgent threat to the welfare, health, or safety of patients, personnel or visitors, a report must be made within 24 hours of detection.*

11 Screening for Excluded Providers and Suppliers

I. Introduction 11.1

II. Relevant Laws 11.1

A. Program Exclusion Authority 11.1

Internet Resources 11.2

Definition 11.2

B. Prohibition on Employing or Contracting With Excluded Individuals/Entities (CMP Law) 11.3

General Rule 11.3

Definitions 11.3

Knowledge Requirement 11.3

C. Reimbursement Prohibition for Excluded Individuals/Entities 11.4

General Rule 11.4

Definitions 11.4

Knowledge Requirement 11.4

D. Special Advisory Bulletin (Sept. 30, 1999) 11.4

E. Updated Special Advisory Bulletin (May 8, 2013) 11.5

III. Consequences of Employing or Contracting with Excluded Individuals/Entities 11.6

A. Return of Overpayment/False Claims 11.6

B. Monetary Penalties and Assessments 11.6

Amount of CMPs 11.7

C. Potential Exclusion for Employer 11.8

D. Medi-Cal Rules and Penalties 11.8

IV. Screening Processes 11.8

A. OIG Program Memoranda 11.9

B. Who to Screen 11.9

Screening Contractors 11.10

C. Lists to Check 11.10
Federal Lists 11.11
Distinctions Between the Lists 11.11
California Lists 11.12
Resources Regarding Other States 11.12
List-Checking Services 11.12
Distinction Between Other Types of Screening and Exclusion Screening 11.12
D. Frequency of Screening 11.14

V. Reporting Requirements 11.14
A. General Rule 11.14
B. Definitions 11.15
C. Process 11.16

FORMS & APPENDICES

HC 11-A OIG Special Advisory Bulletin: The Effect of Exclusion From Participation in Federal Health Care Programs (September 30, 1999)
HC 11-C State Medicaid Excluded Provider Lists

11 Screening for Excluded Providers and Suppliers

I. INTRODUCTION

This chapter describes the legal prohibitions against:

1. Employing or contracting with an individual or entity that has been excluded from participation in a federal health care program; and
2. Receiving reimbursement from a federal health care program for a health care item or service provided by, or at the direction of, an excluded individual or entity.

This chapter also provides information about the screening process used to identify excluded individuals and entities (including contractors and suppliers that do business with hospitals), what steps a provider may take if it discovers that it has employed or contracted with an excluded individual or entity, and the legal consequences for violating the laws regarding excluded individuals/entities.

It seems hospitals are becoming much more experienced with these issues and working with the vendors to screen excluded individuals and entities. However, issues still arise due to confusion regarding the differences between license verifications, background checks, and state and federal exclusions and suspension. Continued focus and training on screening is thus appropriate.

II. RELEVANT LAWS

A. Program Exclusion Authority

The Office of Inspector General (OIG) was established in the U.S. Department of Health and Human Services (DHHS) to identify and eliminate fraud, waste, and abuse in DHHS programs. The OIG carries out its mission through audits, inspections and investigations. In addition, the OIG has the authority to exclude health care providers, individuals, and businesses from participating in Medicare, Medicaid, and other federal health care programs [42 U.S.C. Section 1320a-7; 42 C.F.R. Part 1001]. Individuals and entities may be excluded from federal health care programs for many reasons, such as a conviction relating to patient abuse or health care fraud, student loan defaults, license revocation or suspension, obstruction of investigations, and for employing/contracting with excluded individuals/entities.

Some misconduct results in mandatory exclusion from federal health care programs. Other misconduct is subject to permissive exclusion — that is, the OIG has the discretion to exclude the individual or entity from participation in federal health care programs, but is not legally required to exclude the individual or entity. An example is when a state Medicaid program excludes an individual. The OIG has the ability to exclude the individual, but is not obligated to do so. That is one reason it is important to check state and federal lists.

Sole community physicians and entities that are the sole source of essential specialized services in the community may seek a waiver of exclusion, even if otherwise mandatory.

The period of exclusion may be temporary or permanent, but generally ranges from one to five years, depending on the severity of the misconduct triggering the exclusion. An exclusion remains in effect until the individual or entity has been reinstated in accordance with specified legal procedures. Reinstatement does not occur automatically at the end of a term of exclusion. Rather, an excluded party must apply for reinstatement. [42 C.F.R. Sections 1001.3001-1001.3005]

The state also possesses exclusion authority [Welfare and Institutions Code Sections 14043.6 and 14123].

Internet Resources

The OIG maintains a website at http://oig.hhs.gov/fraud/exclusions.asp that provides useful information about the exclusions program, including a database, relevant laws, and answers to frequently asked questions.

A list of misconduct that triggers the OIG's exclusion authority and the related exclusion period may be found at http://oig.hhs.gov/exclusions/authorities.asp. The OIG has updated its list with statutory references, but a final rule dated Jan. 12, 2017 (82 Fed. Reg. 4100), effective in the spring of 2017, implemented statutory updates and permit exclusions for additional reasons, including a conviction related to obstruction of a government investigation or audit. The final rule also makes clear that the government has a 10-year statute of limitation to exclude an individual or provider.

The OIG has also released a YouTube video regarding exclusion authority (www.youtube.com/watch?v=R3vAeH9XQQs), how to search the OIG list (www.youtube.com/watch?v=9jaaacHpwoc), and the self-disclosure protocol (www.youtube.com/watch?v=QKUOzbV1zSU#t=142).

The 1999 OIG guidance regarding excluded individuals, "OIG Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs," is included at the end of this chapter as CHA Appendix HC 11-A.

The most recent self-disclosure protocol issued by the OIG is available for download at https://oig.hhs.gov/documents/self-disclosure-Info/1006/Self-Disclosure-Protocol-2021.pdf.

In 2013, the OIG released its most recent guidance on the subject, "Updated Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs." It is available for download at https://oig.hhs.gov/exclusions/files/sab-05092013.pdf.

Definition

"Federal health care program" is defined broadly, and includes any plan or program that provides health benefits (whether directly, through insurance, or otherwise), that is funded directly, in whole or in part, by the United States government (except for the Federal Employees Health Benefits Program) or any state health care program [42 U.S.C. Section 1320a-7b(f)]. Therefore, Medicare, Medi-Cal, other states' Medicaid programs, TRICARE, Veterans programs, Maternal and Child Health Services Block Grants, State Children's Health Insurance Program (SCHIP, known as "Healthy Families" in California) and other programs that receive federal funding are included.

B. Prohibition on Employing or Contracting With Excluded Individuals/Entities (CMP Law)

General Rule

Federal law prohibits a person or organization from employing or contracting with an individual or entity that the person/organization knows *or should know* is excluded from participation for the provision of items or services for which payment may be made under a federal health care program [42 U.S.C. Section 1320a-7a(a)(6); 42 C.F.R. Section 1003.110]. This is often referred to as the Civil Monetary Penalty (CMP) law.

A provider or entity that receives federal health care funding may employ or contract with an excluded individual or entity only in very limited situations. Those situations would include instances where the provider pays the individual/entity exclusively with private funds or from other non-federal funding sources, and where the services furnished by the excluded individual/entity relate solely to non-federal health care program patients. Since hospitals often do not know whether a particular patient is covered by a government program until after providing services, the practical effect of an OIG exclusion is to preclude employment or contracting relationships with excluded individuals and entities in any capacity by a health care provider that receives reimbursement, directly or indirectly, from any federal health care program. *(See Special Advisory Bulletin: The Effect of Exclusion From Participation in Federal Health Care Programs, Sept. 1999, described in D. "Special Advisory Bulletin (Sept. 30, 1999)," page 11.4)*

Definitions

"Should know" means that a person acts in deliberate ignorance of the truth or falsity of information, or acts in reckless disregard of the truth or falsity of the information. No proof of specific intent to defraud is required. [42 U.S.C. Section 1320a-7a(i)(7)] Mere negligence (mistake) is not included in the definition of "knows or should know."

"Item or service" includes any particular service claimed to have been provided to a patient and listed in an itemized claim for payment and in the case of a claim based on costs, an entry in the cost report, books of account, or other documents supporting such claim [42 U.S.C. Section 1320a-7a(i)(3)].

Knowledge Requirement

Weaving the above definitions together with the language of the laws, an argument may be made that if a hospital or other provider fails to check the excluded individual/entity list, the hospital or other provider is acting in "deliberate ignorance." Thus, if the hospital or other provider fails to check "the list,"[1] and it employs or contracts with an excluded individual or entity, even if done unknowingly and unintentionally, that hospital or other provider may have violated federal law.

Indeed, the OIG appears to have taken the position that the presence of an excluded individual or entity's name on a government list means that all providers "should know" who is on the list. In this way, the OIG has essentially imposed an affirmative obligation that providers check the list, insisting that a failure to do so before employing or contracting with someone is done at the provider's potential peril. *(See Special Advisory Bulletin: The Effect of Exclusion From Participation in Federal Health Care Programs, Sept. 1999, described in D. "Special Advisory Bulletin (Sept. 30, 1999)," page 11.4.)* If there is an opportunity to

1 "The list" is actually a number of lists or databases. ***(See C. "Lists to Check," page 11.10.)***

check the list, and it was not done, the OIG is likely to argue that the provider should have known about the excluded person's status.

C. Reimbursement Prohibition for Excluded Individuals/Entities

General Rule

Federal law prohibits any payment to be made by Medicare, Medicaid or any other federal health care program for any item or service that:

1. Has been furnished by an individual or entity that has been excluded; or
2. Has been furnished at the medical direction or prescription of a physician (or other authorized person) who is excluded when the person furnishing the item or service knew, or had reason to know, of the exclusion.

[42 U.S.C. Section 1395y(e)(1); 42 C.F.R. Section 1001.1901(b)(1)]

Definitions

"Furnished" means "items or services provided or supplied, directly or indirectly, by any individual or entity." **"Directly"** means the provision or supply of items and services by individuals or entities who request or receive payment from federal health care programs. **"Indirectly"** means the provision or supply of items and services supplied or provided by individuals or entities that do not directly request or receive payment from federal health care programs, but that provide items and services to providers who request or receive payment from these programs for such items or services. [42 C.F.R. Section 1000.10]

The final rule references above expanded these terms to account for payment methodologies other than traditional fee-for-service. The payment methodologies identified by OIG include shared savings payments or performance-based payments, capitated payments, and DRGs. [82 Fed. Reg. 4100, 4103 (Jan. 12, 2017)]

Knowledge Requirement

The difference between the two payment prohibitions described above is potentially important. The second basis for nonpayment appears to include a knowledge requirement, "know or had reason to know," before nonpayment is mandatory. The requirement of such a mental state appears to be a potential limitation to a finding of an overpayment; that is, the provider should not be found liable for an overpayment if it did not know, and had no reason to know, that the item or service was provided at the direction of an excluded person.

However, the federal government has placed great reliance on the first payment prohibition, arguing that any time an excluded person or entity is involved in the chain of furnishing a health care service or item, there can be no payment, regardless of what the provider knew or should have known. Such an interpretation seemingly renders the second basis for nonpayment superfluous, but, so far, the federal government has maintained this stance.

D. Special Advisory Bulletin (Sept. 30, 1999)

The OIG issued a Special Advisory Bulletin, "The Effect of Exclusion From Participation in Federal Health Care Programs (Sept. 30, 1999)," to provide guidance to providers regarding employing or contracting with excluded individuals or entities to provide health care items or services. A copy of this bulletin may be found at the end of this chapter as CHA Appendix HC 11-A.

Prior to the issuance of this Special Advisory Bulletin, it was not clear how the ban on payments for services provided by excluded individuals applied when services provided by those individuals were not billed separately and directly to a federal health care program. The bulletin answered this question, stating that "[t]his payment ban applies to all methods of federal program reimbursement, whether payment results from itemized claims, cost reports, fee schedules or a prospective payment system (PPS)." The bulletin also clarified that the prohibition applies even when the federal payment itself is made to another provider that is not excluded — for example, when a nurse is the excluded provider, but the payment is made to the hospital, which is not excluded.

In addition, the bulletin states that the payment prohibition extends to payment for administrative and management services that are not directly related to patient care, but that are a component of providing items and services to federal health care program beneficiaries. The bulletin clearly states that no federal program payment may be made to cover an excluded individual's salary, expenses, or fringe benefits, regardless of whether they provide direct care or indirect services to federal health care program beneficiaries. The bulletin provides specific examples of services that may not be performed by excluded individuals.

E. Updated Special Advisory Bulletin (May 8, 2013)

The OIG issued a new Special Advisory Bulletin, "Updated Effect of Exclusion from Participation in Federal Health Care Programs (May 8, 2013)," to provide updated guidance to providers regarding employing or contracting with excluded individuals or entities. It is available for download at https://oig.hhs.gov/exclusions/files/sab-05092013.pdf.

The OIG explained that the Updated Special Advisory was intended to address questions that have arisen since its first Special Advisory and disclose what has been learned in the past decade of overseeing exclusions from the federal health care programs. It clarified that common mistakes, such as searching the National Practitioner Database or searching state licensing directories, frequently resulted in liability under the CMP law that could have been avoided. It also stresses that "A provider could be subject to CMP liability if an excluded person participates in any way in the furnishing of items or services that are payable by a Federal health care program." Thus the practical effect is that an excluded person cannot be employed or even volunteer in any capacity in a hospital that participates in Medicare or Medi-Cal. For example, a doctor who was excluded, but becomes a janitor could create liability under the OIG's reasoning. The OIG explains that changing professions does not cure an exclusion. Moreover, the prospective payment system is intended to make a global payment that includes all potential costs that go into a service, including presumably janitorial services. Thus, exclusion is a red flag that should never be ignored.

If a hospital is considering employing an excluded individual, it could seek an Advisory Opinion from OIG. There are at least three examples where the OIG considered a proposed employment of an excluded individual.[2]

2 OIG Advisory Opinion No. 01-16: dated September 2001; OIG Advisory Opinion No. 03-01: dated Jan. 13, 2003; and OIG Advisory Opinion No. 19-05: dated Sept. 6, 2019

III. CONSEQUENCES OF EMPLOYING OR CONTRACTING WITH EXCLUDED INDIVIDUALS/ENTITIES

In addition to having to repay money received from federal health care programs, providers face exposure to monetary penalties and assessments for violating the laws described above [42 U.S.C. Section 1320a-7a(a)(6) and 42 C.F.R. Section 1003.140]. A provider may also be excluded from participation in all federal health care programs, including Medicare and Medicaid [42 U.S.C. Section 1320a-7(b)(7)].

A. Return of Overpayment/False Claims

As mentioned above, regardless of what the provider knew or should have known, if an excluded individual or entity was in the chain of providing health care items or services, whether directly or indirectly, no payment can be made by a federal health care program. Therefore, if a hospital received reimbursement from Medicare, Medi-Cal, or another federal health care program, an overpayment exists. This overpayment is recoverable by the federal health care program or the OIG. The hospital must determine how best to return the overpayment.[3] *(See chapter 15, "Repayment and Self-Disclosure.")*

In addition, the Patient Protection and Affordable Care Act (ACA) of 2010 amended the federal False Claims Act to make the retention of an overpayment a type of false claim if not repaid within 60 days. The overpayment provision is not the only aspect of the False Claims Act that can be implicated by employing or contracting with an excluded person: a knowing submission of a claim that should not be paid due to the involvement of an excluded person or entity is a traditional false claim. As a result, all of the administrative and criminal penalties that could be imposed under the False Claims Act may be implicated for a provider that contracts with or employs an excluded individual or entity. *(See chapter 3, "Federal and State False Claims Acts.")*

B. Monetary Penalties and Assessments

The civil monetary penalty (CMP) statute states that a provider shall be subject to a CMP for violating the prohibitions regarding employing or contracting with an excluded individual or entity, or billing for items or services provided by an excluded individual or entity [42 U.S.C. Section 1320a-7a(a)(6); 42 C.F.R. Section 1003.200]. The OIG regulation implies that imposing a CMP is discretionary, by asserting that a CMP may be imposed only if a provider "knew or should have known" an excluded individual was involved in furnishing items or services for which a claim was submitted. In contrast, there is no knowledge requirement for the more general payment prohibition. This distinction may be helpful, for example, if a hospital checks the excluded provider list and does not find any matches for a particular employee, but later learns that the employee was excluded under a different name or was added to the list after the employer's regular check. In such a case, an overpayment would exist, and the provider would need to repay the overpayment, but the provider would presumably not be subject to a CMP.

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3 Both the most recent Special Advisory and the revised Self-Disclosure Protocol recognize that the employment of an excluded individual is a basis for self-disclosure through the OIG's Self-Disclosure Protocol. The Self-Disclosure Protocol includes a valuable discussion regarding how the OIG calculates recoveries, particularly for services that are not separately billable, and how the OIG will calculate multipliers. Generally, the OIG will calculate a percentage of salary and benefits attributable to federal health care programs and use a minimum of a 1.5 multiplier.

Amount of CMPs

A provider that violates the laws regarding excluded individuals or entities may be subject to:

1. A civil monetary penalty of not more than $10,000 for each item or service, and
2. An assessment of not more than three times the amount claimed (billed) for each item or service.

In determining the amount of the penalty, the OIG will take into consideration the following factors:

1. The nature of the claim or wrongdoing,
2. The degree of culpability,
3. The history of prior offenses,
4. The financial condition of the person against whom the penalties are proposed, and
5. Such other matters as justice may require.

[42 U.S.C. Section 1320a-7a(d); 42 C.F.R. Section 1003.210]

On Sept. 6, 2016, the OIG increased the penalty amount from $10,000 to $14,718 [81 Fed. Reg. 61538, 61543 (Sept. 6, 2016)]. The increase was made to address inflation since the amount was last set in 1997.

In its regulations, the OIG provides examples of mitigating and aggravating circumstances. For example, it will be considered a mitigating circumstance if all the items or services billed for were of the same type and occurred within a short period of time, there were few such items or services, and the total amount claimed or requested was less than $5,000 [42 C.F.R. Section 1003.220(a)]. Another mitigating circumstance would exist if corrective steps were taken promptly after the error was discovered [42 C.F.R. Section 1003.140(a)(2)].

In contrast, it will be considered an aggravating circumstance if the items or services were of several types, or occurred over a lengthy period of time; there were many items or services billed for; the nature and circumstances of the billing indicate a pattern; or the amount claimed or requested was substantial [42 C.F.R. Section 1003.220(b)].

In determining the amount of the penalty, if there are substantial or several mitigating circumstances, the aggregate amount of the penalty should be set at an amount sufficiently less than the maximum. If there are substantial or several aggravating circumstances, the aggregate amount of the penalty and assessment should be set at an amount sufficiently close to or at the maximum. [42 C.F.R. Section 1003.140(c)(1) and (2)]

However, the government takes the position that unless there are extraordinary mitigating circumstances, the aggregate amount of the penalty should never be less than double the approximate amount of damages and costs sustained by the United States, or any state. The approximate amount of damages and costs is the tangible and intangible costs incurred by the government that are attributable to the investigation, prosecution, and administrative review of the case. [42 C.F.R. Section 1003.140(c)(3) and (d)(2)]

The OIG releases the names of each provider and the amount the provider has agreed to pay after going through the self-disclosure process. *(For a detailed discussion of repayment and self-disclosure, see chapter 15.)* It is important to know that even though a provider

may have agreed to make a payment, it is not an admission of liability. For examples of recent settlements reached after employing excluded persons, visit https://oig.hhs.gov/Fraud/enforcement/cmp/index.asp.

C. Potential Exclusion for Employer

The OIG wields the power of permissive exclusion whenever a CMP can be imposed [42 U.S.C. Section 1320a-7(b)(7)]. Therefore, if the OIG were to impose a CMP for employing an excluded individual, it may also be able to exclude the provider that employed the excluded individual.

D. Medi-Cal Rules and Penalties

California has a law specifically addressing the issue of excluded providers. Welfare and Institutions Code Section 14043.61 states that:

> A provider shall be subject to suspension if claims for payment are submitted for the services, goods, supplies, or merchandise provided, directly or indirectly, to a Medi-Cal beneficiary, by an individual or entity that is suspended, excluded, or otherwise ineligible because of a sanction to receive, directly or indirectly, reimbursement from the Medi-Cal program and the individual or entity is listed on either the Suspended and Ineligible Provider List, published by the department, to identify suspended and otherwise ineligible providers, or any list published by the federal Office of Inspector General regarding the suspension or exclusion of individuals or entities from the federal Medicare and Medicaid programs, to identify suspended, excluded, or otherwise ineligible providers.

In addition, as a general rule, providers must reimburse Medi-Cal for any funds received during a period in which material information was not reported, or was falsely reported, to the state Department of Health Care Services (DHCS) [Welfare and Institutions Code Section 14043.3]. Similarly, any instance of fraud or willful misrepresentation by a provider may result in DHCS collecting any Medi-Cal overpayment identified through audit or examination, or withholding payment [Welfare and Institutions Code Section 14017.11]. In addition, if it were established upon audit that a provider obtained payment from Medi-Cal to which it was not entitled, charges and penalties could be assessed [Welfare and Institutions Code Section 14171.6].

DHCS also has the authority to impose any sanction identified by 42 U.S.C. Section 1320a-7a, including the civil monetary penalties (discussed above) [Welfare and Institutions Code Section 14123.25(a)]. Other than imposing sanctions and penalties set forth by 42 U.S.C. Section 1320a-7a, DHCS may impose civil monetary penalties for improperly-calculated cost reports or improper billing, but only where certain warning notices have been issued to the provider [Welfare and Institutions Code Section 14123.25(c)(2)].

IV. SCREENING PROCESSES

Given the potential civil and criminal penalties at issue, screening for excluded individuals and entities is clearly integral to an effective compliance program.

The problem faced by hospitals and other providers is that screening can be difficult, time-consuming and expensive. Unfortunately, the multitude of government agencies involved have done little to streamline the screening process, all while demanding higher levels of

compliance. There is also a potential for errors — a provider may mistype an employee's name, for example. Such errors and mistakes may not insulate a provider from liability. Errors can also be made on the government side with the data entry. For example, the government has confused individuals with the same or similar names on the exclusion lists, resulting in a non-excluded individual being listed on the exclusion list.

The OIG's attention to the perceived problem of employing excluded persons is not dwindling. The 2011 OIG Work Plan specifically identifies employing excluded individuals as a focus area for several types of providers, including hospitals. While no longer on work plans, in subsequent years the amounts collected by the OIG for providers employing excluded individuals has steadily increased. For example, on Oct. 23, 2015, an Illinois hospital settled allegations that it employed two individuals who were excluded from participation in any federal health care programs for $317,660.89. Therefore, compliance officers should devote adequate resources to developing an effective screening program.

A. OIG Program Memoranda

The OIG has issued two program memoranda to State Medicaid Directors regarding screening for excluded individuals/entities: CMS Program Memorandum SMDL #08-003 (June 12, 2008) and CMS Program Memorandum SMDL #09-001 (Jan. 16, 2009).

The first memorandum reminded state Medicaid programs to conduct searches of excluded persons and entities when admitting applicants to the Medicaid program.

The second memorandum, found at https://downloads.cms.gov/cmsgov/archived-downloads/SMDL/downloads/SMD011609.pdf, "advise[d] States of their obligation to direct providers to screen their own employees and contractors for excluded persons." More specifically, the OIG told the states that they should:

1. Advise providers of their obligation to screen all employees and contractors to determine whether any of them have been excluded. States were advised to communicate this obligation to providers upon enrollment and re-enrollment;
2. Explicitly require providers to agree to comply with this obligation as a condition of enrollment;
3. Inform providers that they can search the DHHS-OIG website at http://exclusions.oig.hhs.gov by the names of any individual or entity;
4. Require providers to search the DHHS-OIG website monthly to capture exclusions and reinstatements that have occurred since the last search; and
5. Require that providers immediately report to them any exclusion information discovered.

As of the date of publication of this manual, the Medi-Cal program had not advised or required providers to implement the OIG's recommendations. (Other states, including New York and Indiana, have issued such guidance to providers, including requiring providers to conduct monthly checks of excluded persons lists.)

B. Who to Screen

Hospitals should consider screening the following individuals/entities:

1. Employees — new and existing. Managerial employees and officers and directors should be screened, not just caregiver employees.

2. Medical staff — applicants and current members.
3. Physicians and other professionals who order laboratory, radiology, or other tests/procedures who are not on the medical staff (if the hospital allows this practice).
4. Contractors, including both individuals and businesses — new and current.
5. Persons with an ownership or control interest in the organization of greater than 5 percent, officers, directors, agents and managing employees *(see V. "Reporting Requirements," page 11.14).*
6. Volunteers *(see https://oig.hhs.gov/exclusions/files/sab-05092013.pdf, "OIG Updated Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs (May 8, 2013)")*[4].

Compliance officers should work with human resources and the medical staff office to screen all employees and medical staff members against the excluded provider list. In addition, all hospital departments that contract with individuals and entities outside the hospital, such as purchasing and contracting, should have policies and procedures in place to screen contractors. If a hospital accepts orders for outpatient lab tests or other procedures from practitioners who are not on the medical staff, the hospital should have policies and procedures in place to screen the ordering practitioners. Finally, a department should be designated to screen persons with an ownership or control interest in the organization of greater than 5 percent, officers, directors, agents and managing employees *(see V. "Reporting Requirements," page 11.14)*.

Hospitals should ask all persons to be screened for names they have used in the past, and ask questions regarding exclusion on employment, volunteer, and medical staff applications.

Screening Contractors

The OIG is clear that screening employees only is not enough. Contractors that provide, directly or indirectly, an item or service that is in whole or in part payable by a federal health care program must be screened also. The OIG has stated that employees of contractors who furnish items or services may also create liability for a provider, if the contractor's employee is excluded from federal health care programs. However, the OIG recognizes that providers may be able to reduce or eliminate exposure for liability if the provider can show that it created a reasonable arrangement with the contractor for the contractor to screen its own employees. In addition to requiring contractors to screen their employees, providers may consider including indemnification obligations for contractors that agree to screen, but fail to identify, excluded employees. To the extent a contractor will be tasked with screening its employees, the OIG recommends that the contractor be obligated to verify it is performing its screening obligation. For example, a prudent practice may be requiring the contractor to provide periodic reports showing its screening activity.

C. Lists to Check

Throughout this chapter, we have mentioned checking "the list" of excluded individuals and entities. However, unfortunately, there is no single "list."

4 The OIG takes the position that liability could result if the provider's claim to the federal health care program includes any items or services furnished by an excluded person, even if the excluded person does not receive payments from the provider for his or her services.

The OIG has criticized CMS, state Medicaid programs, and providers for failing to maintain program integrity regarding paying for services involving an excluded individual or entity. Part of the problem is that each state has its own rules and authority for excluding or suspending individuals and entities from participating in its Medicaid programs. Each state thus may maintain its own excluded individuals/entities list(s). In addition, the states do not always effectively communicate with the OIG. The OIG has reported that state Medicaid programs have not historically been reporting exclusions to the federal government, meaning the federal exclusion list is not a reliable single-stop source of exclusions.

A provider should at least screen individuals and entities against its state list and the lists maintained by the federal government. Unfortunately, several states, including California, have poor online access to conduct searches. Other states don't have any online resources for providers to check.

Federal Lists

The OIG maintains its List of Excluded Individuals/Entities (LEIE) Search, which is accessible at http://exclusions.oig.hhs.gov. The OIG exclusion information is found in both online searchable and downloadable formats. The information is updated monthly by OIG, and may be sorted by:

1. The legal basis for the exclusion,
2. The types of individuals/entities that have been excluded, and
3. The state of residence or the state where the entity was doing business.

Another relevant federal resource is General Services Administration (GSA) System for Award Management (SAM), which is available at www.sam.gov/exclusions.

Finally, the OIG revised its exclusion authority in 2016. Part of the revision involved the creation of a "heightened scrutiny" category under the OIG's risk spectrum. *(See* https://oig.hhs.gov/exclusions/files/1128b7exclusion-criteria.pdf*.)* The OIG now maintains a High Risk – Heightened Scrutiny List available at https://oig.hhs.gov/compliance/corporate-integrity-agreements/high-risk.asp. These are generally providers or supplies that settled fraud allegations with the government, but refused to enter a Corporate Integrity Agreement. OIG asserts these providers or supplies are "high risk."

Distinctions Between the Lists

The LEIE contains only the OIG exclusions. The GSA SAM database includes what used to be listed on the GSA Excluded Parties List System, the SAM and the OIG's exclusions. Therefore, SAM appears to be more comprehensive, but the OIG warns that while SAM is supposed to include the OIG updates, it does not always. Therefore, the OIG places primary focus on providers searching the LEIE database.

Also, SAM includes individuals and entities that have been debarred from contracting with the federal government, as well as individuals and entities that have been excluded from federal health care programs. Debarment is not the same as exclusion, so searching the SAM can result in "false positive" search results, if the only issue is screening for excluded providers.

With its most recent guidance, the OIG has seemed to downplay the value of searching the SAM database. But it has not gone so far as to retract prior guidance that both of these lists

should be searched prior to employing or contracting with an individual or entity and again on a regular basis for all current employees and contractors. *(See D. "Frequency of Screening," page 11.14.)*

In short, the most prudent practice is to search both the LEIE and the SAM. The OIG "High Risk – Heightened Scrutiny" List is not addressed in the OIG guidance and it is not mandatory to check this list. However, it is provided to make more individuals aware of its existence.

California Lists

The Medi-Cal program publishes a searchable Microsoft Excel™ spreadsheet identifying excluded and suspended providers. It is possible to conduct a search of the spreadsheet by visiting the "Medi-Cal Suspended and Ineligible Provider List" website at http://files.medi-cal.ca.gov/pubsdoco/SandILanding.aspx.

Listing an individual or provider on the Medi-Cal Suspended and Ineligible Provider List does not mean that individual is necessarily excluded from all federal health care programs. An individual or provider may be excluded by Medi-Cal only. The practical impact may be that the hospital cannot effectively employ that individual, but legally the prohibition applies only to Medi-Cal, unless the individual is listed on another exclusion list. That is because in some instances the Medi-Cal program excludes, but OIG exercises its discretion not to exclude, the same individual or provider.

This author has taken the position that DHCS exceeds its authority when it excludes individuals who do not and cannot enroll as a provider. However, the author is not aware of any precedential legal decisions that can be cited for this position. Therefore, if an individual practitioner (i.e., non-provider) is identified on the list, counsel should be consulted to evaluate potential defenses and whether an overpayment exists.

Resources Regarding Other States

If a provider frequently does business in other states or with out-of-state contractors, it may be prudent to check those state resources. At present, the OIG has not aggregated links to each of the state resources. CHA Appendix 11-C, "State Medicaid Excluded Provider Lists," is a chart showing state lists available on the internet. While efforts have been made to locate a list for each state, the fact that a state is not listed does not mean that the state does not have an excluded persons list. It is always advisable to contact the state program at issue to confirm the presence or lack of any database.

List-Checking Services

Private businesses exist that, for a fee, check various federal and state excluded entities lists on behalf of providers. In addition, the National Practitioner Data Bank will check excluded entities lists for physicians and other professionals it monitors, for an additional fee.

Distinction Between Other Types of Screening and Exclusion Screening

Licensure and participation in federal health care programs are distinct, even if related, concepts. A health care provider may need to be licensed to participate in federal health care programs in certain capacities. However, just because someone is licensed does not mean that individual participates in federal health care programs or has not been excluded from participation. For example, one can be licensed to practice medicine as a doctor, but choose not to participate in federal health care programs. Similarly, one can be excluded from federal

health care programs, but still be licensed to practice medicine as a doctor, at least for a short period of time.[5]

Reviewing the exclusion status and the licensure status of an individual is not interchangeable. A licensure check is not sufficient to determine if an individual has been excluded. Exclusion from a federal health care program is a specific sanction by the state or federal government in response to various types of omissions or misconduct. Exclusion may have an effect on a provider or supplier's license to practice a profession or specialty, but the two concepts are distinct, and the relevant government entities do not always communicate seamlessly, so a proper compliance program should always be careful to distinguish between licensure checks and the screening of excluded individuals.

When employing individuals, a licensure check is typically performed to ensure the applicant is indeed licensed. A common licensure check is through relevant state boards or agencies, such as the Board of Registered Nursing, the Medical Board of California, etc. The National Practitioner Data Bank collects information that is reported by various state agencies also, but it does not necessarily collect information regarding exclusions and it is not a resource for screening for excluded individuals.

In summary, just because someone is licensed does not mean that person has not been excluded. The exclusion screening process should not rely on licensure checks.

Similarly, with the passage of the Affordable Care Act, Section 1902(kk)(7) of the Social Security Act was amended. It now provides that the state Medicaid agency must require all ordering or referring physicians or other professionals providing services under the state plan be enrolled as participating providers [42 U.S.C. Section 1396a(kk)(7)]. All providers also had to obtain NPI numbers, and "the State Medicaid agency must require all claims for payment for items and services that were ordered or referred to contain the National Provider Identifier (NPI) of the physician or other professional who ordered or referred such items or services" [42 C.F.R. Section 455.440].

As a result, California implemented Welfare and Institutions Code Section 14043.1(b) and (o), which defines an "applicant" and "provider," requiring a "provider" to be enrolled in Medi-Cal. It also implemented Welfare and Institutions Code Section 14043.15(b)(3), which states "This subdivision does not remove the requirement that each claim for reimbursement from the Medi-Cal program identify the place of service and the rendering, ordering, referring, and prescribing provider, where applicable." Medi-Cal also released the DHCS 6219, which is the Medi-Cal Ordering/Referring/Prescribing (ORP) Provider Application. The state amended its state plan to comply with the new federal laws.

DHCS has taken steps to inform providers about the changes. The DHCS guidance explains that the above authority means that, "If the ordering, referring or prescribing provider's name or NPI on the claim of the billing provider is not enrolled in the Medi-Cal program or Medicare, the claim will not be paid."[6] Later, in a different publication, Medi-Cal states "If the

5 An individual who has been excluded from a federal health care program is likely to lose his or her license, as the wrong-doing that resulted in exclusion is likely to also result in the loss of a license. Moreover, many boards will suspend or revoke licensure if there has been an exclusion. However, there is usually a delay and occasionally there are errors. Therefore, no hospital should rely on a licensure check to determine whether someone has been excluded from a federal health care program.

6 The sentence makes it seem as if enrollment in Medicare alone may be sufficient, among other ambiguities. Such guidance may conflict with federal law, but it may nonetheless be the position of the state agency tasked with implementation.

ORP provider's name or NPI on the claim of the billing provider is not enrolled in the Medi-Cal program or Medicare, claims from the 'filing providers' (e.g., pharmacies, DMEs, etc.) will be denied." Then in other guidance, Medi-Cal states that after a grace period, it would start to deny claims effective Jan. 1, 2014 In practice, it seems that Medi-Cal and its contractors have not been entirely consistent with their denials, which means some claims that should have been denied, have not been.

Therefore, hospitals may be screening physicians and other ordering or referring providers for enrollment in Medicare and/or Medi-Cal. However, this is not the same as screening for an excluded individual. The impact of an un-enrolled ordering or referring physician may be similar to the effect of an excluded individual ordering or referring services, at least with respect to overpayment allegations.

D. Frequency of Screening

The Special Advisory Bulletin issued on Sept. 30, 1999, found at the end of this chapter as CHA Appendix HC 11-A, states that health care providers should check the OIG List of Excluded Individuals/Entities:

> prior to hiring or contracting with individuals or entities. In addition, if they have not already done so, health care providers should periodically check the OIG web site for determining the participation/exclusion status of current employees and contractors.

As discussed under A. "OIG Program Memoranda," page 11.9, guidance from CMS/OIG to the states has repeatedly requested that providers check the excluded individuals/entities list monthly.

Because neither the OIG nor Medi-Cal has legally required California providers to do this, monthly checks are not technically mandated. However, it may be a prudent practice to add monthly checks to a compliance program. Hospitals should at least perform an initial check of new employees, medical staff, and contractors along with regular checks at intervals to be determined by the hospital of existing employees, medical staff and contractors. In addition, any provider under a corporate integrity agreement (CIA) should check that agreement to determine whether it mandates any particular frequency of screening (typical CIAs contain an annual requirement).

V. REPORTING REQUIREMENTS

A. General Rule

Federal law requires, as a condition of participation in Medicare or Medicaid, hospitals, nursing facilities, and other entities (other than an individual practitioner or group of practitioners) to disclose to the Secretary of DHHS, or to the appropriate state agency, the name of any person who:

1. Has a direct or indirect ownership or control interest of 5 percent or more in the entity, or with an ownership or control interest;
2. Is an officer, director, agent, or managing employee of that entity; or
3. Who was described in 1. but is no longer so described because of a transfer of ownership or control interest, in anticipation of (or following) a conviction,

assessment, or exclusion described in B., below, against the person, to an immediate family member or a member of the household of the person who continues to maintain an interest described in 1, above.

And

1. Who has been convicted of any offense subject to mandatory exclusions or specified offenses subject to permissive exclusion (fraud, theft, embezzlement, breach of fiduciary responsibility, other financial misconduct related to health care or to another government program; obstruction of an investigation; or controlled substance violation);
2. Against whom a CMP has been assessed under the CMP law [42 U.S.C. Section 1320-7a] or under this provision of law [42 U.S.C. Section 1320a-8]; or
3. Who has been excluded from participation under Medicare or a state health care program.

[42 U.S.C. Sections 1320a-3(a) and 1320a-3a]

(See also 42 U.S.C. Section 1320a-7(b)(8).)

A provider may be excluded from participation in Medicare and other federally-funded health care programs for failing to disclose to DHHS as required by law [42 U.S.C. Section 1320a-7(b)(9)].

B. Definitions

"Immediate family member" means the husband or wife; natural or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-, mother-, daughter-, son-, brother-, or sister-in-law; grandparent or grandchild; and the spouse of a grandparent or grandchild [42 U.S.C. Section 1320a-7(j)(1)].

"Managing employee" means an individual, including a general manager, business manager, administrator, and director, who exercises operational or managerial control over the entity, or who directly or indirectly conducts the day-to-day operations of the entity [42 U.S.C. Section 1320a-5(b)].

"Member of the household" means any individual sharing a common abode as part of a single-family unit, including domestic employees and others who live together as a family unit, but not including a roomer or boarder [42 U.S.C. Section 1320a-7(j)(2)].

"Person with an ownership or control interest" means a person who:

1. Has directly or indirectly (as determined by the Secretary in regulations) an ownership interest of 5 percent or more in the entity, or is the owner of a whole or part interest in any mortgage, deed of trust, note, or other obligation secured (in whole or in part) by the entity or any of the property or assets thereof, which whole or part interest is equal to or exceeds 5 percent of the total property and assets of the entity; or
2. Is an officer or director of the entity, if the entity is organized as a corporation; or
3. Is a partner in the entity, if the entity is organized as a partnership.

C. Process

If a hospital becomes aware that it employed or contracted with an excluded individual or entity, the hospital should consult with its attorney regarding repaying any amounts paid by federal health care programs *(see A. "Return of Overpayment/False Claims," page 11.6)*. In addition, the hospital should consider self-disclosure. *(For a detailed discussion of repayment and self-disclosure, see chapter 15.)* These decisions should be made only after consultation with an experienced attorney. The OIG has been clear in its most recent guidance that there will be overpayment issues and mandatory minimum penalty multipliers. A disclosure should not be made without assessing the financial impact, which can vary depending on the federal health care programs at issue. The OIG has a youtube video regarding disclosures available at www.youtube.com/watch?v=QKUOzbV1zSU#t=142.

OIG Special Advisory Bulletin: The Effect of Exclusion From Participation in Federal Health Care Programs (September 30, 1999)

September 1999

A. Introduction

The Office of Inspector General (OIG) was established in the U.S. Department of Health and Human Services to identify and eliminate fraud, waste, and abuse in the Department's programs and to promote efficiency and economy in Departmental operations. The OIG carries out this mission through a nationwide program of audits, inspections, and investigations. In addition, the OIG has been given the authority to exclude from participation in Medicare, Medicaid and other Federal health care programs[1] individuals and entities who have engaged in fraud or abuse, and to impose civil money penalties (CMPs) for certain misconduct related to Federal health care programs (sections 1128 and 1128A of the Social Security Act (the Act)).

Recent statutory enactments have strengthened and expanded the OIG's authority to exclude individuals and entities from the Federal health care programs. These laws also expanded the OIG's authority to assess CMPs against individuals and entities that violate the law. With this expanded authority, the OIG believes that it is important to explain the effect of program exclusions under the current statutory and regulatory provisions.

The Health Insurance Portability and Accountability Act (HIPAA) of 1996, Public Law 104-191, authorized the OIG to provide guidance to the health care industry to prevent fraud and abuse, and to promote high levels of ethical and lawful conduct. To further these goals, the OIG issues Special Advisory Bulletins about industry practices or arrangements that potentially implicate the fraud and abuse authorities subject to enforcement by the OIG.

In order to assist all affected parties in understanding the breadth of the payment prohibitions that apply to items and services provided to Federal program beneficiaries,[2] this Special Advisory Bulletin provides guidance to individuals and entities that have been excluded from Federal health care programs, as well as to those who might employ or contract with an excluded individual or entity to provide items or services reimbursed by a Federal health care program.

B. Statutory Background

In 1977, in the Medicare-Medicaid Anti-Fraud and Abuse Amendments, Public Law 95-142, Congress first mandated the exclusion of physicians and other practitioners convicted of program-related crimes from participation in Medicare and Medicaid (now codified at section 1128 of the Act). This was followed in 1981 with Congressional enactment of the Civil Monetary Penalties Law (CMPL), Public Law 97-35, to further address health care fraud and abuse (section 1128A of the Act). The CMPL authorizes the Department and the OIG to impose CMPs, assessments and program exclusions against individuals and entities who submit false or fraudulent, or otherwise improper claims for Medicare or Medicaid payment. "Improper claims" include claims submitted by an excluded individual or entity for items or services furnished during a period of program exclusion.

To enhance the OIG's ability to protect the Medicare and Medicaid programs and beneficiaries, the Medicare and Medicaid Patient and Program Protection Act of 1987, Public Law 100-93, expanded and revised the OIG's administrative sanction authorities by, among other things, establishing certain mandatory and discretionary exclusions for various types of misconduct.

The enactment of HIPAA in 1996 and the Balanced Budget Act (BBA) of 1997, Public Law 105-33, further expanded the OIG's sanction authorities. These statutes extended the application and scope of the current CMP and exclusion authorities beyond programs funded by the Department to all "Federal health care programs." BBA also authorized a new CMP authority to be imposed against health care providers or entities that employ or enter into contracts with excluded individuals for the provision of services or items to Federal program beneficiaries.

In the discussion that follows, it should be understood that the prohibitions being described apply to items and services provided, directly or indirectly, to Federal program beneficiaries. The ability of an excluded individual or entity to render items and services to others is not affected by an OIG exclusion.

C. Exclusion from Federal Health Care Programs

The effect of an OIG exclusion from Federal health care programs is that no Federal health care program payment may be made for any items or services (1) furnished by an excluded individual or entity, or (2) directed or prescribed by an excluded physician (42 CFR 1001.1901). This payment ban applies to all methods of Federal program reimbursement, whether payment results from itemized claims, cost reports, fee schedules or a prospective payment system (PPS). Any items and services furnished by an excluded individual or entity are not reimbursable under Federal health care programs. In addition, any items and services furnished at the medical direction or prescription of an excluded physician are not reimbursable when the individual or entity furnishing the services either knows or should know of the exclusion. This prohibition applies even when the Federal payment itself is made to another provider, practitioner or supplier that is not excluded.

The prohibition against Federal program payment for items or services furnished by excluded individuals or entities also extends to payment for administrative and management services not directly related to patient care, but that are a necessary component of providing items and services to Federal program beneficiaries. This prohibition continues to apply to an individual even if he or she changes from one health care profession to another while excluded.[3] In addition, no Federal program payment may be made to cover an excluded individual's salary, expenses or fringe benefits, regardless of whether they provide direct patient care.

Set forth below is a listing of some of the types of items or services that are reimbursed by Federal health care programs which, when provided by excluded parties, violate an OIG exclusion. These examples also demonstrate the kinds of items and services that excluded parties may be furnishing which will subject their employer or contractor to possible CMP liability.

- Services performed by excluded nurses, technicians or other excluded individuals who work for a hospital, nursing home, home health agency or physician practice, where such services are related to administrative duties, preparation of surgical trays or review of treatment plans if such services are reimbursed directly or indirectly (such as through a PPS or a bundled payment) by a Federal health care program, even if the individuals do not furnish direct care to Federal program beneficiaries;

- Services performed by excluded pharmacists or other excluded individuals who input prescription information for pharmacy billing or who are involved in any way in filling prescriptions for drugs reimbursed, directly or indirectly, by any Federal health care program;

- Services performed by excluded ambulance drivers, dispatchers and other employees involved in providing transportation reimbursed by a Federal health care program, to hospital patients or nursing home residents;

- Services performed for program beneficiaries by excluded individuals who sell, deliver or refill orders for medical devices or equipment being reimbursed by a Federal health care program;

- Services performed by excluded social workers who are employed by health care entities to provide services to Federal program beneficiaries, and whose services are reimbursed, directly or indirectly, by a Federal health care program;

- Administrative services, including the processing of claims for payment, performed for a Medicare intermediary or carrier, or a Medicaid fiscal agent, by an excluded individual;

- Services performed by an excluded administrator, billing agent, accountant, claims processor or utilization reviewer that are related to and reimbursed, directly or indirectly, by a Federal health care program;

- Items or services provided to a program beneficiary by an excluded individual who works for an entity that has a contractual agreement with, and is paid by, a Federal health care program; and

- Items or equipment sold by an excluded manufacturer or supplier, used in the care or treatment of beneficiaries and reimbursed, directly or indirectly, by a Federal health care program.

D. Violation of an OIG Exclusion By an Excluded Individual or Entity

An excluded party is in violation of its exclusion if it furnishes to Federal program beneficiaries items or services for which Federal health care program payment is sought. An excluded individual or entity that submits a claim for reimbursement to a Federal health care program, or causes such a claim to be submitted, may be subject to a CMP of $10,000 for each item or service furnished during the period that the person or entity was excluded (section 1128A(a)(1)(D) of the Act). The individual or entity may also be subject to treble damages for the amount claimed for each item or service. In addition, since reinstatement into the programs is not automatic, the excluded individual may jeopardize future reinstatement into Federal health care programs (42 CFR 1001.3002).

E. Employing an Excluded Individual or Entity

As indicated above, BBA authorizes the imposition of CMPs against health care providers and entities that employ or enter into contracts with excluded individuals or entities to provide items or services to Federal program beneficiaries (section 1128A(a)(6) of the Act; 42 CFR 1003.102(a)(2)). This authority parallels the CMP for health maintenance organizations that employ or contract with excluded individuals (section 1857(g)(1)(G) of the Act). Under the CMP authority, providers such as hospitals, nursing homes, hospices and group medical practices may face CMP exposure if they submit claims to a Federal health care program for health care items or services provided, directly or indirectly, by excluded individuals or entities.

Thus, a provider or entity that receives Federal health care funding may only employ an excluded individual in limited situations. Those situations would include instances where the provider is both able to pay the individual exclusively with private funds or from other non-federal funding sources, and where the services furnished by the excluded individual relate solely to non-federal program patients.

In many instances, the practical effect of an OIG exclusion is to preclude employment of an excluded individual in any capacity by a health care provider that receives reimbursement, indirectly or directly, from any Federal health care program.

F. CMP Liability for Employing or Contracting with an Excluded Individual or Entity

If a health care provider arranges or contracts (by employment or otherwise) with an individual or entity who is excluded by the OIG from program participation for the provision of items or services reimbursable under such a Federal program, the provider may be subject to CMP liability if they render services reimbursed, directly or indirectly, by such a program. CMPs of up to $10,000 for each item or service furnished by the excluded individual or entity and listed on a claim submitted for Federal program reimbursement, as well as an assessment of up to three times the amount claimed and program exclusion may be imposed. For liability to be imposed, the statute requires that the provider submitting the claims for health care items or services furnished by an excluded individual or entity "knows or should know" that the person was excluded from participation in the Federal health care programs (section 1128A(a)(6) of the Act; 42 CFR 1003.102(a)(2)). Providers and contracting entities have an affirmative duty to check the program exclusion status of individuals and entities prior to entering into employment or contractual relationships, or run the risk of CMP liability if they fail to do so.

G. How to Determine If an Individual or Entity is Excluded

In order to avoid potential CMP liability, the OIG urges health care providers and entities to check the OIG List of Excluded Individuals/Entities on the OIG web site (www.hhs.gov/oig) prior to hiring or contracting with individuals or entities. In addition, if they have not already done so, health care providers should periodically check the OIG web site for determining the participation/exclusion status of current employees and contractors. The web site contains OIG program exclusion information and is updated in both on-line searchable and downloadable formats. This information is updated on a regular basis. The OIG web site sorts the exclusion of individuals and entities by: (1) the legal basis for the exclusion, (2) the types of individuals and entities that have been excluded, and (3) the State where the excluded individual resided at the time they were excluded or the State where the entity was doing business. In addition, the entire exclusion file may be downloaded for persons who wish to set up their own database. Monthly updates are posted to the downloadable information on the web site.

H. Conclusion

In accordance with the expanded sanction authority provided in HIPAA and BBA, and with limited exceptions[4], an exclusion from Federal health care programs effectively precludes an excluded individual or entity from being employed by, or under contract with, any practitioner, provider or supplier to provide any items and services reimbursed by a Federal health care program. This broad prohibition applies whether the Federal reimbursement is based on itemized claims, cost reports, fee schedules or PPS. Furthermore, it should be recognized that an exclusion remains in effect until the individual or entity has been reinstated to participate in Federal health care programs in accordance with the procedures set forth at 42 CFR 1001.3001 through 1001.3005. Reinstatement does not occur automatically at the end of a term of exclusion, but rather, an excluded party must apply for reinstatement.

If you are an excluded individual or entity, or are considering hiring or contracting with an excluded individual or entity, and question whether or not the employment arrangement may violate the law, the OIG Advisory Opinion process is available to offer formal binding guidance on whether an employment or contractual arrangement may be in violation of the OIG's exclusion and CMP authorities. The process and procedure for submitting an advisory opinion request can be found at 42 CFR 1008, or on the OIG web site at www.hhs.gov/oig.

1. A Federal health care program is defined as any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government or a State health care program (with the exception of the Federal Employees Health Benefits Program) (section 1128B(f) of the Act). The most significant Federal health care programs are Medicare, Medicaid, Tricare and the Veterans programs.

2. A Federal program beneficiary is an individual that receives health care benefits that are funded, in whole or in part, by a Federal health care program.

3. For example, the prohibition against Federal program payment for items and services would continue to apply in the situation where an excluded pharmacist completes his or her medical degree and becomes a licensed physician.

4. In certain instances, a State health care program may request a waiver of an exclusion if an individual or entity is the sole community physician or the sole source of essential specialized services in a community (42 CFR 1001.1801(b)).

APPENDIX HC 11-C

State Medicaid Excluded Provider List

STATE	NAME OF LIST	LINK	ADDL. DIRECTION TO FIND LINK
Alabama	Medicaid Sanction List	http://medicaid.alabama.gov/CONTENT/7.0_Fraud_Abuse/7.7_Suspended_Providers.aspx	Download list
Alaska		http://dhss.alaska.gov/Commissioner/Pages/ProgramIntegrity/default.aspx	
Arizona		http://www.azahcccs.gov/OIG/ExludedProviders.aspx	
Arkansas	Department of Human Services Medicaid Sanctions	https://ardhs.sharepointsite.net/ExcludedProvidersList/Forms/AllItems.aspx	Download list
California	Department of Health Care Services (Medi-Cal)	http://files.medi-cal.ca.gov/pubsdoco/manual/man_query.asp?wsearch=(%23filename+*_*z03*.*)&wflogo=suspended+and+ineligible+provider+list&wflogoh=32&wflogow=418&walt=suspended+and+ineligible+provider+list&wpath=pubsdoco%2Fpublications%2Fmasters-mtp%2Fzonlineonly%2Fsusp100-49_z03%2F	
Connecticut	Administrative Actions List Medicaid	http://www.ct.gov/dss/cwp/view.asp?a=2349&q=310706	
Florida	Health Care Medicaid Sanctions	http://apps.ahca.myflorida.com/dm_web/(S(etg4kpjadtfebu2vntsynrh3))/default.aspx	Four separate types of administrative actions are searchable
Hawaii		http://www.med-quest.us/providers/ProviderExclusion_ReinstatementList.html	
Idaho	Provider Exclusion List	http://healthandwelfare.idaho.gov/AboutUs/FraudReportPublicAssistanceFraud/tabid/136/Default.aspx	Click on “What are Excluded Providers?” to get the active link
Illinois	Medicaid Sanction Providers	http://www.state.il.us/agency/oig/download.asp	

STATE	NAME OF LIST	LINK	ADDL. DIRECTION TO FIND LINK
Kansas		http://www.kdheks.gov/hcf/medicaid_program_integrity/index.htm	search "Termination List"
Kentucky	The Kentucky Medicaid Excluded/ Termed Provider List	http://chfs.ky.gov/dms/	Look at the bottom right hand corner of the web page to access the list and follow the links — updated Kentucky Medicaid Excluded/ Termed Provider List
Louisiana		https://adverseactions.dhh.la.gov/	
Maine	Medicaid Excluded Providers	https://mainecare.maine.gov/mhpviewer.aspx?FID=MEEX	
Maryland	Sanctioned Providers and Entities	http://dhmh.maryland.gov/oig/SitePages/related-links.aspx	Scroll down to the state section
Massachusetts		http://www.mass.gov/eohhs/gov/newsroom/masshealth/providers/list-of-suspended-or-excluded-masshealth-providers.html	
Michigan	Medicaid Sanctioned Providers List	http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-16459–,00.html	
Minnesota		http://www.dhs.state.mn.us/main/idcplg?IdcService=GET_DYNAMIC_CONVERSION&RevisionSelectionMethod=LatestReleased&dDocName=dhs16_177378	
Mississippi		http://www.medicaid.ms.gov/resources/	Click on "Sanctioned Provider List"
Nebraska		http://dhhs.ne.gov/medicaid/Pages/med_pi_sanc.aspx	
New Jersey	Disqualified Providers	http://nj.gov/njomig/disqualified/	Site provides additional links

STATE	NAME OF LIST	LINK	ADDL. DIRECTION TO FIND LINK
New York	Office of Medicaid Inspector General (OMIG)	https://www.omig.ny.gov/search-exclusions	
North Dakota		http://www.nd.gov/dhs/services/medicalserv/medicaid/fraud-abuse.html	Click "ND Medicaid Provider Exclusion List"
Ohio	Medicaid Exclusion	http://jfs.ohio.gov/OHP/providers/TerminatedProviders.stm	
Pennsylvania	Medicheck Precluded Providers List	http://www.dhs.state.pa.us/learnaboutdhs/fraudandabuse/medichecklist/index.htm	
South Carolina	Medicaid Excluded Providers	https://www.scdhhs.gov/site-page/excluded-providers-list	
Tennessee		http://www.tn.gov/tenncare/terminated.shtml	
Texas	Office of Inspector General	https://oig.hhsc.state.tx.us/Exclusions/About.aspx	
Washington		http://www.hca.wa.gov/medicaid/provider/Pages/termination.aspx	
West Virginia		http://www.wvmmis.com/provider_enrollment.screen	
Wyoming		http://www.health.wyo.gov/healthcarefin/medicaid/home.html	Scroll to near the bottom of the web page and click on the link — "Wyoming Provider Exclusion List."
District of Columbia		http://ocp.dc.gov/page/excluded-parties-list	

12 Hospital Signage Requirements

I. Introduction and Scope of Chapter 12.1

II. Signage Chart 12.1

A. Signage Chart Contents 12.2

Name of Sign 12.2

Who Must Comply 12.2

Description of Requirement 12.2

Location/Language/Sign and Font Size 12.2

Sample Sign 12.2

III. Posting Signs in Languages Other Than English 12.2

A. State Law 12.3

B. Federal Law 12.3

Hospital Signage Requirements Chart 12.4

FORMS & APPENDICES

HC 12-C	Notice of Community Service Obligation (CHFCLI)
HC 12-D	Notice of Community Service Obligation (CHFFA)
HC 12-E	Notice of Hill-Burton Obligation
HC 12-F	Nutritional Advice
HC 12-H	Referrals: It's Your Choice
1-A^{S}	Patient Rights *(Combines Title 22 and other California laws, The Joint Commission and Medicare Conditions of Participation requirements)*
4-B^{S}	Be Informed (Breast Cancer)
4-C^{S}	Be Informed (Prostate Cancer)
9-9^{S}	Notice for Emergency Room
10-A^{S}	Baby Stalking Sign
10-B^{S}	Safe Surrender Site Sign
10-C^{S}	Obstetrical Care Notice

12 Hospital Signage Requirements

I. INTRODUCTION AND SCOPE OF CHAPTER

California health facilities are required by state and federal statutes and regulations to post various signs. This chapter addresses signage requirements that affect general acute care hospitals, acute psychiatric hospitals, skilled nursing facilities, psychiatric health facilities, clinical laboratories, pharmacies and clinics. Requirements pertaining to licensed health care professionals who often work in these health facilities (for example, physicians) are also addressed.

This chapter does not address patient notices that are not required to be in the form of a sign. For example, hospitals are required to give patients handouts about advance directives, child car seats and many other topics. Because these are not signage requirements, they are not included in this chapter or on the accompanying signage chart. *(See CHA's* Consent Manual *for a partial list of handout and other patient information requirements.)*

This chapter does not address signage requirements that are not unique to health care facilities (for example, building/elevator/physical plant requirements) or food handling/cafeteria requirements. This chapter also does not address human resources/employment/OSHA signage requirements. State- and federally-required employment-related signs may be obtained from the California Chamber of Commerce (www.calchamber.com). CalChamber provides a single poster with the state and federal notices every California employer must post.

Hospitals should review their contracts, settlement agreements, corporate integrity agreements, accreditation organization requirements, grants and other similar documents for additional signage obligations.

II. SIGNAGE CHART

A Hospital Signage Requirements chart is included at the end of this chapter. While every attempt has been made to identify all health-related signs, it was not possible to read every state and federal statute and regulation to identify every possible requirement. CHA does not represent or warrant that every signage requirement has been included in the accompanying chart. Hospitals should consult legal counsel for exhaustive research on this topic.

NOTE: CHA is grateful to Terri Cammarano, formerly Vice President and General Counsel of Hoag Memorial Hospital Presbyterian, who commissioned Hooper, Lundy & Bookman, PC, to develop a chart of signage requirements. That chart served as the basis for the chart included in this chapter. Research on the original chart was conducted by John Hellow and Abigail Grigsby of Hooper, Lundy & Bookman, PC.

Each row of the Hospital Signage Requirements chart represents a statute or regulation that imposes a signage requirement on a health facility or a health care professional. The columns of the chart are described below.

A. Signage Chart Contents

Name of Sign

The first column contains a phrase that CHA has chosen to reference the sign. The name has no particular legal significance.

Who Must Comply

The second column lists the type(s) of health facility or health care professional(s) that must post the sign — for example, general acute care hospitals or physicians.

Description of Requirement

The third column describes the legal requirement regarding the sign and the legal citation. All statutes and regulations referenced in this column can be found on the Internet. The document at the beginning of this manual (before chapter 1) — titled "Where to Find Laws Referenced in the Manual" — explains how federal and state statutes and regulations are abbreviated in the official legal citation and gives the web addresses for state statutes, state regulations, federal statutes and federal regulations.

Location/Language/Sign and Font Size

Some of the laws imposing a signage requirement specify where in the facility the sign(s) must be posted. This information is found in the fourth column.

The fourth column also describes any sign size, font size or foreign language requirements in the law *(see also III. "Posting Signs in Languages Other Than English" below)*. In addition, if the law contains any other requirements — for example, that the sign must be "conspicuous" or "prominently posted" or other specifications — they are also listed in this column.

Sample Sign

CHA has developed many sample signs that hospitals may download and print. Where available, the CHA form number or appendix number is shown under "Sample Sign" in the fourth column. The CHA sample signs are available to download at www.calhospital.org/publications/forms-and-appendices. An "S" at the end of the form/appendix number indicates that the sign is available in Spanish as well as English.

A few signs have been developed by state or federal government agencies. The web address for such signs is also provided under "Sample Sign" in the fourth column.

III. POSTING SIGNS IN LANGUAGES OTHER THAN ENGLISH

The Hospital Signage Requirements chart includes a column that indicates whether the statute or regulation mandating the sign requires that it be printed in a language other than English. However, hospitals should be aware that even if the particular law requiring the sign does not address foreign language requirements, there are both state and federal laws addressing hospital interpreter/translation requirements in general. *(See chapter 1 of CHA's* Consent Manual *for detailed information regarding state and federal interpreter/translation services requirements.)*

A. State Law

The state law regarding hospitals' general interpretation/translation responsibilities is vague regarding which signs, if any, must be posted in languages other than English. Health and Safety Code Section 1259 requires general acute care hospitals to adopt and annually review a policy for providing language assistance services to patients with "language or communication barriers," which are defined as barriers experienced by individuals who are limited English speaking or non-English speaking individuals who speak the same primary language and who comprise at least 5 percent of the population of the geographical area served by the hospital or of the actual patient population of the hospital.

Health and Safety Code Section 1259 does not specify if or when signs should be translated into foreign languages; it requires the hospital to "review all standardized written forms, waivers, documents, and informational materials available to patients upon admission to determine which to translate into languages other than English." Hospitals should consider which signs should be translated into which languages as part of their annual review of their interpretation/translation policy.

There are no state laws regarding general interpretation/translation requirements applicable to other health facilities or health care professionals.

B. Federal Law

Federal law requires hospitals and certain other entities to take specified steps to ensure meaningful access for individuals with language barriers. The U.S. Department of Health and Human Services Office for Civil Rights (OCR) enforces compliance with the federal requirements, and has issued regulations at 45 C.F.R. part 92 and a Limited English Proficiency Policy Guidance, found at www.hhs.gov/ocr/civilrights/resources/specialtopics/lep/index.html.

OCR has not specified in detail when signs must be translated into foreign languages; the hospital's implementation plan should address this issue.

HOSPITAL SIGNAGE REQUIREMENTS			
NAME OF SIGN	**WHO MUST COMPLY**	**DESCRIPTION OF REQUIREMENT**	**LOCATION/ LANGUAGE/ SIGN AND FONT SIZE**
Abortion Not Provided	Nonprofit hospitals and other facilities and clinics organized or operated by a religious corporation, or other religious organization, and licensed under Health & Safety Code Section 1200 *et seq.* or 1250 *et seq.*	A facility or clinic that does not permit the performance of abortions on its premises must post notice of this prohibition. (This law states that it does not apply to the treatment of medical emergencies or spontaneous abortions; it isn't clear whether this language modifies the signage requirement or not.) **Legal Authority** Health & Safety Code Section 123420(c)	Signs must be posted in an area of the facility or clinic that is open to patients and prospective admittees.
Activity Schedule	Skilled nursing facilities	Post the activity schedule. *(See also "Consumer Information," page 12.11 of this chart.)* **Legal Authority** Title 22, California Code of Regulations, Section 72381(d)(5)	Must be posted conspicuously in large visible print.
Accountable Care Organization Participant	Participants in an Accountable Care Organization (ACO)	ACO participants must post a sign notifying notify beneficiaries: 1. That each ACO participant and providers/ suppliers are participating in the Medicare Shared Savings Program; 2. Of the opportunity to decline claims data sharing; and 3. Whether he or she may designate a provider or supplier as responsible for coordinating their overall care, and the process for doing so. **Legal Authority** 42 C.F.R. Section 425.312(a)	ACO participants must post signs in their facilities and in settings in which beneficiaries receive primary care. The ACO must use template language developed by CMS, which is available in the ACO Marketing Toolkit.
Ambulance Replenishing	Hospitals that replenish ambulances	The notice must include the category of ambulance providers that qualifies for replenishment, the drugs or medical supplies included in the replenishment program, and the procedures for documenting and replenishing. *(See V. "Ambulance Replenishing," page 7.42, for more information about this requirement.)* **Legal Authority** 42 C.F.R. Section 1001.952(v)	The notice must be posted conspicuously in the receiving hospital's emergency room or other location where the ambulance providers deliver patients. **Sample Sign** CHA Appendix HC 7-A

HOSPITAL SIGNAGE REQUIREMENTS			
NAME OF SIGN	**WHO MUST COMPLY**	**DESCRIPTION OF REQUIREMENT**	**LOCATION/ LANGUAGE/ SIGN AND FONT SIZE**
Autoclave and Sterilizer Instructions	General acute care hospitals, acute psychiatric hospitals, skilled nursing facilities, primary care clinics	Instructions for operating autoclaves and sterilizers must be posted in the area where the autoclaves and sterilizers are located. **Legal Authority** Title 22, California Code of Regulations, Sections 70833(b) (general acute care hospitals); 71637(b) (acute psychiatric hospitals); 72619(b) (skilled nursing facilities); and 75064(c) (primary care clinics)	In the area where the autoclaves and sterilizers are located.
Baby Stalking	Hospitals or clinics with a neonatal unit, maternity ward, or birthing center	If a hospital wants the police to be able to arrest "baby stalkers" — persons who loiter around newborn nurseries, possibly posing a concern for infant security — the hospital must post signs. The hospital is not required to post the signs, but if no signs are posted, the police will not make an arrest. The sign must advise visitors that access to the area is restricted to persons having lawful business within. **Legal Authority** Penal Code Section 602(x)	At a minimum, signs must be posted at each entrance to the neonatal unit, maternity ward, or birthing center. **Sample Sign** CHA Appendix 10-A[S]
Breast Cancer: Be Informed	Every person or entity who owns or operates a health facility or clinic, or who is licensed as a physician and rents or owns the premises where his/her practice is located	The law requires the following text: ***Be Informed*** Upon a diagnosis of breast cancer, your physician and surgeon is required to provide you a written summary of alternative efficacious methods of treatment, pursuant to Section 109275 of the California Health & Safety Code. Your physician and surgeon may choose to provide the summary prior to the performance of a screening or biopsy for breast cancer at your request or at the physician and surgeon's discretion, when appropriate. The information about methods of treatment was developed by the State Department of Public Health to inform patients of the advantages, disadvantages, risks, and descriptions of procedures. **Legal Authority** Health & Safety Code Section 109277	Signs must be posted where a physician performs breast cancer screening or biopsy as an outpatient service, or in a reasonably proximate area. A sign posted at the patient registration area constitutes compliance with this law. The signs must be conspicuously displayed so as to be readable. The sign must be at least 8½ by 11 inches. The words "BE INFORMED" must be at least 1/2 inch tall and centered on a single line with no other text. The message must be in English, Spanish and Chinese. **Sample Sign** CHA Appendix 4-B[S]

HOSPITAL SIGNAGE REQUIREMENTS			
NAME OF SIGN	**WHO MUST COMPLY**	**DESCRIPTION OF REQUIREMENT**	**LOCATION/ LANGUAGE/ SIGN AND FONT SIZE**
California Health Facility Construction Loan Insurance Notice of Community Service Obligation	Facilities that receive a loan insured by California Health Facility Construction Loan Insurance	A facility that receives a loan insured by California Health Facility Construction Loan Insurance must offer reasonable assurances that the facility's services will be available to all persons residing or employed in the facility's service area. The law requires the facility to post a sign with the following general wording: ***Notice of Community Service Obligation*** This facility has agreed to make its services available to all persons residing or employed in this area. This facility is prohibited by law from discriminating against Medi-Cal and Medicare patients. Should you believe you may be eligible for Medi-Cal or Medicare, you should contact our business office (or designated person or office) for assistance in applying. You should also contact our business office (or designated person or office) if you are in need of a physician to provide you with services at this facility. If you believe that you have been refused services at this facility in violation of the community service obligation you should inform [designated person or office] and the Department of Healthcare Access and Information. **Legal Authority** Health & Safety Code Section 129065(d)	Signs must be posted in appropriate areas within the facility, including, but not limited to, admissions offices, emergency rooms, and business offices. Signs must be multilingual if the borrower serves a multilingual community. **Sample Sign** CHA Appendix HC 12-C

HOSPITAL SIGNAGE REQUIREMENTS			
NAME OF SIGN	**WHO MUST COMPLY**	**DESCRIPTION OF REQUIREMENT**	**LOCATION/ LANGUAGE/ SIGN AND FONT SIZE**
CHFFA Revenue Bond Borrowers Notice of Community Service Obligation	Facilities that borrow revenue bond funds from a local authority or the California Health Facilities Financing Authority (CHFFA)	A facility that borrows revenue bond funds from a local authority or CHFFA must offer reasonable assurances that the facility's services will be available to all persons residing or employed in the facility's service area. The law requires the facility to post a sign with the following general wording: ***Notice of Community Service Obligation*** This facility has agreed to make its services available to all persons residing or employed in this area. This facility is prohibited by law from discriminating against Medi-Cal and Medicare patients. Should you believe you may be eligible for Medi-Cal or Medicare, you should contact our business office [or designated person or office] for assistance in applying. You should also contact our business office [or designated person or office] if you are in need of a physician to provide you with services at this facility. If you believe that you have been refused services at this facility in violation of the community service obligation you should inform [designated person or office] and the California Health Facilities Financing Authority. **Legal Authority** Government Code Section 15459.1	Signs must be posted in appropriate areas within the facility, including, but not limited to, admissions offices, emergency rooms, and business offices. Signs must be multilingual if the borrower serves a multilingual community. **Sample Sign** CHA Appendix HC 12-D
Chargemaster Availability	A general acute care hospital, acute psychiatric hospital, or special hospital that uses a charge description master. However, small and rural hospitals, as defined in Health & Safety Code Section 124840, are exempt.	Hospitals must post a sign informing patients that the charge description master is available on the hospital's website, in writing, or electronically at the hospital location. **Legal Authority** Health & Safety Code Section 1339.51	Signs must be posted in the emergency department (if any), admissions office, and billing office. The signs must be "clear and conspicuous."

HOSPITAL SIGNAGE REQUIREMENTS			
NAME OF SIGN	**WHO MUST COMPLY**	**DESCRIPTION OF REQUIREMENT**	**LOCATION/ LANGUAGE/ SIGN AND FONT SIZE**
Charity Care	General acute care hospitals, acute psychiatric hospitals, and special hospitals, except hospitals operated by the California Department of State Hospitals or the Department of Corrections and Rehabilitation. **"Hospital"** means a facility that is required to be licensed under subdivision (a), (b) or (f) of Section 1250, except a facility operated by the California Department of State Hospitals or the Department of Corrections and Rehabilitation.	Hospitals must post a "notice of the hospital's policy for financially qualified and self-pay patients." **Legal Authority** Health & Safety Code Section 127410(c).	Signs must be clearly and conspicuously posted in locations that are visible to the public, including the emergency department (if any), billing office, admissions office, and other outpatient settings, including observation units, at a minimum. Signs must be translated into those languages spoken by a "substantial number of non-English-speaking people" (persons who do not speak English or who are unable to effectively communicate in English because it is not their native language) who comprise 5 percent or more of the people served by the hospital.
Charity Care	All hospitals exempt from taxation under Internal Revenue Code Section 501(c)(3)	Tax-exempt hospitals must "set up conspicuous public displays (or other measures reasonably calculated to attract patients' attention) that notify and inform patients" about the hospital's financial assistance policy. **Legal Authority** 26 C.F.R. Section 1.501(r)-4(b)(5)	Information must be available in public locations in the hospital facility, including at a minimum, the emergency room (if any) and admissions areas.
Citation Availability	Skilled nursing facilities	Skilled nursing facilities must post a sign stating that copies of all final uncorrected citations issued by CDPH will be made promptly available to anyone who so requests. **Legal Authority** Health & Safety Code Section 1429(b)	Signs must be prominently posted in a place or places in plain view of patients or residents; visitors; and persons who inquire about placement in the facility.

HOSPITAL SIGNAGE REQUIREMENTS			
NAME OF SIGN	**WHO MUST COMPLY**	**DESCRIPTION OF REQUIREMENT**	**LOCATION/ LANGUAGE/ SIGN AND FONT SIZE**
Citations (Class A and AA)	Skilled nursing facilities	Skilled nursing facilities must post each class "AA" and "A" citation (or copies thereof), along with a cover sheet, for 120 days (or until the citation is withdrawn or dismissed by CDPH). The citation/cover sheet must include: 1. The full name of the facility in at least 28-point type. 2. The full address of the facility in at least 20-point type. 3. Whether the citation is class "AA" or class "A." 4. The plan of correction. The facility may post a statement disputing the citation or a statement showing the appeal status, or both. **Legal Authority** Health & Safety Code Section 1429(a)	Citations must be prominently posted in a place or places in plain view of patients or residents; visitors; and persons who inquire about placement in the facility. This must include at least the following locations: 1. An area accessible and visible to members of the public. 2. An area used for employee breaks. 3. An area used by residents for communal functions, such as dining, resident council meetings, or activities. The citation, along with a cover sheet, must be posted on white or light-colored paper, at least 8½ by 11 inches. The text must be in a clear and easily readable font. *(See the required font size in the third column of this row.)*
Clinic Hours	Primary care clinics, psychology clinics	Must post a schedule of the hours and days during which the clinic is open and the times during which the various medical services are offered. Changes in the schedules must be posted in advance of the change. **Legal Authority** Title 22, California Code of Regulations, Sections 75058 (primary care clinics) and 75349 (psychology clinics)	The schedule must be conspicuously posted in the clinic for public view and information.

HOSPITAL SIGNAGE REQUIREMENTS			
NAME OF SIGN	**WHO MUST COMPLY**	**DESCRIPTION OF REQUIREMENT**	**LOCATION/ LANGUAGE/ SIGN AND FONT SIZE**
Complaints (CDPH District Office)	General acute care hospitals, acute psychiatric hospitals, special hospitals	Hospitals must post a notice with the telephone number of the California Department of Public Health (CDPH) district office where complaints regarding the hospital may be reported. CDPH will tell the hospital which phone number to put in the notice. **Legal Authority** Health & Safety Code Section 1288.4; Title 22, California Code of Regulations, Section 71507(d)	Signs must be posted conspicuously, in a prominent location within the premises and accessible to public view. CHA Appendix 1-A[S], CHA Form 9-9[S], and CHA Form 13-1[S], contain a space for the hospital to include the required information.
Complaint and Client Advocacy Group Information	Skilled nursing facilities certified for Medicare and Medicaid	Skilled nursing facilities must post the names, addresses, email addresses, and telephone numbers of all pertinent agencies and advocacy groups such as the state survey agency (CDPH), the state licensure office (CDPH), adult protective services, the state long-term care ombudsman program, the protection and advocacy network, home- and community-based service programs, and the Medicaid fraud control unit. Skilled nursing facilities must also post a statement that a resident may file a complaint with the state survey agency concerning any suspected violation of state or federal nursing facility regulations, including but not limited to resident abuse, neglect, exploitation, misappropriation of resident property in the facility, non-compliance with advance directive requirements and requests for information regarding returning to the community. **Legal Authority** 42 C.F.R. Section 483.10(g)(5)	

HOSPITAL SIGNAGE REQUIREMENTS			
NAME OF SIGN	**WHO MUST COMPLY**	**DESCRIPTION OF REQUIREMENT**	**LOCATION/ LANGUAGE/ SIGN AND FONT SIZE**
Consumer Information	Skilled nursing facilities	The following consumer information must be posted: 1. Name, license number and date of employment of the current administrator of the facility. 2. A listing of all services and special programs provided in the facility and those provided through written contracts. 3. The current and following week's menus for regular and therapeutic diets. (See also Menus) 4. A notice that the facility's written admission and discharge policies are available upon request. 5. Most recent licensing visit report supported by the related follow-up plan of correction visit reports. 6. The names and addresses of all previous owners of the facility. 7. A listing of all other skilled nursing and intermediate care facilities owned by the same person, firm, partnership, association, corporation or parent or subsidiary corporation, or a subsidiary of the parent corporation. 8. A statement that an action to revoke the facility's license is pending, if such an action has been initiated by the filing of an accusation, pursuant to Government Code Section 11503, and the accusation has been served on the licensee. 9. A notice of the name, address and telephone number of the CDPH district office having jurisdiction over the facility. **Legal Authority** Title 22, California Code of Regulations, Section 72503	The information must be posted in a prominent location accessible to the public.

HOSPITAL SIGNAGE REQUIREMENTS			
NAME OF SIGN	**WHO MUST COMPLY**	**DESCRIPTION OF REQUIREMENT**	**LOCATION/ LANGUAGE/ SIGN AND FONT SIZE**
Consumer Information (psychiatric health facilities)	Psychiatric health facilities	Psychiatric health facilities must post the following consumer information: 1. Name of the current administrator of the facility. 2. A notice that the facility's written admission and discharge policies are available upon request. 3. Most recent licensing visit report supported by the related follow-up plan of correction visit reports or a posted statement that such documents are available upon request for public review at the facility. 4. A notice of the name, address and telephone number of the Department of Health Care Services division having jurisdiction over the facility. **Legal Authority** Title 22, California Code of Regulations, Section 77045(c)	The information must be posted in a prominent location accessible to public view.
Dental Employees	Any person, company, or association engaged in the practice of dentistry	The name of every person employed in the dental office in the practice of dentistry must be displayed. **Legal Authority** Business & Professions Code Section 1700(c)	The information must be displayed in a conspicuous place in the dental office.
Dialysis Clinic — notice of Medicare coverage	Chronic dialysis clinics	Chronic dialysis clinics must post a notice stating that questions about Medicare coverage for patients with end stage renal disease should be directed to the Health Insurance Counseling and Advocacy Program (HICAP) at (800) 434-0222. **Legal Authority** Health & Safety Code Section 1210	Notice must be posted in prominent location visible to all patients in large font type.

HOSPITAL SIGNAGE REQUIREMENTS			
NAME OF SIGN	**WHO MUST COMPLY**	**DESCRIPTION OF REQUIREMENT**	**LOCATION/ LANGUAGE/ SIGN AND FONT SIZE**
Dietetic Service Work Schedules (hospitals)	General acute care hospitals, acute psychiatric hospitals	Current work schedules by job titles and weekly duty schedules must be posted in the dietetic service area. **Legal Authority** Title 22, California Code of Regulations, Sections 70275(d) (general acute care hospitals) and 71245 (acute psychiatric hospitals)	Schedules must be posted in the dietetic service area.
Dietetic Service Work Schedules (skilled nursing facilities)	Skilled nursing facilities	Current work schedules by job titles and weekly time schedules by job titles. **Legal Authority** Title 22, California Code of Regulations, Section 72351(d)	Schedules must be posted in the dietetic service area.
Elder Justice Act: Nonretaliation for Reporting Crime Against Elder Person	Long-term care facilities that receive at least $10,000 in federal funds annually	Facilities must post signs informing employees of their right to file a complaint with the state survey agency (CDPH) if they feel the facility has retaliated against an employee or individual who reported a suspected crime under the Elder Justice Act, and how to file such a complaint with CDPH. **Legal Authority** 42 U.S.C. Section 1320b-25	A sign must be posted conspicuously in an appropriate location. CMS has stated that signs may be posted in the same area that the SNF posts other required employment-related signs. The size and font of these signs should be no less than the minimum required for other required employment-related signs.
Emergency Medical Services: Basic	Hospitals with a basic emergency services supplemental service	A basic emergency medical service must be identified to the public by an exterior sign that says: ***Basic Emergency Medical Service, Physician On Duty*** **Legal Authority** Title 22, California Code of Regulations, Section 70413(j)	Exterior signs must be "clearly visible from public thoroughfares."

HOSPITAL SIGNAGE REQUIREMENTS			
NAME OF SIGN	**WHO MUST COMPLY**	**DESCRIPTION OF REQUIREMENT**	**LOCATION/ LANGUAGE/ SIGN AND FONT SIZE**
Emergency Medical Services: Comprehensive	Hospitals with a comprehensive emergency services supplemental service	A comprehensive emergency medical service must be identified to the public by an exterior sign that says: ***Comprehensive Emergency Medical Service, Physician On Duty*** **Legal Authority** Title 22, California Code of Regulations, Section 70453(j)	Exterior signs must be "clearly visible from public thoroughfares."
Emergency Medical Services: Standby	Hospitals with a standby emergency medical services supplemental service	State regulations require that standby emergency medical services must be identified to the public by an exterior sign that says: ***Standby Emergency Medical Service, Physician On Call*** However, Health & Safety Code Section 1255.3 requires CDPH to designate signage requirements for a standby emergency medical service located in an urban area, and states that the signage shall not include the word "emergency." CDPH has not yet changed its signage requirement as required by Health & Safety Code Section 1255.3. **Legal Authority** Title 22, California Code of Regulations, Section 70651(i)	Exterior signs must be "clearly visible from public thoroughfares."

HOSPITAL SIGNAGE REQUIREMENTS			
NAME OF SIGN	**WHO MUST COMPLY**	**DESCRIPTION OF REQUIREMENT**	**LOCATION/ LANGUAGE/ SIGN AND FONT SIZE**
EMTALA: It's the Law!	Hospitals that participate in Medicare (including psychiatric hospitals)	Hospitals must post (in a form specified by the Secretary of the U.S. Department of Health and Human Services) the rights of individuals with respect to examination and treatment for emergency medical conditions and women in labor, and whether the hospital participates in the Medicaid program (Medi-Cal in California). Hospitals generally combine this requirement with the EMTALA-related signage (under California law) requirements on page 12.16 of this chart. **Legal Authority** 42 U.S.C. Section 1395cc(a)(1)(N)(iii) and (iv); 42 C.F.R. Section 489.20(q)	Signs must be posted in a place or places likely to be noticed by all individuals entering the dedicated emergency department (on- and off-campus), as well as those individuals waiting for examination and treatment in areas other than traditional emergency departments (e.g., entrances, admitting area, waiting rooms, treatment areas). Posting of signs is not required in off-campus departments that are not dedicated emergency departments. Signs must be clear and in simple terms. Signs must be posted in English and other major languages that are common to the population of the hospital service area. The letters within the signs must be clearly readable at a distance of at least 20 feet, or from the expected vantage point of dedicated emergency department patrons. **Sample Sign** CHA Form 9-9[S]

HOSPITAL SIGNAGE REQUIREMENTS			
NAME OF SIGN	**WHO MUST COMPLY**	**DESCRIPTION OF REQUIREMENT**	**LOCATION/ LANGUAGE/ SIGN AND FONT SIZE**
EMTALA-related signage (under California law)	All hospitals	Hospitals must post a sign informing the public of their right to emergency services and care without regard to ability to pay. These signs must give the address of the CDPH district office to which patients may submit complaints about the hospital. Hospitals generally combine this requirement with the EMTALA: It's the Law! signage requirements on page 12.15 of this chart. **Legal Authority** Health & Safety Code Section 1317.3(d)	Signs must be prominently posted in the emergency room. **Sample Sign** CHA Form 9-9[S]
End-Stage Renal Disease Quality Incentive Program: Performance Score Certificate	Renal dialysis services providers and facilities	The Medicare Dialysis Quality Incentive Program isssues two-page "Performance Score Certificates" (PSCs) that providers and facilities must post. CMS will electronically notify facilities that the PSC is available to download and provide a link. The facility must post both pages of the certificate within fifteen business days of CMS releasing the PSC. The notice must be posted until the end of the calendar year. **Legal Authority** 42 U.S.C. Section 1395rr(h)(6)(C)	The PSC must be prominently displayed in patient areas.
Evacuation Plan	General acute care hospitals, acute psychiatric hospitals, skilled nursing facilities, psychiatric health facilities	Facilities must post the evacuation plan that is part of the written fire and internal disaster program. The posted plan must include evacuation routes and the locations of fire alarm boxes and fire extinguishers. Skilled nursing facilities must also post the emergency telephone number of the local fire department. **Legal Authority** Title 22, California Code of Regulations, Sections 70743 (general acute care hospitals); 71541 (acute psychiatric hospitals); 72553 (skilled nursing facilities); and 77129 (psychiatric health facilities)	The plan must be posted throughout the facility.
Financial Assistance Policies		*See "Charity Care," page 12.8 and "Hill-Burton Community Service Assurance and Uncompensated Care Service," page 12.19 of this chart.*	

HOSPITAL SIGNAGE REQUIREMENTS			
NAME OF SIGN	**WHO MUST COMPLY**	**DESCRIPTION OF REQUIREMENT**	**LOCATION/ LANGUAGE/ SIGN AND FONT SIZE**
Health Facility: closure of entire facility; elimination or relocation of a supplemental service	General acute care hospitals, acute psychiatric hospitals (except county facilities subject to Health & Safety Code Section 1442.5) This law does not apply to a hospital that is forced to close or eliminate a service due to a natural disaster or state of emergency that prevents the hospital from operating at its current level.	At least 120 days prior to closing a facility, or 90 days prior to eliminating or relocating a supplemental service to a different campus, a sign must be posted that includes: 1. A description of the proposed closure, elimination, or relocation. The description must be limited to publicly available data, including the number of beds eliminated, if any; the probable decrease in the number of personnel; and a summary of any service that is being eliminated, if applicable. 2. A description of the three nearest available comparable services in the community. If the health facility closing the services serves Medi-Cal or Medicare patients, the facility must specify if the providers of the nearest available comparable services serve these patients. 3. A telephone number and address for each of the following, where interested parties may offer comments: a. The health facility. b. The parent entity, if any, or contracted company, if any, that acts as the corporate administrator of the health facility. c. The chief executive officer. **"Supplemental service"** means an organized inpatient or outpatient service that is not required to be provided by law or regulation. A list of supplemental services for general acute care hospitals is found in Title 22, California Code of Regulations, Sections 70401-70657 and for acute psychiatric hospitals at Title 22, California Code of Regulations, Secton 71403. If the level of emergency services is being reduced or eliminated, the hospital must also comply with the signage requirement described in the row immediately below. **Legal Authority** Health & Safety Code Section 1255.25; Title 22, California Code of Regulations, Section 70067	A sign must be posted at the entrance of all affected facilities and at the entrance of eveny community clinic in the hospital's county that gives permission for this posting. **NOTE:** In addition to signage, notice must be provided to the public, CDPH, the Board of Supervisors, on websites, in newspapers, and in other ways. *(See Health & Safety Code Sections 1255.1-1255.25 for details.)*

HOSPITAL SIGNAGE REQUIREMENTS			
NAME OF SIGN	**WHO MUST COMPLY**	**DESCRIPTION OF REQUIREMENT**	**LOCATION/ LANGUAGE/ SIGN AND FONT SIZE**
Health Facility: reduction or elimination of level of emergency services	General acute care hospitals	At least 180 days prior to a planned reduction or elimination of the level of emergency services, a notice must be posted at the entrance of every community clinic in the hospital's county that gives permission for this posting. This requirement is in addition to the signage requirement described in the row immediately above, if it is applicable (e.g., the emergency service is being eliminated or reduced). **Legal Authority** Health & Safety Code Section 1255.1	

HOSPITAL SIGNAGE REQUIREMENTS			
NAME OF SIGN	**WHO MUST COMPLY**	**DESCRIPTION OF REQUIREMENT**	**LOCATION/ LANGUAGE/ SIGN AND FONT SIZE**
Hill-Burton Community Service Assurance and Uncompensated Care Service	Recipients of federal funding under the Hill-Burton Act that have not completed their Hill-Burton obligations. Only 15 facilities in California remain subject to this requirement; for a list, go to www.hrsa.gov/get-health-care/affordable/hill-burton/facilities.html.	A facility receiving federal funding under Title VI or XVI of the Public Health Service Act (Hill-Burton grants to modernize hospitals) must make its facility (or that portion constructed or renovated with federal funds) available to all persons residing or employed in the geographic area it serves, and provide uncompensated services. The facility must acknowledge this obligation by making a "community service assurance" and posting a sign to that effect. The facility must also post a sign regarding the provision of uncompensated care. The Secretary of the U.S. Department of Health and Human Services will provide the required signs in English and Spanish. **Legal Authority** 42 C.F.R. Sections 124.504(b) (uncompensated care) and 124.604 (community service)	The law does not specify where the community service signs must be posted. Signs about uncompensated care must be posted in "appropriate areas in the facility, including, but not limited to, the admissions areas, the business office, and the emergency room." Signs must be posted in English and Spanish. If 10 percent or more of households in the facility's service area usually speak a language other than English or Spanish, the facility must translate the sign into that language(s) and post signs similar in size and legibility to the English and Spanish signs. In addition, the facility must make reasonable efforts to communicate the contents of the posted notice to persons it has reason to believe cannot read the notice. **Sample Signs** Facilities may obtain the signs in English and Spanish at www.hrsa.gov/get-health-care/affordable/hill-burton/facilities.html.
HIV: Notice of Free Anonymous HIV Test Sites	Blood bank and plasma center collection sites	Blood banks and plasma centers must post a list of locations within the proximate geographic area (including addresses and phone numbers) where anonymous HIV testing is available without charge. **Legal Authority** Health & Safety Code Section 1603.3(d)	The sign must be "prominently displayed" at each collection site.

HOSPITAL SIGNAGE REQUIREMENTS			
NAME OF SIGN	**WHO MUST COMPLY**	**DESCRIPTION OF REQUIREMENT**	**LOCATION/ LANGUAGE/ SIGN AND FONT SIZE**
Housekeeping Schedules and Procedures	Skilled nursing facilities	Skilled nursing facilities must post schedules and procedures that indicate the areas of the facility to be cleaned daily, weekly or monthly **Legal Authority** Title 22, California Code of Regulations, Section 72621(b)	
Human Trafficking and Slavery	General acute care hospitals with emergency rooms, urgent care centers	Specified facilities must post signs developed by the California Department of Justice regarding human trafficking and slavery. The signs contain the following language: If you or someone you know is being forced to engage in any activity and cannot leave — whether it is commercial sex, housework, farm work, construction, factory, retail, or restaurant work, or any other activity — text 233-733 (Be Free) or call the National Human Trafficking Hotline 1-888-373-7888 or the California Coalition to Abolish Slavery and Trafficking (CAST) at 1-888-KEY-2-FRE(EDOM) or 1-888-539-2373 to access help and services. Victims of slavery and human trafficking are protected under United States and California law. The hotlines are: • Available 24 hours a day, 7 days a week. • Toll-free. • Operated by nonprofit, nongovernmental organizations. • Anonymous and confidential. • Accessible in more than 160 languages. • Able to provide help, referral to services, training, and general information. **Legal Authority** Civil Code Section 52.6	A sign must be posted in a conspicuous place near the public entrance of the emergency room, urgent care center or in another conspicuous location in clear view of the public and employees where similar notices are customarily posted. The sign must be at least 81/2 by 11 inches, written in 16-point font. The signs must be posted in English, Spanish and one other language that is the most widely spoken language in the county where the hospital or urgent care center is located and for which translation is mandated by the federal Voting Rights Act (52 U.S.C. Section 10301 *et seq.*). **Sample Signs** Signs and required languages for each county are available at the Department of Justice's website: www.oag.ca.gov/human-trafficking/model-notice.

HOSPITAL SIGNAGE REQUIREMENTS			
NAME OF SIGN	**WHO MUST COMPLY**	**DESCRIPTION OF REQUIREMENT**	**LOCATION/ LANGUAGE/ SIGN AND FONT SIZE**
Infant Feeding	General acute care hospitals and special hospitals that have a perinatal unit	General acute care hospitals and special hospitals that have a perinatal unit must have an infant-feeding policy that applies to all infants in a perinatal unit. The policy must promote breast-feeding, utilizing guidance provided by the Baby-Friendly Hospital Initiative or the CDPH Model Hospital Policy Recommendations. The policy may include guidance on formula supplementation or bottle-feeding, if preferred by the mother or when exclusive breast-feeding is contraindicated for the mother or infant. The policy must be posted. **Legal Authority** Health & Safety Code Section 123366(d)	The policy must be clearly posted in the perinatal unit or on the hospital or health system website.

HOSPITAL SIGNAGE REQUIREMENTS			
NAME OF SIGN	**WHO MUST COMPLY**	**DESCRIPTION OF REQUIREMENT**	**LOCATION/ LANGUAGE/ SIGN AND FONT SIZE**
Interpreter Services ("Point to Your Language")	Pharmacies (except hospital pharmacies that are accessible only to hospital staff)	The law requires pharmacies to post a sign containing the following text: *Point* to your language. Interpreter services will be provided to you upon request at no cost. The pharmacy must use the sign provided by the Board of Pharmacy, unless the pharmacy has received prior approval to use another format or display methodology. **Legal Authority** Title 16, California Code of Regulations, Section 1707.6(c)	The sign must be located in a place conspicuous to and readable by a prescription drug consumer, or adjacent to each counter in the pharmacy where dangerous drugs are dispensed or furnished. The text must be repeated in at least the following languages: Arabic, Armenian, Cambodian, Cantonese, Farsi, Hmong, Korean, Mandarin, Russian, Spanish, Tagalog, and Vietnamese. The pharmacy may post this notice in paper form or on a video screen if a consumer can easily point to and touch the statement identifying the language in which he or she requests assistance. Otherwise, the notice must be made available on a flyer or handout clearly visible from and kept within easy reach of each counter in the pharmacy where dangerous drugs are dispensed or furnished, available at all hours that the pharmacy is open. The flyer or handout must be at least 81/2 by 11 inches. **Sample Sign** www.pharmacy.ca.gov/publications/point_to_your_language.pdf

HOSPITAL SIGNAGE REQUIREMENTS			
NAME OF SIGN	**WHO MUST COMPLY**	**DESCRIPTION OF REQUIREMENT**	**LOCATION/ LANGUAGE/ SIGN AND FONT SIZE**
Interpreter Services (state)	General acute care hospitals	Hospitals must post signs that advise patients and their families that interpreter services are available upon request, list the languages for which interpreter services are available, the procedure for obtaining an interpreter, instruct patients to direct complaints about interpreter service problems to the California Department of Public Health (CDPH), and provide the address and phone number of the CDPH local district office, including a TDD number for the hearing impaired. **Legal Authority** Health & Safety Code Section 1259(c)(3)	The signs must be posted in "conspicuous locations" in the emergency room, the admitting area, the entrance, and in outpatient areas, at a minimum.
Laundry Procedures	Skilled nursing facilities	Skilled nursing facilities must post written procedures for handling, storage, transportation and processing of linens. **Legal Authority** Title 22, California Code of Regulations, Section 72623(d)	Procedures must be posted in the laundry.
License (clinics)	Primary care clinics, psychology clinics	The license must be conspicuously posted. **Legal Authority** Title 22, California Code of Regulations, Sections 75204 (primary care clinics) and 75315 (psychology clinics)	The licence must be posted in a location accessible to public view.
License (home health agency)	Home health agencies	The license, or a true copy thereof, must be conspicuously posted. **Legal Authority** Title 22, California Code of Regulations, Section 74677	The license must be posted in a location accessible to public view in the main business area.
License (hospital license)	General acute care hospitals, acute psychiatric hospitals	Hospitals must post the original or a copy of their license issued by CDPH. **Legal Authority** Title 22, California Code of Regulations, Sections 70123 (general acute care hospitals) and 71121 (acute psychiatric hospitals)	The license must be posted conspicuously in a prominent location within the licensed premises and accessible to public view.

HOSPITAL SIGNAGE REQUIREMENTS			
NAME OF SIGN	**WHO MUST COMPLY**	**DESCRIPTION OF REQUIREMENT**	**LOCATION/ LANGUAGE/ SIGN AND FONT SIZE**
License (professional clinical counselor)	Licensed professional clinical counselors	Licensed professional clinical counselors must post their license in their primary place of practice. This requirement does not apply to hospitals, but if a hospital employs a professional clinical counselor who works at the hospital as his/her primary place of practice, the hospital should help the counselor comply with his/her legal obligation by posting the license in an appropriate place. **Legal Authority** Business & Professions Code Section 4999.70	The license must be posted in a conspicuous place in the counselor's primary place of practice.
License (psychiatric health facilities)	Psychiatric health facilities	The license, or a true copy thereof, must be posted. **Legal Authority** Title 22, California Code of Regulations, Section 77045	The license must be posted a prominent location within the licensed premises and accessible to public view.
License (skilled nursing facilities)	Skilled nursing facilities	The license, or a true copy thereof, must be posted. **Legal Authority** Title 22, California Code of Regulations, Section 72209	The license must be posted conspicuously in a location accessible to public view within the facility.
Mammography: Accreditation Certificate	A mammography facility — a hospital, outpatient department, clinic, radiology practice, mobile unit, physician office, or other facility as determined by the Secretary of the U.S. Department of Health and Human Services, that conducts breast cancer screening or diagnosis through mammography activities.	The U.S. Secretary of Health and Human Services issues a certification of accreditation to accredited mammography facilities. **Legal Authority** 42 U.S.C Section 263b(b)(1)(A)(iii)	The certificate must be prominently displayed.

HOSPITAL SIGNAGE REQUIREMENTS			
NAME OF SIGN	**WHO MUST COMPLY**	**DESCRIPTION OF REQUIREMENT**	**LOCATION/ LANGUAGE/ SIGN AND FONT SIZE**
Mammography: Equipment and Facility Accreditation Certificate	Facilities that operate mammogram machines	CDPH issues Mammography X-Ray Equipment and Facility Accreditation Certificates. **Legal Authority** Health & Safety Code Section 115115	The certificate must be posted on each X-ray machine specifically dedicated to mammography.
Mammography: Licenses, Permits, and Certificates	Facilities that operate mammogram machines	Must publicly post all licenses, permits, and certificates issued by CDPH relating to the use of mammography equipment. **Legal Authority** Health & Safety Code Section 115060(e)(5)	Licenses, permits and certificates must be publicly posted.
Mammography: Serious Violations	Facilities that operate mammogram machines	Facilities that operate mammogram machines must post notices of serious violations — Level 1 deviations (identified by an inspector) from federal Mammography Quality Standards Act of 1992 (42 U.S.C. Section 263b) standards that may seriously compromise the quality of mammography services offered by the facility. The notice must be posted within two working days after receipt. The notice must remain posted for at least five working days, or until action correcting the violation has been completed, whichever is later. **Legal Authority** Health & Safety Code Section 115102	Notices must be posted in an area that is visible to patients.
Medi-Cal Provider Identification	Medi-Cal providers	Medi-Cal provider applicants must be identifiable as a medical/health care provider or business, by permanently attached signage that identifies the name of the provider or business as shown on the Medi-Cal application, unless the applicant or provider is a substance use disorder clinic. The provider must have regular and permanently posted business hours. **Legal Authority** Title 22, California Code of Regulations, Section 51000.60(c)(9)	
Medicare and Medicaid Benefits	Skilled nursing facilities certified for Medicare and Medicaid	A skilled nursing facility must display written information about how to apply for and use Medicare and Medicaid (Medi-Cal) benefits, and how to receive refunds for previous payments covered by such benefits. **Legal Authority** 42 C.F.R. Section 483.10(i)(13)	The information must be prominently displayed in the facility.

HOSPITAL SIGNAGE REQUIREMENTS			
NAME OF SIGN	**WHO MUST COMPLY**	**DESCRIPTION OF REQUIREMENT**	**LOCATION/ LANGUAGE/ SIGN AND FONT SIZE**
Menus	General acute care hospitals, acute psychiatric hospitals	Menus for regular and routine modified diets must be written at least one week in advance, dated and posted in the kitchen at least three days in advance. **Legal Authority** Title 22, California Code of Regulations, Sections 70273(g) (general acute care hospitals) and 71243(g) (acute psychiatric hospitals)	Menus must be posted in the kitchen.
Menus	Skilled nursing facilities	Menus for regular and therapeutic diets shall be written at least one week in advance, dated and posted in the kitchen at least one week in advance. If any meal served varies from the planned menu, the change and the reason for the change must be noted in writing on the posted menu in the kitchen. **Legal Authority** Title 22, California Code of Regulations, Section 72341	Menus must be posted in the kitchen.

HOSPITAL SIGNAGE REQUIREMENTS			
NAME OF SIGN	**WHO MUST COMPLY**	**DESCRIPTION OF REQUIREMENT**	**LOCATION/ LANGUAGE/ SIGN AND FONT SIZE**
No Smoking/ Smoking Permitted	General acute care hospitals, acute psychiatric hospitals	Hospitals must post signs informing patrons where smoking is, and is not, permitted. California law states that smoking is prohibited in patient care areas, waiting rooms, and visiting rooms, except those areas specifically designated as smoking areas. Smoking is not permitted in a patient room unless all persons assigned to the room have requested a smoking room. **NOTE:** Smoking areas also should have a Proposition 65 sign *(see "Proposition 65 Warnings," page 12.42 of this chart).* **Legal Authority** Health & Safety Code Section 1286	Hospitals must post signs as noted in 1. or 2. below: 1. Signs stating that smoking is unlawful must be posted in all areas of the facility where smoking is unlawful; or 2. Signs stating "smoking permitted" must be posted in all areas where smoking is lawfully permitted. Facilities choosing this option must also post signs near all major entrances stating that smoking is unlawful except in areas designated "smoking permitted." No signs are required to be posted in patient rooms. The Joint Commission requires that any locations where smoking is permitted be physically separate from care, treatment, and service areas. *(See TJC* Comprehensive Accreditation Manual for Hospitals*, EC.02.01.03)* Signs must be clearly legible and posted "conspicuously."

HOSPITAL SIGNAGE REQUIREMENTS			
NAME OF SIGN	**WHO MUST COMPLY**	**DESCRIPTION OF REQUIREMENT**	**LOCATION/ LANGUAGE/ SIGN AND FONT SIZE**
No Smoking/ Smoking Permitted	Clinics	Clinics must post signs informing patrons where smoking is, and is not, permitted. California law states that smoking is not permitted in patient areas of a clinic except those rooms designated for occupancy exclusively by smokers. **NOTE:** Smoking areas also should have a Proposition 65 sign *(see "Proposition 65 Warnings," page 12.42 of this chart).* **Legal Authority** Health & Safety Code Section 1234	Clinics must post signs as noted in 1 or 2 below: 1. Signs stating that smoking is unlawful must be posted in all areas of the clinic where smoking is unlawful; or 2. Signs stating "smoking permitted" must be posted in all areas where smoking is lawfully permitted. Clinics choosing this option must also post signs near all major entrances stating that smoking is unlawful except in areas designated "smoking permitted." Signs must be clearly legible and posted "conspicuously."
No Smoking: Cafeteria/Other Dining Area	General acute care hospitals, acute psychiatric hospitals, special hospitals, skilled nursing facilities, and clinics as defined in Health & Safety Code Section 1200	A facility that has a cafeteria or other dining area whose occupied capacity is 50 or more persons must designate a contiguous area of at least 20% of the dining area as a nonsmoking section. **NOTE:** Smoking areas also should have a Proposition 65 sign *(see "Proposition 65 Warnings," page 12.42 of this chart).* **Legal Authority** Health & Safety Code Section 118890	Signs of sufficient number must be posted in locations as to be readily seen by persons within the area.

HOSPITAL SIGNAGE REQUIREMENTS			
NAME OF SIGN	**WHO MUST COMPLY**	**DESCRIPTION OF REQUIREMENT**	**LOCATION/ LANGUAGE/ SIGN AND FONT SIZE**
No Smoking/No Open Flames	Skilled nursing facilities	Skilled nursing facilities must provide designated areas for smoking, as well as a designated area for nonsmoking patients. Nonsmoking areas (which include kitchen areas) must be identified by prominently placed "No Smoking" signs. In addition, smoking and open flames are not permitted in any rooms or spaces where oxygen cylinders are stored or where oxygen is in use. These rooms and spaces must be identified by prominently posted "No Smoking" or "No Open Flame" signs. **NOTE:** Smoking areas also should have a Proposition 65 sign *(see "Proposition 65 Warnings," page 12.42 of this chart).* **Legal Authority** Title 22, California Code of Regulations, Sections 72507 and 72351(i)	Signs must be posted prominently in nonsmoking areas.
No Surprises Act Disclosure Notice	Hospitals, ambulatory surgery centers, physicians and other providers covered by the No Surprises Act	Must post the notice developed by CMS called "Your Rights and Protections Against Surprise Medical Bills" **Legal Authority** 45 C.F.R. Section 149.430	Must be posted "prominently" in emergency department and central location in outpatient department (where ptients schedule care, check in for appointments, or pay bils), at least. **Sample sign** www.cms.gov/files/document/model-disclosure-notice-patient-protections-against-surprise-billing-providers-facilities-health.pdf
Notice of Privacy Practices	Covered entities under HIPAA	Each covered entity under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 must post its Notice of Privacy Practices. The notice must also be available on the covered entity's website for downloading. For more information on what must be included in the notice, see CHA's *California Health Information Privacy Manual*, chapter 3. **Legal Authority** 45 C.F.R. Section 164.520(c)(2)(iii)(B)	Notices must be posted in a clear and prominent location where it is reasonable to expect individuals seeking services to be able to read it.

HOSPITAL SIGNAGE REQUIREMENTS			
NAME OF SIGN	**WHO MUST COMPLY**	**DESCRIPTION OF REQUIREMENT**	**LOCATION/ LANGUAGE/ SIGN AND FONT SIZE**
Notice to Consumers (about dentists)	Licensed dentists engaged in the practice of dentistry	The law requires the following text: ***Notice*** Dentists are licensed and regulated by the Dental Board of California (877) 729-7789 www.dbc.ca.gov **Legal Authority** Business & Professions Code Section 1611.3; Title 16, California Code of Regulations, Section 1065	Signs must be prominently posted in a conspicuous location accessible to public view on the premises where the dentist provides the licensed services and accessible electronically for patients receiving detnal services through telehealth. Signs must be printed in at least 48-point type font. Notices must also be accessible electronically for patients receiving dental services through telehealth. **Sample Sign** www.dbc.ca.gov/formspubs/ntcsign.pdf **NOTE:** The Dental Board of California has not yet updated its sample sign to include dental assistants.

HOSPITAL SIGNAGE REQUIREMENTS			
NAME OF SIGN	**WHO MUST COMPLY**	**DESCRIPTION OF REQUIREMENT**	**LOCATION/ LANGUAGE/ SIGN AND FONT SIZE**
Notice to Consumers (about pharmacies)	Pharmacies (except hospital pharmacies that are accessible only to hospital staff)	The law requires pharmacies to post a sign containing the following text: ***Notice to Consumers*** California law requires a pharmacist to speak with you every time you get a new prescription. You have the right to ask for and receive from any pharmacy prescription drug labels in 12-point font. Interpreter services are available to you upon request at no cost. Before taking your medicine, be sure you know: the name of the medicine and what it does; how and when to take it, for how long, and what to do if you miss a dose; possible side effects and what you should do if they occur; whether the new medicine will work safely with other medicines or supplements; and what foods, drinks, or activities should be avoided while taking the medicine. Ask the pharmacist if you have any questions. This pharmacy must provide any medicine or device legally prescribed for you, unless it is not covered by your insurance; you are unable to pay the cost of a copayment; or the pharmacist determines doing so would be against the law or potentially harmful to health. If a medicine or device is not immediately available, the pharmacy will work with you to help you get your medicine or device in a timely manner. You may ask this pharmacy for information on drug pricing and of generic drugs. **Legal Authority** Business & Professions Code Section 4122; Title 16, California Code of Regulations, Section 1707.6	The sign must be prominently posted, in a place conspicuous to and readable by a prescription drug consumer. The pharmacy must use the notice provided by the Board of Pharmacy, unless the pharmacy has received prior approval to use another format or display methodology. Alternatively, a pharmacy may use a video screen to display the notice, as long as the video screen meets the following criteria: 1. The video screen is at least 24-inches diagonally. 2. The pharmacy uses the video image notice provided by the Board of Pharmacy. 3. The text remains on the screen for at least 60 seconds. 4. No more than five minutes elapse between displays of a particular notice, measured from the time the notice stops displaying to the time it begins to redisplay. The screen must be located in a place conspicuous to and readable by prescription drug consumers.

HOSPITAL SIGNAGE REQUIREMENTS			
NAME OF SIGN	**WHO MUST COMPLY**	**DESCRIPTION OF REQUIREMENT**	**LOCATION/ LANGUAGE/ SIGN AND FONT SIZE**
Notice to Consumers (about physical therapists)	Licensed physical therapists engaged in the practice of physical therapy	The Physical Therapy Board of California has developed a sign, NTC 12-01, Aug. 2, 2012, that must be posted or provided to patients as a handout. **Legal Authority** Title 16, California Code of Regulations, Section 1398.15	The sign must be posted in an area visible to patients on the premises where services are provided. **NOTE:** A written handout may be provided to each patient in lieu of posting a sign. An acknowledgment of receipt, signed and dated by the patient or patient's representative, must be retained in the medical record. **Sample Sign** www.ptbc.ca.gov/laws/ntc_consumer.shtml
Notice to Consumers (about physicians)	Physicians engaged in the practice of medicine	The law requires the following text: ***Notice to Consumers*** Medical doctors are licensed and regulated by the Medical Board of California (800) 633-2322 www.mbc.ca.gov **Legal Authority** Title 16, California Code of Regulations, Section 1355.4 *The Medical Board of California has proposed to change the text of this sign during 2022. For the current status of this proposal, go to www.mbc.ca.gov/About/Laws.	A sign must be prominently posted in an area visible to patients on the premises where the physician provides the licensed services. The sign must be printed in at least 48-point type in Arial font. **NOTE:** A written handout may be provided to each patient in lieu of posting a sign. *(See the regulation text for details about handout requirements.)* **Sample Sign** www.mbc.ca.gov/Download/Documents/notices.pdf

HOSPITAL SIGNAGE REQUIREMENTS			
NAME OF SIGN	**WHO MUST COMPLY**	**DESCRIPTION OF REQUIREMENT**	**LOCATION/ LANGUAGE/ SIGN AND FONT SIZE**
Notice to Consumers (about physician assistants)	Physician assistants providing medical services	The law requires the following text: ***Notification To Consumers*** Physician assistants are licensed and regulated by the Physician Assistant Board (916) 561-8780 www.pac.ca.gov **Legal Authority** Title 16, California Code of Regulations, Section 1399.547	A sign must be prominently posted in an area visible to patients on the premises where the physician assistant provides the licensed services. The sign must be printed in at least 48-point type in Arial font. **NOTE:** A written handout may be provided to each patient in lieu of posting a sign. *(See the regulation text for details about handout requirements.)*
Notice to Consumers (about polysomnography professionals)	Polysomnography profressionals	The law requires the following text: ***Notice to Consumers*** Medical doctors and polysomnographic technologists, technicians and trainees are licensed and regulated by the Medical Board of California. (800) 633-2322 www.mbc.ca.gov **Legal Authority** Title 16, California Code of Regulations, Section 1379.58. *The Medical Board of California has proposed to change the text of this sign during 2022. For the current status of this proposal, go to www.mbc.ca.gov/About/Laws.	A sign must be prominently posted in an area visible to patients on the premises where the registrant provides services. The sign must be printed in at least 48-point Arial font. **NOTE:** A written handout may be provided to each patient in lieu of posting a sign. *(See the regulation text for details about handout requirements.)*

HOSPITAL SIGNAGE REQUIREMENTS			
NAME OF SIGN	**WHO MUST COMPLY**	**DESCRIPTION OF REQUIREMENT**	**LOCATION/ LANGUAGE/ SIGN AND FONT SIZE**
Notice to Consumers (about psychologists)	Licensed psychologists, registered psychologists and registered psychological assistants	The law requires the following text: ***Notice to Consumers*** The Department of Consumer Affair's Board of Psychology receives and responds to questions and complaints regarding the practice of psychology. If you have questions or complaints, you may contact the board by email at bopmail@dca.ca.gov, on the Internet at www.psychology.ca.gov, by calling 1-866-503-3221, or by writing to the following address: Board of Psychology 1625 North Market Blvd., Suite 215 Sacramento, California 95834 **Legal Authority** Business & Professions Code Section 2936; Title 16, California Code of Regulations, Section 1396.5	A sign must be posted in a conspicuous location in the licensee or registrant's principal psychological business office. Licensed psychologists who provide services to a client in a language other than English must post the sign in that language(s).
Nutritional Advice	Any person in commercial practice providing nutritional advice who is not a licensed, certified, or registered healing arts professional acting within their scope of practice	If a hospital employee provides nutritional advice outside their scope of practice, or the employee providing nutritional advice is not a licensed/certified/registered healing arts professional, the following notice must be posted: ***Notice*** State law allows any person to provide nutritional advice or give advice concerning proper nutrition — which is the giving of advice as to the role of food and food ingredients, including dietary supplements. This state law does NOT confer authority to practice medicine or to undertake the diagnosis, prevention, treatment, or cure of any disease, pain, deformity, injury, or physical or mental condition, and specifically does not authorize any person other than one who is a licensed health practitioner to state that any product might cure any disease, disorder, or condition. **Legal Authority** Business & Professions Code Section 2068	A sign must be posted in an easily-visible and prominent place in the advice-giver's place of business. The sign must be at least 81/2 by 11 inches and must be legibly printed with lettering no smaller than 1/2 inches in length, except the lettering of the word "NOTICE" must not be smaller than 1 inch in length. **Sample Sign** CHA Appendix HC 12-F

HOSPITAL SIGNAGE REQUIREMENTS			
NAME OF SIGN	**WHO MUST COMPLY**	**DESCRIPTION OF REQUIREMENT**	**LOCATION/ LANGUAGE/ SIGN AND FONT SIZE**
Observation Unit	General acute care hospitals with observation units	The sign must identify the observation unit area as an "outpatient" area. The sign must use the term "outpatient" ihn the title of the designated area. **Legal Authority** Health & Safety Code Section 1253.7(c)	
Obstetrical Care Notice	General acute care hospitals holding an obstetrical services permit	California law prohibits general acute care hospitals from implementing different standards of obstetrical care based upon the patient's source of payment or ability to pay for medical services. (This law was triggered by the practice of an anesthesiology group to require up-front cash payment for epidurals from uninsured maternity patients.) Each hospital must adopt a written policy of its nondiscrimination in this regard and post notice of this policy. **Legal Authority** Health & Safety Code Section 1256.2	The sign must be posted in the obstetrical admitting areas of the hospital, in the predominant language or languages spoken in the hospital's service area. **Sample Sign** CHA Appendix 10-C[S]
Outpatient Settings Accreditation Information	Accredited Outpatient Settings	An accredited outpatient setting must post its certificate of accreditation and the name and telephone number of the accrediting agency with instructions on the submission of complaints. An "outpatient setting" means any facility, clinic, unlicensed clinic, center, office, or other setting that is not part of a general acute care hospital, and where anesthesia, except local anesthesia or peripheral nerve blocks, or both, is used in compliance with the community standard of practice, in doses that, when administered have the probability of placing a patient at risk for loss of the patient's life-preserving protective reflexes. "Outpatient setting" also means facilities that offer in vitro fertilization. "Outpatient setting" does not include a setting where anxiolytics and analgesics are administered, when done so in compliance with the community standard of practice, in doses that do not have the probability of placing the patient at risk for loss of the patient's life-preserving protective reflexes. **Legal Authority** Health & Safety Code Sections 1248 and 1248.15(a)	The certificate and notice must be posted in a location visible to staff and patients.

HOSPITAL SIGNAGE REQUIREMENTS			
NAME OF SIGN	**WHO MUST COMPLY**	**DESCRIPTION OF REQUIREMENT**	**LOCATION/ LANGUAGE/ SIGN AND FONT SIZE**
Patient Rights (federal)	General acute care hospitals and acute psychiatric hospitals that are certified for Medicare and Medicaid	Hospitals are required by federal law to inform patients of their rights. Federal law does not specify these rights, although the preamble to the final rule provides some guidance. Federal law also does not specify how a hospital must inform a patient — whether verbally, by a handout, or by a sign; the federal government leaves it to the hospital to determine how best to notify each patient. The U.S. Department of Health and Human Services (DHHS) indicated in the preamble to the final rule regarding patient rights that posting notices in the facility may suffice. However, patients who come to the facility in an emergency condition are unlikely to be able to read and comprehend posted notices. For these patients, a handout may provide better notice. (Surveyors are required to interview patients who are blind, deaf or limited English proficient to determine if they were informed of their rights in a language and manner they understand.) CHA has combined this requirement with the state patient rights requirement (page 12.38) and developed CHA Appendix 1-A. Hospitals may wish to use CHA Appendix 1-A as both a sign and a handout to ensure that each patient receives notice of his/her rights. Each hospital's handout should also include the patient's visitation rights. These are not included in CHA Appendix 1-A because each hospital will have different visitation policies. **Legal Authority** 42 C.F.R. Section 482.13	
Patient Rights (LGBT) — *see SNF LGBT Rights*			

HOSPITAL SIGNAGE REQUIREMENTS			
NAME OF SIGN	**WHO MUST COMPLY**	**DESCRIPTION OF REQUIREMENT**	**LOCATION/ LANGUAGE/ SIGN AND FONT SIZE**
Patient Rights (mental health patients)	Facilities (including general acute care hospitals, acute psychiatric hospitals, and psychiatric health facilities) that treat involuntarily detained or voluntarily admitted mental health patients	The following rights must be posted: Each person voluntarily admitted or involuntarily detained for mental health evaluation or treatment has the following rights: 1. To wear his or her own clothes; to keep and use his or her own personal possessions including his or her toilet articles; and to keep and be allowed to spend a reasonable sum of his or her own money for canteen expenses and small purchases. 2. To have access to individual storage space for his or her private use. 3. To see visitors each day. 4. To have reasonable access to telephones, both to make and receive confidential calls or to have such calls made for them. 5. To have ready access to letter-writing materials, including stamps, and to mail and receive unopened correspondence. 6. To refuse convulsive treatment including, but not limited to, any electroconvulsive treatment, any treatment of the mental condition which depends on the induction of a convulsion by any means, and insulin coma treatment. 7. To refuse psychosurgery. Psychosurgery is defined as those operations currently referred to as lobotomy, psychiatric surgery, and behavioral surgery, and all other forms of brain surgery if the surgery is performed for the purpose of any of the following: a. Modification or control of thoughts, feelings, actions, or behavior rather than the treatment of a known and diagnosed physical disease of the brain. b. Modification of normal brain function or normal brain tissue in order to control thoughts, feelings, actions, or behavior. *(continued)*	The list of rights must be prominently posted in English and Spanish, and in the predominant languages of the community. This list shall be posted in all wards and common living areas. **Sample Sign** Sign may be found at www.dhcs.ca.gov/services/pages/office-of-patients-rights.aspx.

HOSPITAL SIGNAGE REQUIREMENTS			
NAME OF SIGN	**WHO MUST COMPLY**	**DESCRIPTION OF REQUIREMENT**	**LOCATION/ LANGUAGE/ SIGN AND FONT SIZE**
Patient Rights (mental health patients) *(continued)*	Facilities (including general acute care hospitals, acute psychiatric hospitals, and psychiatric health facilities) that treat involuntarily detained or voluntarily admitted mental health patients	*(continued)* c. Treatment of abnormal brain function or abnormal brain tissue in order to modify thoughts, feelings, actions or behavior when the abnormality is not an established cause for those thoughts, feelings, actions, or behavior. Psychosurgery does not include prefrontal sonic treatment wherein there is no destruction of brain tissue. The Director of Health Care Services and the Director of State Hospitals shall promulgate appropriate regulations to assure adequate protection of patients' rights in such treatment. 8. To see and receive the services of a patient advocate who has no direct or indirect clinical or administrative responsibility for the person receiving mental health services. 9. If you believe a right of yours has been abused, punitively withheld, or unreasonably denied, you may file a complaint with the Patients'/Residents' Advocate: [insert name, phone number, and hours during which the advocate may be contacted]. **Legal Authority** Welfare & Institutions Code Section 5325; Title 9, California Code of Regulations, Sections 860 and 862; Title 22, California Code of Regulations, Section 71507	The list of rights must be prominently posted in English and Spanish, and in the predominant languages of the community. This list shall be posted in all wards and common living areas. **Sample Sign** Sign may be found at www.dhcs.ca.gov/services/pages/office-of-patients-rights.aspx.
Patient Rights (state)	General acute care hospitals	Hospitals are required by state law to post a list of patient rights. CHA has combined this state requirement with the federal patient rights requirement (above) and developed CHA Appendix 1-A[S]. **Legal Authority** Title 22, California Code of Regulations, Section 70707	The signs must be posted in English and Spanish in "appropriate places within the hospital so that such rights may be read by patients." **Sample Signs** CHA Appendix 1-A[S]

HOSPITAL SIGNAGE REQUIREMENTS			
NAME OF SIGN	**WHO MUST COMPLY**	**DESCRIPTION OF REQUIREMENT**	**LOCATION/ LANGUAGE/ SIGN AND FONT SIZE**
Patient Rights: Patients in a Psychiatric Unit of a General Acute Care Hospital	General acute care hospitals with psychiatric units	A sign must be posted informing patients in the psychiatric unit of their rights. The text must include: All patients shall have rights which include, but are not limited to, the following: 1. To wear his own clothes; to keep and use his own personal possessions including his toilet articles; and to keep, and be allowed to spend, a reasonable sum of his own money for canteen expenses and small purchases. 2. To have access to individual storage space for his private use. 3. To see visitors each day. 4. To have reasonable access to telephones, both to make and receive confidential calls. 5. To have ready access to letter writing materials, including stamps, and to mail and receive unopened correspondence. 6. To refuse shock treatment. 7. To refuse lobotomy. 8. To be informed of the provisions of law regarding complaints and of procedures for registering complaints confidentially, including, but not limited to, the address and telephone number of the complaint receiving unit of the Department. 9. All other rights as provided by law or regulations. **Legal Authority** Title 22, California Code of Regulations, Section 70577(k)	The sign must be "prominently" posted in English and Spanish. **Sample Sign** Sign may be found at www.dhcs.ca.gov/services/pages/office-of-patients-rights.aspx.
Patient Rights: Psychiatric Health Facilities	Psychiatric health facilities	The governing body of the psychiatric health facility is required to adopt and implement written policies regarding patients' rights to ensure compliance with Welfare and Institutions Code Sections 5325, 5325.1, 5326, 5326.1, 5326.9, 5326.95 and 5520 through 5550. A list of these rights must be posted in the facility. **Legal Authority** Title 22, California Code of Regulations, Section 77099	Signs must be posted in appropriate places within the psychiatric health facility so that such rights may be read by patients. In English and in the predominant language of the community, if other than English. **Sample Sign** Sign may be found at www.dhcs.ca.gov/services/pages/office-of-patients-rights.aspx.

HOSPITAL SIGNAGE REQUIREMENTS			
NAME OF SIGN	**WHO MUST COMPLY**	**DESCRIPTION OF REQUIREMENT**	**LOCATION/ LANGUAGE/ SIGN AND FONT SIZE**
Patient Rooms	General acute care hospitals, acute psychiatric hospitals, skilled nursing facilities	Each patient room must be labeled with a number, letter or combination of the two for identification. **Legal Authority** Title 22, California Code of Regulations, Sections 70811(b) (general acute care hospitals), 71661(b) (acute psychiatric hospitals) and 72609 (skilled nursing facilities)	
Patient Rooms Approved for Use by Ambulatory Patients Only	General acute care hospitals, acute psychiatric hospitals, skilled nursing facilities	Patient rooms approved for use by ambulatory patients only must be identified with a sign that says: "Reserved for Ambulatory Patients." **Legal Authority** Title 22, California Code of Regulations, Sections 70811(d) (general acute care hospitals), 71661(d) (acute psychiatric hospitals) and 72609 (skilled nursing facilities)	Signs must be posted on the outside of the door or on the wall alongside the door where they are visible to persons entering the room. Letters must be at least 11/2 centimeters (1/2 inch) high.
Pharmacy (Medicare patients)	Pharmacies that participate in the Medi-Cal program (retail pharmacies only, not pharmacies located in a hospital that is accessible only to hospital staff)	Pharmacies may charge Medicare beneficiaries no more than the Medi-Cal reimbursement rate, plus an amount set by the Department of Health Care Services (DHCS) for electronic transmission charges, for prescription medications. This does not apply to prescriptions that are covered by insurance, over-the-counter medications, or compounded prescriptions. DHCS is required to provide signs to participating pharmacies that remind Medicare beneficiaries to ask that the charge for their prescription be the same amount as the Medi-Cal reimbursement rate and provide DHCS' phone number, e-mail address, and web address. **Legal Authority** Business & Professions Code Section 4425	Signs must be prominently displayed at the point of service and the point of sale.
Phlebotomist Certificate	Clinical laboratories that employ a Limited Phlebotomy Technicians Certified Phlebotomy Technician I, or Certified Phlebotomy Technician II	Phlebotomy technicians may perform skin punctures only if they have posted their current, valid state phlebotomy certificates at the work location in the laboratory employing the technician. (While performing skin punctures away from the posted location, phlebotomy technicians must carry a current, valid ID card issued by CDPH showing the technician's name, certificate type and effective dates.) **Legal Authority** Title 17, California Code of Regulations, Section 1034	Post certificates in the work location in the laboratory employing the technician.

HOSPITAL SIGNAGE REQUIREMENTS			
NAME OF SIGN	**WHO MUST COMPLY**	**DESCRIPTION OF REQUIREMENT**	**LOCATION/ LANGUAGE/ SIGN AND FONT SIZE**
Physician Availability	Skilled nursing facilities	Skilled nursing facilities must make arrangements for a physician(s) to be available to furnish emergency medical care if the attending physician, or designee, is unavailable. The phone numbers of those physicians must be posted. **Legal Authority** Title 22, California Code of Regulations, Section 72301(g)	The phone numbers must be posted in a conspicuous place in the facility.
Practitioner Identification	Healing arts professionals licensed under Division 2 of the Business & Professions Code who are not working in a hospital, SNF, lab or other health facility	Healing arts professionals must communicate the following information to each patient: 1. The professional's name. 2. The professional's state-granted practitioner license type. 3. The highest level of academic degree (nurses and pharmacists need not include this information). The information may be communicated by a handout at the patient's initial office visit or by a sign. Some physicians must include board certification (ABMS/MBC) information rather than state-granted practitioner license type. This requirement does not apply to professionals working in a facility licensed under Health & Safety Code Section 1250 (which includes general acute care hospitals, acute psychiatric hospitals, skilled nursing facilities, and other facilities) or a clinical laboratory. **Legal Authority** Business & Professions Code Section 680.5	If a sign is used, it must be prominently display in an area visible to patients in the practitioner's office.
Program Flexibility	General acute care hospitals, acute psychiatric hospitals, skilled nursing facilities, psychiatric health facilities	All hospitals must maintain continuous compliance with licensing requirements. However, CDPH can approve the use of alternate concepts, methods, procedures, equipment, personnel qualifications, etc., if these exceptions are carried out with provisions for safe and adequate patient care. The prior written approval of CDPH is required. CDPH's written approval (or a copy) must be posted. **Legal Authority** Title 22, California Code of Regulations, Sections 70129(d), 70307(b), 70363(b) (general acute care hospitals); 71127, 71307 (acute psychiatric hospitals); 72213 (skilled nursing facilities); and 77045(b) (psychiatric health facilities)	CDPH approval must be posted immediately adjacent to the facility's license *(see "License (hospital license)," page 12.23 or "License (skilled nursing facilities)," page 12.24 of this chart).*

HOSPITAL SIGNAGE REQUIREMENTS			
NAME OF SIGN	**WHO MUST COMPLY**	**DESCRIPTION OF REQUIREMENT**	**LOCATION/ LANGUAGE/ SIGN AND FONT SIZE**
Proposition 65 Warnings	Most hospitals and facilities are required to comply with this law; see column to the right for details.	Persons or entities that expose any individual (such as a patient, visitor, or employee) to a chemical known to the state to cause cancer or reproductive toxicity must provide "clear and reasonable warnings." A list of such chemicals may be found at www.oehha.ca.gov/proposition-65/proposition-65-list. The warning requirement applies to consumer products exposure, occupational exposure, and environmental exposure. A hospital will likely be required to post different signs in different areas — enclosed parking facilities, areas where wood dust exists (construction area), cafeteria, vehicle repair areas, dental offices, near diesel generators, etc. The warning message must contain specified language. The language required depends upon whether it relates to a consumer product, occupational exposure, or environmental exposure; however, the message must clearly communicate that the chemical in question is known to the state to cause cancer, or birth defects or other reproductive harm. The method employed to transmit the warning must be reasonably calculated to make the warning message available to the individual prior to exposure. Some methods include labeling products, posting signs, or publishing notices in a newspaper. This law does not does not apply to a city, county, or district or any department or agency thereof or the state or any department or agency thereof or the federal government or any department or agency thereof. [Title 27, California Code of Regulations, Section 25102(k)] *(continued)*	**Sample Sign** Sample signs may be found at www.p65warnings.ca.gov/sample-warnings-and-translations-businesses

HOSPITAL SIGNAGE REQUIREMENTS			
NAME OF SIGN	**WHO MUST COMPLY**	**DESCRIPTION OF REQUIREMENT**	**LOCATION/ LANGUAGE/ SIGN AND FONT SIZE**
Proposition 65 *(continued)*	Most hospitals and facilities are required to comply with this law; see column to the right for details	*(continued)* Exemptions from signage requirement: 1. An exposure for which federal law governs warning in a manner that preempts state authority. 2. An exposure that takes place less than 12 months after the Office of Environmental Health Hazard Assessment lists the chemical. 3. An exposure for which the person responsible can show that the exposure poses no significant risk assuming lifetime exposure at the level in question for substances known to the state to cause cancer, and that the exposure will have no observable effect assuming exposure at 1000 times the level in question for substances known to the state to cause reproductive toxicity, based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis or the listing of such chemical. A complete discussion of Proposition 65 (the Safe Drinking Water and Toxic Enforcement Act of 1986) is beyond the scope of this Hospital Signage Requirements chart. *(See chapter 5 of CHA's* Consent Manual*, and your legal counsel, for more information.)* **Legal Authority** Health & Safety Code Section 25249.5 *et seq.*; Title 27, California Code of Regulations, Section 25600 *et seq.*	

HOSPITAL SIGNAGE REQUIREMENTS			
NAME OF SIGN	**WHO MUST COMPLY**	**DESCRIPTION OF REQUIREMENT**	**LOCATION/ LANGUAGE/ SIGN AND FONT SIZE**
Prostate Cancer: Be Informed	Every person or entity who owns or operates a health facility or clinic, or who is licensed as a physician and rents or owns the premises where his/her practice is located	The law requires the following text: ***Be Informed*** If you are a patient being treated for any form of prostate cancer, or prior to performance of a biopsy for prostate cancer, your physician and surgeon is urged to provide you a written summary of alternative efficacious methods of treatment, pursuant to Section 109280 of the California Health & Safety Code. The information about methods of treatment was developed by the State Department of Public Health to inform patients of the advantages, disadvantages, risks, and descriptions of procedures. The sign must also include the web address of CDPH and the Medical Board of California, and a notice stating that updated prostate cancer summaries are available at these websites. **Legal Authority** Health & Safety Code Section 109282	Signs must be posted where a physician performs prostate cancer screening or treatment, or in a reasonably proximate area. A sign posted at the patient registration area constitutes compliance with this law. The signs must be conspicuously displayed so as to be readable. The sign must be at least 81/2 by 11 inches. The words "BE INFORMED" must be at least 1/2 inch tall and centered on a single line with no other text. The message must be in English, Spanish and Chinese. **Sample Sign** CHA Appendix 4-C[S]
Provider-Based Off-Campus Outpatient Locations	Hospitals that participate in Medicare and have off-campus, provider-based outpatient services	Provider-based facilities must make patients aware that they are entering a facility of the main provider (hospital) and will be billed accordingly. Technically, the law does not require signage, but most facilities use signage to fulfill this requirement. In addition, prior to delivery of services, the patient must receive written notice regarding his/her potential financial liability. If the exact type and extent of care needed are not known, the patient must receive a written explanation that the beneficiary will incur a coinsurance liability to the hospital that he or she would not incur if the facility were not provider-based; an estimate based on typical or average charges for visits to the facility; and a statement that the patient's actual liability will depend upon the actual services furnished by the hospital. **Legal Authority** 42 C.F.R. Section 413.65(d)(4) and (g)(7)	The notice or signage must be one that Medicare beneficiaries can read and understand.

HOSPITAL SIGNAGE REQUIREMENTS			
NAME OF SIGN	**WHO MUST COMPLY**	**DESCRIPTION OF REQUIREMENT**	**LOCATION/ LANGUAGE/ SIGN AND FONT SIZE**
Radiation: Caution (federal)	Persons or entities licensed by the Nuclear Regulatory Commission	Depending on the level of radiation, the area must be marked with a sign(s) that contains the radiation symbol and text as follows: 1. Radiation area (area where an individual could receive a dose in excess of 0.005 rem in 1 hour at 30 cm from source or from any surface the radiation penetrates): "CAUTION, RADIATION AREA." 2. High radiation area (area where an individual could receive a dose in excess of 0.1 rem in 1 hour at 30 cm from source or any surface the radiation penetrates): "CAUTION, HIGH RADIATION AREA" or "DANGER, HIGH RADIATION AREA." 3. Very high radiation area (area where an individual could receive a dose in excess of 500 rads rem in 1 hour at 1 meter from source or from any surface the radiation penetrates): "GRAVE DANGER, VERY HIGH RADIATION AREA." 4. Airborne radioactivity area (area where radioactive material is dispersed in the air in the form of dusts, fumes, particulates, mists, vapors, or gases): "CAUTION, AIRBORNE RADIOACTIVITY AREA" or "DANGER, AIRBORNE RADIOACTIVITY AREA." 5. Areas/room where licensed material is used or stored in an amount exceeding 10 times the quantity specified in appendix C to 10 C.F.R. Part 20: "CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER, RADIOACTIVE MATERIAL(S)." However, areas or rooms with permanently installed X-ray machines as the only source of radiation must post the signage specified under "Radiation: Caution (state)," page 12.45. **Legal Authority** 10 C.F.R. Sections 20.1003 and 20.1902	The signs must be conspicuous.
Radiation: Caution (state)	Users of X-rays in medicine, dentistry, osteopathy, chiropractic, podiatry, and veterinary medicine	Areas or rooms with permanently installed X-ray machines as the only source of radiation must have a sign(s) that says: ***Caution: X-Ray*** This sign must be used instead of the signs required by 10 C.F.R. Section 20.1902 *(see "Radiation: Caution (federal)," page 12.45)*. **Legal Authority** Title 17, California Code of Regulations, Section 30305(c)	

HOSPITAL SIGNAGE REQUIREMENTS			
NAME OF SIGN	**WHO MUST COMPLY**	**DESCRIPTION OF REQUIREMENT**	**LOCATION/ LANGUAGE/ SIGN AND FONT SIZE**
Radiation Safety Information	Persons/entities licensed to possess radioactive material, registered as possessing a reportable source of radiation, or otherwise possessing a source of radiation under the Radiation Control Law	Users must post the following: 1. A current copy of Title 17, California Code of Regulations, Section 30255. 2. Applicable licenses for radioactive material. 3. A copy of operating and emergency procedures applicable to work with sources of radiation. If posting of any document(s) listed above is not practicable, the user may post a notice that describes the document and states where it may be examined. **Legal Authority** Title 17, California Code of Regulations, Section 30255(b)(2)	Documents/notices/ forms posted pursuant to this law must be conspicuous and must appear in a sufficient number of places to permit individuals engaged in work under the license/registration to observe them on the way to or from any particular work location to which the documents/notices/ forms apply.
Radiation Safety (notice to employees)	Persons/entities licensed to possess radioactive material, registered as possessing a reportable source of radiation, or otherwise possessing a source of radiation under the Radiation Control Law	Users must post a current copy of CDPH Form RH-2364 (Notice to Employees — Standards for Protection Against Radiation) **Legal Authority** Title 17, California Code of Regulations, Section 30255(b)(3)	The notice must be conspicuously posted in a sufficient number of places to permit individuals working in or frequenting any portion of a controlled area to observe a copy on the way to or from the area. **Sample Sign** https://www.cdph.ca.gov/Programs/CEH/DRSEM/Pages/RHB.aspx
Radiation Safety Violations	Persons/entities licensed to possess radioactive material, registered as possessing a reportable source of radiation, or otherwise possessing a source of radiation under the Radiation Control Law	Users must post any notice of violation involving radiological working conditions or any order issued pursuant to the Radiation Control Law and any required response from the user. Notices of violations must be posted within two working days of receipt. The user's response, if any, must be posted within two working days after dispatch by the user. The documents must remain posted for a minimum of five working days or until action correcting the violation has been completed, whichever is later. **Legal Authority** Title 17, California Code of Regulations, Section 30255(b)(4)	Notices of violations must be conspicuously posted and must appear in a sufficient number of places to permit individuals engaged in work under the license/registration to observe them on the way to or from any particular work location to which the violations apply.

HOSPITAL SIGNAGE REQUIREMENTS			
NAME OF SIGN	**WHO MUST COMPLY**	**DESCRIPTION OF REQUIREMENT**	**LOCATION/ LANGUAGE/ SIGN AND FONT SIZE**
Radiation technologist certificates/ permits	Users of X-rays in medicine, dentistry, osteopathy, chiropractic, podiatry, and veterinary medicine	Users must display either: 1. A copy of the current certificate or permit for each certified radiologic technologist or supervisor and operator, or 2. A list of all such persons containing: a. Each individual's name, the applicable certificate or permit number, and the expiration date in at least 12-point font and b. The statement "A copy of the individual's certificate or permit is available for viewing upon request." in at least 14-point font. Users that post the list must keep a copy of each certificate or permit for each individual on the list. **Legal Authority** Title 17, California Code of Regulations, Section 30305(e) and (f)	See font size requirements in the cell to the left.
Referrals	Organizations in which a licensee under Division 2 of the Business & Professions Code (healing arts professionals) or a licensee's immediate family member has a significant beneficial interest (such as a financial interest)	It is illegal for specified healing arts professionals to charge, bill or otherwise solicit payment from a patient of, or refer a patient to, an organization in which the licensee or the licensee's immediate family member has a significant beneficial interest, unless the licensee first discloses that information to the patient. This law permits notice to be given by posting a sign or providing a handout. However, a written handout is required to be given to patients at the time of a referral by Business & Professions Code Section 650.01(f) and by 42 C.F.R. Section 489.20(u). **Legal Authority** Business & Professions Code Section 654.2	If a sign is used, it must be posted conspicuously in an area that is likely to be seen by all patients who use the facility. If the referrals, billings, or other solicitations are between licensees who contract with multispecialty clinics or who practice as members of the same group on the same physical premises, the sign may be posted at a single location that is a common area or registration area. **Sample Sign** CHA Appendix HC 12-H

HOSPITAL SIGNAGE REQUIREMENTS			
NAME OF SIGN	**WHO MUST COMPLY**	**DESCRIPTION OF REQUIREMENT**	**LOCATION/ LANGUAGE/ SIGN AND FONT SIZE**
Safe for Patients' Belongings	Hospitals	A hospital that wishes to limit liability for patient valuables must notify patients of the availability of a fireproof safe. The sign must state that the safe exists and that the hospital will not be liable for money, jewelry, documents, furs, or other small articles of unusual value unless placed in the safe. The hospital may wish to add "electronic devices" to the list. *(See chapter 20 of CHA's* Consent Manual *for more information about liability for patients' belongings.)* **Legal Authority** Civil Code Section 1860	The sign must be posted conspicuously in the Admissions Office or in the patient's room. Alternatively, a handout may be given to the patient.
Safe Surrender Site (for abandoned newborns)	Public and private hospitals	The signs must notify the public where to surrender a newborn baby (under 72 hours of age). The sign must include the logo designed by the California Department of Social Services. *(See CHA's* Consent Manual*, chapter 13, for complete information on hospitals' responsibilities regarding surrendered newborns.)* **Legal Authority** Health & Safety Code Section 1255.7	Signs must be posted in the location designated by the hospital to be the newborn surrender site. Most hospitals have designated the ED, but the hospital can designate any location. **Sample Sign** CHA Appendix 10-B[S]

HOSPITAL SIGNAGE REQUIREMENTS			
NAME OF SIGN	**WHO MUST COMPLY**	**DESCRIPTION OF REQUIREMENT**	**LOCATION/ LANGUAGE/ SIGN AND FONT SIZE**
SNF Facility Rating	Skilled nursing facilities that are certified for Medicare or Medi-Cal purposes	Skilled nursing facilities must post the overall facility rating information determined by the federal Centers for Medicare & Medicaid Services (CMS). The sign must include: 1. The full name of the facility in at least 28-point font. 2. The full address of the facility in at least 20-point font. 3. The most recent overall star rating given by CMS. A facility has seven business days from receipt to post an updated rating. The star rating must be aligned in the center of the page in at least 2-inch print. The star rating must be expressed as the number of stars given by CMS. 4. The following text in at least 28-point font: "The above number is out of 5 stars." 5. The following text in at least 14-point font: "This facility is reviewed annually and has been licensed by the State of California and certified by the federal Centers for Medicare and Medicaid Services (CMS). CMS rates facilities that are certified to accept Medicare or Medicaid. CMS gave the above rating to this facility. A detailed explanation of this rating is maintained at this facility and will be made available upon request. This information can also be accessed online at the Nursing Home Compare Internet website at www.medicare.gov/NHcompare. Like any information, the Five-Star Quality Rating System has strengths and limits. The criteria upon which the rating is determined may not represent all of the aspects of care that may be important to you. You are encouraged to discuss the rating with facility staff. The Five-Star Quality Rating System was created to help consumers, their families, and caregivers compare nursing homes more easily and help identify areas about which you may want to ask questions. Nursing home ratings are assigned based on ratings given to health inspections, staffing, and quality measures. Some areas are assigned a greater weight than other areas. These ratings are combined to calculate the overall rating posted here." *(continued)*	

HOSPITAL SIGNAGE REQUIREMENTS			
NAME OF SIGN	**WHO MUST COMPLY**	**DESCRIPTION OF REQUIREMENT**	**LOCATION/ LANGUAGE/ SIGN AND FONT SIZE**
SNF Facility Rating *(continued)*	Skilled nursing facilities that are certified for Medicare or Medi-Cal purposes	*(continued)* 6. The following text in at least 14-point font: "State licensing information on skilled nursing facilities is available on the State Department of Public Health's website at: www.cdph.ca.gov, under Programs, Licensing and Certification, Health Facilities Consumer Information System." **Legal Authority** Health & Safety Code Section 1418.21	Signs must be posted in at least the following locations: 1. An area accessible and visible to members of the public. 2. An area used for employee breaks. 3. An area used by residents for communal functions, such as dining, resident council meetings, or activities. The information must be posted on white or light-colored paper. *(See required font sizes in the third column of this row.)*
SNF Grievance Process	Skilled nursing facilities that are certified for Medicare or Medi-Cal purposes	SNFs must post or notify each resident individually information about the right to file grievances orally or in writing; the right to file grievances anonymously; the contact information of the grievance official's name, business address (mailing and email) and phone number; a reasonable expected time frame for completing the review of the grievance; the right to obtain a written decision regarding the grievance; and the contact information of independent entities with whom grievances may be filed (the pertinent state agency, quality improvement organization, state survey agency and state long-term care ombudsman program or protection and advocacy system. **Legal Authority** 42 C.F.R. Section 483.10(j)	Notices must be posted in prominent locations throughout the facility

HOSPITAL SIGNAGE REQUIREMENTS			
NAME OF SIGN	**WHO MUST COMPLY**	**DESCRIPTION OF REQUIREMENT**	**LOCATION/ LANGUAGE/ SIGN AND FONT SIZE**
SNF LGBT Rights	Skilled nursing facilities	Every SNF must post the following notice: "[Name of facility] does not discriminate and does not permit discrimination, including, but not limited to, bullying, abuse, or harassment, on the basis of actual or perceived sexual orientation, gender identity, gender expression, or HIV status, or based on association with another individual on account of that individual's actual or perceived sexual orientation, gender identity, gender expression, or HIV status. You may file a complaint with the Office of the State Long-Term Care Ombudsman [provide contact information] if you believe that you have experienced this kind of discrimination." **Legal Authority** Health & Safety Code Section 1439.51(c)	The sign must be posted alongside the SNF's nondiscrimination policy in all places and on all materials where that policy is posted.
SNF Patient Census and Staffing Information	Skilled nursing facilities	A SNF must post the following information daily at the beginning of each shift: 1. Facility name. 2. The current date. 3. The total number and the actual hours worked by the following categories of licensed and unlicensed nursing staff directly responsible for resident care per shift: registered nurses, licensed vocational nurses, and certified nurse aides. 4. Resident census. The posting must include the actual number of licensed and certified nursing staff directly responsible for the care of patients for that particular day on each shift. The posting must also designate the patient assignment by specifying each room and bed to which each certified nurse assistant is assigned and the assignment of each licensed nurse and any other direct caregiver not assigned to a specific room or beds. **Legal Authority** 42 C.F.R. Section 483.35(g); Health & Safety Code Section 1276.65(f); Title 22, California Code of Regulations, Section 72329.1(i)	The information must be publicly displayed in a clearly visible place, readily accessible to visitors and residents.

HOSPITAL SIGNAGE REQUIREMENTS			
NAME OF SIGN	**WHO MUST COMPLY**	**DESCRIPTION OF REQUIREMENT**	**LOCATION/ LANGUAGE/ SIGN AND FONT SIZE**
SNF Survey Results	Skilled nursing facilities that are certified for Medicare or Medi-Cal purposes	SNFs must post (1) the results of the most recent survey of the facility, and (2) notice of the availability of reports of any surveys, certifications, and complaint investigations during the 3 preceding years, and any plan of correction in effect. **Legal Authority** 42 C.F.R. Section 483.10(g)(11)	Notices must be posted in a place prominent and readily accessible to residents; family members and legal representatives of residents; and the public
Special Permit	General acute care hospitals	CDPH issues a special permit for basic EMS, burn center, cardiovascular surgery service, chronic dialysis unit, comprehensive EMS, intensive care newborn nursery, psychiatric unit, radiation therapy service, and renal transplant center. The special permit, or a copy, must be posted. **Legal Authority** Title 22, California Code of Regulations, Section 70359	Permits must be posted conspicuously in a prominent location within the licensed premises and accessible to public view.
Staffing information — *see SNF Patient Census and Staffing Information*			
Water Temperature	General acute care hospitals, acute psychiatric hospitals, skilled nursing facilities	Taps delivering water at 51.6 degrees Celsius (125 degrees Fahrenheit) or higher must be identified prominently by warning signs. **Legal Authority** Title 22, California Code of Regulations, Sections 70863(f) (general acute care hospitals) and 71665(f) (acute psychiatric hospitals)	No specific location is specified in the law; presumably the sign should be close to the tape where people will see it before using the tap. Letters must be 5 cm (2 inches) high.

APPENDIX HC 12-C

Notice of Community Service Obligation (CHFCLI)

This facility has agreed to make its services available to all persons residing or employed in this area.

This facility is prohibited by law from discriminating against Medi-Cal and Medicare patients. If you believe you may be eligible for Medi-Cal or Medicare, you should contact the office or person below for assistance in applying.

_____

_____

[insert contact information for the business office or another designated person or office]

You should also contact the person or office named above if you need a physician to provide you with services at this facility.

If you believe that you have been refused services at this facility in violation of the community service obligation, you should inform the person or office named above and the Office of Statewide Health Planning and Development.

Do Not Remove This Sign

This sign is required to be posted according to Health and Safety Code Section 129065(d).

APPENDIX HC 12-D

Notice of Community Service Obligation (CHFFA)

This facility has agreed to make its services available to all persons residing or employed in this area.

This facility is prohibited by law from discriminating against Medi-Cal and Medicare patients. If you believe you may be eligible for Medi-Cal or Medicare, you should contact the office or person below for assistance in applying.

_____

_____

[insert contact information for the business office another designated person or office]

You should also contact the person or office named above if you need a physician to provide you with services at this facility.

If you believe that you have been refused services at this facility in violation of the community service obligation, you should inform the person or office named above and the California Health Facilities Financing Authority.

Do Not Remove This Sign

This sign is required to be posted according to Government Code Section 15459.1.

APPENDIX HC 12-E

Notice of Hill-Burton Obligation

This hospital (or other facility) is required by law to give a reasonable amount of service at no cost or less than full cost to people who cannot pay.

If you think that you are eligible for these services, please contact our business office and ask for assistance.

_____

_____

(Office location)

If you are not satisfied with the results, you may contact

_____

_____

(State Hill-Burton Agency Address)

Do Not Remove This Sign

This sign is required to be posted according to 42 C.F.R. Sections 124.504(b) and 124.604.

APPENDIX HC 12-F

Nutritional Advice

State law allows any person to provide nutritional advice or give advice concerning proper nutrition — which is the giving of advice as to the role of food and food ingredients, including dietary supplements.

This state law does NOT confer authority to practice medicine or to undertake the diagnosis, prevention, treatment, or cure of any disease, pain, deformity, injury, or physical or mental condition and specifically does not authorize any person other than one who is a licensed health practitioner to state that any product might cure any disease, disorder, or condition.

Do Not Remove This Sign

This sign is required to be posted according to Business & Professions Code Section 2068.

APPENDIX HC 12-H

Referrals: It's Your Choice

You may choose any organization or person you wish for obtaining services that any of our health care professionals orders or requests for you.

Our health care professionals refer patients to certain organizations or persons that they have a financial interest or affiliation with. Other organizations and persons are available to provide services to you. Your choice may be affected by the terms of your health insurance coverage.

Potential sources of information about other organizations or persons include the local medical association, Yellow Pages, or Internet. Our health care professionals are happy to discuss alternatives with you.

Do Not Remove This Sign

This sign is required to be posted according to Business & Professions Code Section 654.2.

APPENDIX 1-A

Patient Rights

(Combines Title 22 and other California laws,
The Joint Commission and Medicare Conditions of Participation requirements)

You have the right to:

1. Considerate and respectful care, and to be made comfortable. You have the right to respect for your cultural, psychosocial, spiritual, and personal values, beliefs and preferences.
2. Have a family member (or other representative of your choosing) and your own physician notified promptly of your admission to the hospital.
3. Know the name of the licensed health care practitioner acting within the scope of his or her professional licensure who has primary responsibility for coordinating your care, and the names and professional relationships of physicians and nonphysicians who will see you.
4. Receive information about your health status, diagnosis, prognosis, course of treatment, prospects for recovery and outcomes of care (including unanticipated outcomes) in terms you can understand. You have the right to access your medical records. You will receive a separate "Notice of Privacy Practices" that explains your rights to acess your records. You have the right to effective communication and to participate in the development and implementation of your plan of care. You have the right to participate in ethical questions that arise in the course of your care, including issues of conflict resolution, withholding resuscitative services, and forgoing or withdrawing life-sustaining treatment.
5. Make decisions regarding medical care, and receive as much information about any proposed treatment or procedure as you may need in order to give informed consent or to refuse a course of treatment. Except in emergencies, this information shall include a description of the procedure or treatment, the medically significant risks involved, alternate courses of treatment or nontreatment and the risks involved in each, and the name of the person who will carry out the procedure or treatment.
6. Request or refuse treatment, to the extent permitted by law. However, you do not have the right to demand inappropriate or medically unnecessary treatment or services. You have the right to leave the hospital even against the advice of members of the medical staff, to the extent permitted by law.
7. Be advised if the hospital/licensed health care practitioner acting within the scope of his or her professional licensure proposes to engage in or perform human experimentation affecting your care or treatment. You have the right to refuse to participate in such research projects.
8. Reasonable responses to any reasonable requests made for service.
9. Appropriate assessment and management of your pain, information about pain, pain relief measures and to participate in pain management decisions. You may request or reject the use of any or all modalities to relieve pain, including opiate medication, if you suffer from severe chronic intractable pain. The doctor may refuse to prescribe the opiate medication, but if so, must inform you that there are physicians who specialize in the treatment of pain with methods that include the use of opiates.

10. Formulate advance directives. This includes designating a decision maker if you become incapable of understanding a proposed treatment or become unable to communicate your wishes regarding care. Hospital staff and practitioners who provide care in the hospital shall comply with these directives. All patients' rights apply to the person who has legal responsibility to make decisions regarding medical care on your behalf.
11. Have personal privacy respected. Case discussion, consultation, examination and treatment are confidential and should be conducted discreetly. You have the right to be told the reason for the presence of any individual. You have the right to have visitors leave prior to an examination and when treatment issues are being discussed. Privacy curtains will be used in semi-private rooms.
12. Confidential treatment of all communications and records pertaining to your care and stay in the hospital. You will receive a separate "Notice of Privacy Practices" that explains your privacy rights in detail and how we may use and disclose your protected health information.
13. Receive care in a safe setting, free from mental, physical, sexual or verbal abuse and neglect, exploitation or harassment. You have the right to access protective and advocacy services including notifying government agencies of neglect or abuse.
14. Be free from restraints and seclusion of any form used as a means of coercion, discipline, convenience or retaliation by staff.
15. Reasonable continuity of care and to know in advance the time and location of appointments as well as the identity of the persons providing the care.
16. Be informed by the physician, or a delegate of the physician, of continuing health care requirements and options following discharge from the hospital. You have the right to be involved in the development and implementation of your discharge plan. Upon your request, a friend or family member may be provided this information also.
17. Know which hospital rules and policies apply to your conduct while a patient.
18. Designate a support person as well as visitors of your choosing, if you have decision-making capacity, whether or not the visitor is related by blood, marriage, or registered domestic partner status, unless:
    - No visitors are allowed.
    - The facility reasonably determines that the presence of a particular visitor would endanger the health or safety of a patient, a member of the health facility staff, or other visitor to the health facility, or would significantly disrupt the operations of the facility.
    - You have told the health facility staff that you no longer want a particular person to visit.

    However, a health facility may establish reasonable restrictions upon visitation, including restrictions upon the hours of visitation and number of visitors. The health facility must inform you (or your support person, where appropriate) of your visitation rights, including any clinical restrictions or limitations. The health facility is not permitted to restrict, limit, or otherwise deny visitation privileges on the basis of race, color, national origin, religion, sex, gender identity, sexual orientation, or disability.
19. Have your wishes considered, if you lack decision-making capacity, for the purposes of determining who may visit. The method of that consideration will comply with federal law and be disclosed in the hospital policy on visitation. At a minimum, the hospital shall include any persons living in your household and any support person pursuant to federal law.

20. Examine and receive an explanation of the hospital's bill regardless of the source of payment.
21. Exercise these rights without regard to, and be free of discrimination on the basis of, sex, economic status, educational background, race, color, religion, ancestry, national origin, sexual orientation, gender identity/expression, disability, medical condition, marital status, age, registered domestic partner status, genetic information, citizenship, primary language, immigration status (except as required by federal law) or the source of payment for care.
22. File a grievance. If you want to file a grievance with this hospital, you may do so by writing or by calling *(name, address and phone number of hospital)*: _____ _____. The grievance committee will review each grievance and provide you with a written response within _____ days. The written response will contain the name of a person to contact at the hospital, the steps taken to investigate the grievance, the results of the grievance process, and the date of completion of the grievance process. Concerns regarding quality of care or premature discharge will also be referred to the appropriate Utilization and Quality Control Peer Review Organization (PRO).
23. File a complaint with the California Department of Public Health regardless of whether you use the hospital's grievance process. The California Department of Public Health's phone number and address is: *(local address and phone number of CDPH)* _____ _____ _____.
24. File a complaint with the Department of Fair Employment and Housing at www.dfeh.ca.gov, (800) 884-1684 or (800) 700-2320 (TTY) or 2218 Kausen Dr., #100, Elk Grove, CA 95758.
25. File a complaint with the Medical Board of California at www.mbc.ca.gov/consumers/complaints, (800) 633-2322 or 2005 Evergreen St., #1200, Sacramento, CA 95815.

This Patient Rights document incorporates the requirements of the The Joint Commission; Title 22, California Code of Regulations, Section 70707; Health and Safety Code Sections 1262.6, 1288.4, and 124960; and 42 C.F.R. Section 482.13 (Medicare Conditions of Participation).

NOTE: Accreditation organizations, such as The Joint Commission, may also require that the hospital post a notice informing patients how they may file a complaint with the accreditation organization. Hospitals should check with their accreditation organizations and revise this Appendix accordingly.

In addition, this document does not include the following information that hospitals must provide patients:

1. Any hospital limitations based on conscience on honoring specific treatment requests.
2. The hospital's visitor policy.

APPENDIX 1-AS

Derechos Del Paciente

(Combina el Título 22 y otras leyes de California, los requisitos de La Comisión Conjunta y de las condiciones de participación de Medicare)

Usted tiene el derecho a:

1. Recibir una atención considerada y respetuosa, y a sentirse cómodo. Usted tiene derecho a ser respetado por sus valores, creencias y preferencias culturales, psicosociales, espirituales y personales.
2. Que le avisen de inmediato a un familiar (u otro representante de su elección) y a su propio médico que ha sido admitido en el hospital.
3. Saber el nombre del profesional de atención médica certificado que actúa en el marco de su certificación profesional y que tiene la responsabilidad principal de coordinar su atención, y los nombres y las relaciones profesionales de los médicos y empleados de salud que lo verán.
4. Recibir información acerca de su estado de salud, diagnóstico, prognosis, tratamiento, posibilidades de recuperación y resultados de la atención (incluidos los resultados no esperados) con términos que usted pueda comprender. Usted tiene el derecho al acceso de su historial médico. Recibirá una “Notificación de Prácticas Privadas” separada en la que se explica sus derechos de acceso a su historial. Tiene derecho a tener una comunicación efectiva y participar en el desarrollo e implementación de su plan de atención. También puede participar en cuestiones éticas que surjan durante su atención, incluidos temas sobre resolución de conflictos, negación a recibir servicios de resucitación, y continuación o retiro del tratamiento para mantener la vida.
5. Tomar decisiones sobre su atención y recibir toda la información sobre cualquier tratamiento o procedimiento propuesto que pueda necesitar para dar su consentimiento informado o negarse al tratamiento. Excepto en casos de emergencia, esta información incluirá una descripción del procedimiento o tratamiento, los riesgos médicamente significativos que implican, los tratamientos alternativos o no tratamientos, y los riesgos que cada uno incluye, y el nombre de la persona que realizará el procedimiento o tratamiento.
6. Solicitar o negarse a recibir tratamiento, en la medida que lo permita la ley. Sin embargo, usted no tiene derecho a exigir tratamientos o servicios inadecuados o que no sean médicamente necesarios. Tiene derecho a abandonar el hospital incluso en contra de la recomendación de los miembros del personal médico, en la medida que lo permita la ley.
7. Ser notificado si el hospital o el profesional de atención médica certificado que actúa en el marco de su certificación profesional proponen participar o realizar experimentos en humanos que afecten su atención o tratamiento. Tiene derecho a negarse a participar en tales proyectos de investigación.
8. Recibir respuestas razonables a toda solicitud razonable que realice sobre los servicios.

9. Recibir una evaluación y un control adecuados de su dolor, información sobre el dolor y medidas para el alivio del dolor, y a participar en decisiones acerca del control del dolor. También puede solicitar o rechazar el uso de cualquiera o de todas las modalidades para aliviar el dolor, incluidos los medicamentos opiáceos si sufre de dolor crónico grave persistente. El médico puede negarse a recetar medicamentos opiáceos, pero si es así, debe informarle a usted que existen médicos que se especializan en el tratamiento del dolor con métodos que incluyen el uso de opiáceos.
10. Formular instrucciones anticipadas. Esto incluye designar a una persona que tome las decisiones si usted no puede comprender un tratamiento propuesto o si no puede comunicar sus deseos con respecto a la atención. El personal y los profesionales de la salud que proporcionan atención en el hospital cumplirán dichas instrucciones. Todos los derechos del paciente se aplican a la persona que tiene la responsabilidad legal de tomar las decisiones relacionadas con la atención médica en su nombre.
11. Que su privacidad sea respetada. La discusión del caso, las consultas, los exámenes y el tratamiento son confidenciales y se deben realizar con discreción. Tiene derecho a que le indiquen la razón de la presencia de cualquier persona. También tiene derecho a que las visitas se retiren antes de un examen y cuando se habla de temas relacionados con el tratamiento. Se usarán cortinas para privacidad en habitaciones semiprivadas.
12. Recibir tratamiento confidencial de todas las comunicaciones y registros relacionados con su atención y permanencia en el hospital. Usted recibirá un “Aviso sobre prácticas de privacidad” (Notice of Privacy Practices) por separado que explica en detalle sus derechos a la privacidad y cómo podemos utilizar y divulgar la información protegida sobre su salud.
13. Recibir atención en un entorno seguro, donde no haya abuso mental, físico, sexual ni verbal, ni tampoco abandono, explotación o acoso. Usted tiene derecho a acceder a servicios de protección y defensa, lo que incluye notificarles a las agencias del gobierno sobre abandono o abuso.
14. No tener restricciones ni estar aislado de ninguna forma por decisión del personal como medio de coerción, disciplina, conveniencia o represalia.
15. Recibir una atención razonablemente continua y saber por adelantado la hora y el lugar de las citas, así como también la identidad de las personas que proporcionan la atención médica.
16. Ser informado por el médico, o un representante del médico, de los requisitos y opciones de atención médica continua luego de ser dado de alta del hospital. También tiene derecho a participar en el desarrollo e implementación de su plan para ser dado de alta. Si lo solicita, un amigo o un familiar también pueden recibir esta información.
17. Conocer las reglas y políticas del hospital que se aplican a su conducta mientras sea paciente del hospital.
18. Designar un acompañante así como también visitas que usted elija, si tiene la capacidad de tomar decisiones, independientemente de que la visita sea un familiar de sangre, por matrimonio o una pareja de hecho registrada, a menos que:
    - No se permitan visitas.

- El establecimiento determine de manera razonable que la presencia de una visita en particular podría poner en peligro la salud o la seguridad de un paciente, de un miembro del personal del establecimiento de salud o de otras visitas en el establecimiento, o podría interrumpir de manera significativa las funciones de dicho establecimiento.
- Usted le haya notificado al personal del establecimiento de salud que ya no desea que una persona determinada lo visite.

Sin embargo, un establecimiento de salud puede establecer restricciones razonables para las visitas, incluidas restricciones sobre los horarios de visita y la cantidad de personas. El establecimiento de salud debe informarle a usted (o a su acompañante, cuando corresponda) sobre sus derechos de visita, incluidas las restricciones o limitaciones clínicas. El establecimiento de salud no puede restringir, limitar o, de otro modo, negar los privilegios de visita por razones de raza, color, nacionalidad, religión, sexo, identidad de género, orientación sexual o discapacidad.

19. Que sus deseos sean tenidos en cuenta si no tiene la capacidad de tomar decisiones para determinar quién lo puede visitar. El método de dicha consideración cumplirá con la ley federal y se divulgará en las políticas del hospital sobre las visitas. Como mínimo, el hospital incluirá toda persona que viva en su hogar y acompañante de conformidad con la ley federal.
20. Evaluar y recibir una explicación de la cuenta del hospital, independientemente de la fuente de pago.
21. Ejercer estos derechos sin importar su, y estar libre de discriminación basada en, sexo, situación económica, nivel de educación, raza, color, religión, ascendencia, nacionalidad de origen, orientación sexual, identidad/expresión de género, discapacidad, condición médica, estado civil, edad, concubinato registrado, información genética, ciudadanía, idioma primario, estatus migratorio (excepto según lo requerido por ley federal) o la fuente de pago para su atención médica.
22. Presentar una queja. Si desea presentar una queja con este hospital, puede hacerlo por escrito o por teléfono (nombre, dirección y número de teléfono del hospital): _____ _____. El comité de quejas analizará cada queja y le dará una respuesta por escrito dentro de _____ días. La respuesta por escrito incluirá el nombre de la persona con la que debe comunicarse en el hospital, las medidas tomadas para investigar la queja, los resultados del proceso conciliatorio, y la fecha de finalización del proceso conciliatorio. Las inquietudes relacionadas con la calidad de la atención o el haber sido dado de alta prematuramente también se derivarán a la Organización de Revisión Profesional de la Utilización y Calidad de los Servicios (Utilization and Quality Control Peer Review Organization [PRO]) correspondiente.
23. Presentar una queja en el Departamento de Salud Pública de California (California Department of Public Health, CDPH), independientemente de que utilice el proceso de quejas del hospital. El número de teléfono y la dirección del Departamento de Salud Pública de California son: (dirección local y número de teléfono del CDPH) _____ _____
24. Presentar una queja en el Departmento de Empleo y Vivienda Justa en (800) 884-1684 o (800) 700-2320 (TTY) o 2218 Kausen Dr., #100, Elk Grove, CA 95758.

25. Presentar una queja en el Junta Médica de California en www.mbc.ca.gov/consumers/complaints, (800) 633-2322 o 2005 Evergreen St., #1200, Sacramento, CA 95815.

Este documento sobre los Derechos del paciente incorpora los requisitos de la Comisión Conjunta (The Joint Commission), Título 22 del Código de Regulaciones de California, artículo 70707; artículos 1262.6, 1288.4, y 124960 del Código de Salud y Seguridad y Título 42 del Código de Reglamentaciones Federales (C.F.R.), artículo 482.13 (Condiciones de participación de Medicare).

OBSERVACIÓN: Las organizaciones de acreditación, como la Comisión Conjunta, pueden también exigir que el hospital publique un aviso donde informe a los pacientes cómo pueden presentar una queja ante la organización de acreditación. Los hospitales deben corroborar con sus organizaciones de acreditación y revisar este Apéndice según sea adecuado.

Además, este documento no incluye la siguiente información que los hospitales deben proporcionar a los pacientes:

1. Cualquier limitación del hospital basada en la conciencia sobre el cumplimiento de solicitudes de tratamiento específicas.
2. La política de visitantes del hospital.

BE INFORMED

Upon a diagnosis of breast cancer, your physician and surgeon is required to provide you a written summary of alternative efficacious methods of treatment, pursuant to Section 109275 of the California Health & Safety Code. Your physician and surgeon may choose to provide the summary prior to the performance of a screening or biopsy for breast cancer at your request or at the physician and surgeon's discretion, when appropriate.

The information about methods of treatment was developed by the State Department of Public Health to inform patients of the advantages, disadvantages, risks, and description of procedures.

See www.mbc.ca.gov/publications/ for a copy of the information.

MANTÉNGASE INFORMADA

De acuerdo con el Artículo 109275 del Código de Salubridad y Seguridad de California, los médicos y cirujanos deben entregar a las pacientes que reciben un diagnóstico de cáncer de mama una síntesis por escrito de métodos alternativos eficaces de tratamiento. Su médico y cirujano pueden optar por entregarle esta síntesis antes de que usted se someta a un examen o biopsia por cáncer de mama cuando usted lo solicita o a criterio del médico y cirujano, cuando corresponda.

La información acerca de los métodos de tratamiento fue elaborada por el Departamento de Salud Pública del Estado a fin de informar a los pacientes de las ventajas, desventajas, riesgos y descripción de los procedimientos.

Visite www.mbc.ca.gov/publications/ para ver una copia de la información.

通知

診斷爲乳癌後，你的醫生和外科醫生必須按照加州衛生條例第 109275 條給你提供一份有關各種其他有效治療辦法的書面摘要。你的醫生和外科醫生可應你的要求在做乳癌篩檢或切片檢查之前，或依其自己酌情選擇的時候，給你提供該份書面摘要。

各種療法的資訊由加州公共衛生廳提供，以使患者了解其好處、壞處、危險和治療程序。 見網址 www.mbc.ca.gov/publications/ 可得到一份資訊。

CALIFORNIA HOSPITAL ASSOCIATION

1215 K Street, Suite 800 • Sacramento, CA 95814 • (916) 443-7401

BE INFORMED

If you are a patient being treated for any form of prostate cancer, or prior to performance of biopsy for prostate cancer, your physician and surgeon is urged to provide you with a written summary of alternative efficacious methods of treatment, pursuant to Section 109280 of the California Health & Safety Code.

The information about methods of treatment was developed by the State Department of Public Health to inform patients of the advantages, disadvantages, risks, and description of procedures.

See www.mbc.ca.gov/publications/ for updated prostate cancer summaries.

MANTÉNGASE INFORMADO

De acuerdo con el Artículo 109280 del Código de Salubridad y Seguridad de California, se urge a los médicos y cirujanos de los pacientes que reciben tratamiento para cualquier forma de cáncer de próstata o que se someterán a una biopsia por cáncer de próstata que entreguen a dichos pacientes una síntesis de métodos alternativos eficaces de tratamiento.

La información acerca de los métodos de tratamiento fue elaborada por el Departamento de Salud Pública de California a fin de informar a los pacientes de las ventajas, desventajas, riesgos y descripción de los procedimientos.

Visite www.mbc.ca.gov/publications/ para ver las síntesis más actuales sobre el cáncer de próstata.

通知

如果你是前列腺癌患者或如要進行前列腺癌的切片檢查，按照加州衛生安全規則第109280 部份，你的醫生和外科醫生需要向你提供一份有關各種有效療法的書面摘要。

各種療法的資訊由加州公共衛生廳提供，以使患者了解其好處、壞處、危險和治療程序。 見網址 www.mbc.ca.gov/publications/ 可得到 有關前列腺癌的最新摘要。

CALIFORNIA HOSPITAL ASSOCIATION

1215 K Street, Suite 800 • Sacramento, CA 95814 • (916) 443-7401

FORM 9-9

Notice for Emergency Room

It's the Law!

If You Have a Medical Emergency or Are in Labor

You have the right to receive, within the capabilities of this hospital's staff and facilities:

- An appropriate medical screening examination;
- Necessary stabilizing treatment (including treatment for an unborn child);
- And, if necessary, an appropriate transfer to another facility even if you cannot pay, you do not have medical insurance or you are not entitled to Medicare or Medicaid.

This hospital [does/does not] participate in the Medi-Cal program.

If you have any questions concerning this hospital's emergency services policy, please ask the admitting nurse or contact (title of other contact person at hospital) _____.

If you have any complaints concerning the services you have received from this hospital, you may contact:

California Department of Public Health, Licensing and Certification

_____ *District Office

_____

_____

** Fill in the name, address and telephone number of the appropriate CDPH district office.*

NOTE: This sign must be large enough to be clearly readable by patients from a distance of 20 feet or the expected vantage point of the patients.

Reference: 42 U.S.C. Section 1395cc(a)(1)(N)(iii) and (iv); 42 C.F.R. Section 489.20(q); Health and Safety Code Section 1317.3(d)

FORM 9-9S

Aviso para la Sala de Emergencias

¡La ley lo exige!

Si tiene una emergencia médica o está en trabajo de parto

Tiene derecho a recibir, dentro de las posibilidades del personal y las instalaciones de este hospital:

- Un examen médico de evaluación adecuado;
- La atención necesaria para estabilizarlo/a (incluida la atención de un niño por nacer);
- Si fuera necesario, el traslado a otro establecimiento adecuado, aunque usted no pueda pagar, no tenga seguro médico o no tenga derecho a recibir los servicios de Medicare o Medicaid.

Este hospital [sí/no] participa en el programa Medi-Cal.

Si usted tiene cualquier pregunta respecto a las normas relativas a servicios de emergencia de este hospital, favor de preguntar a la enfermera de admisiones o póngase en contacto con (puesto e alguna otra persona representante del hospital) _____.

Si usted tiene cualquier queja relacionada con los servicios que ha recibido de este hospital, puede ponerse en contacto con:

Departamento de Salud Pública, Certificación y Licencias

_____*Oficina de Destrito

_____

_____

** Fill in the name, address and telephone number of the appropriate DPH district office.*

NOTE: This sign must be large enough to be clearly readable by patients from a distance of 20 feet or the expected vantage point of the patients.

Reference: 42 U.S.C. Section 1395cc(a)(1)(N)(iii) and (iv); 42 C.F.R. Section 489.20(q); Health and Safety Code Section 1317.3(d)

RESTRICTED ACCESS

Only family members of infants and sanctioned visitors are allowed in this area.

Pursuant to Section 602 of the California Penal Code

ACCESO RESTRINGIDO

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13 Patient Safety Organizations

I. Introduction 13.1

A. The Patient Safety and Quality Improvement Act of 2005 — The Framework 13.1

The Statute 13.2

The Federal Regulations 13.2

Government Oversight 13.2

Strategies to Improve Patient Safety: Final Report to Congress 13.3

B. Key Definitions 13.3

C. Preemption 13.5

II. How to Implement a Patient Safety Evaluation System 13.6

A. Contract With an AHRQ-Listed PSO 13.6

B. Key Elements Necessary to Establish a PSES 13.6

C. Determine What is and is Not Patient Safety Work Product 13.8

What is Patient Safety Work Product? 13.9

What is NOT Patient Safety Work Product? 13.9

D. Structural Components of a Patient Safety Evaluation System 13.9

E. Patient and Provider Identifiers, Restrictions and Security Requirements 13.10

Patient Identifiers 13.10

Provider Identifiers 13.10

The Relationship with HIPAA and State Health Information Privacy Laws 13.11

List of Direct Identifiers 13.11

III. Confidentiality of Patient Safety Work Product 13.12

A. Permitted Disclosures 13.12

Patient Safety Activities 13.12

Business Operations 13.12

Authorized by Identified Providers 13.12

Accrediting Bodies 13.13

Nonidentifiable PSWP 13.13

Research 13.13

Food and Drug Administration 13.13

Law Enforcement 13.13

Criminal Proceedings 13.13

Disclosure to Permit Equitable Relief for Reporting Individuals 13.13

B. Required Reporting, Root Cause Analyses and Medical Staff Peer Review 13.14

C. De-Designating PSWP 13.14

D. Violations of the Confidentiality Requirements and Enforcement 13.14

Safe Harbor 13.14

E. Training for Employees and Hospital Medical Staff 13.15

IV. Asserting and Defending the Protections Under the PSA 13.15

A. Asserting the Protections and Privileges 13.15

B. Defending the Privilege 13.17

C. Case Law 13.17

Dual Purpose Documents 13.18

13 Patient Safety Organizations

I. INTRODUCTION

The Patient Safety and Quality Improvement Act (PSQIA or the Patient Safety Act) of 2005 was passed by Congress and signed by the President to facilitate and accelerate improvements in health care quality and patient safety. The law encourages the voluntary and confidential reporting of events that may adversely affect patients to Patient Safety Organizations (PSOs). PSOs then aggregate and analyze the patient safety data to identify and better understand underlying causes of risks or harm and report those findings back to participating providers.

This law was enacted in response to growing concern about patient safety and premised in large part upon the broad framework described in the Institute of Medicine's seminal report, *To Err is Human: Building a Safer Health System*, published in 2000. The Patient Safety Act and its implementing regulations provide the framework for driving quality improvement by creating a protected environment in which health care providers can report incidents of near miss, adverse or unintended events, to generate robust data for analysis and research; thereby, accelerating and advancing improvements in quality and care processes.

Prior to the enactment of the Patient Safety Act, patient safety improvement efforts were hampered by health care providers' fears that trial lawyers, government agencies, or others might obtain and misuse this type of information. This fear may have resulted in under-reporting of events and an unwillingness to share lessons learned. The Patient Safety Act alleviates these fears by providing federal legal confidentiality protections to the information that is assembled and reported by providers to a PSO, and to information developed by a PSO for the conduct of patient safety activities. This protected information-gathering and feedback mechanism increases the amount of data available in condensed periods of time to identify patterns of failures or errors, propose measures to reduce or eliminate patient safety risks, and thus speed the implementation of improvements in patient care and quality.

The compliance officer should be aware of the law, the requirements for maintaining confidentiality protections, and the restrictions on disclosure of the information generated.

Additional information about the Patient Safety Act may be found at https://pso.ahrq.gov/resources/act.

A. The Patient Safety and Quality Improvement Act of 2005 — The Framework

The goal of the Patient Safety Act is to create voluntary reporting and feedback mechanisms designed to encourage the free flow of confidential protected quality information through a network of PSOs to generate evidence-based improvements. To help accomplish this goal, the Patient Safety Act provides federal confidentiality protections for health care professionals and medical staff members, as well as for information submitted through a hospital's Patient Safety Evaluation System (PSES) to a PSO. It is critically important for hospitals to distinguish information that falls under the protections of the Patient Safety Act from information that does not. Making this distinction depends on understanding key definitions, processes, and components of the Patient Safety Act, which are described in this chapter.

The Statute

The Patient Safety and Quality Improvement Act of 2005 (P.L. 109-41) amended Title IX of the Public Health Service Act (42 U.S.C. Section 299 *et seq.*) by inserting Sections 299b-21 through 299b-26. The framework is as follows:

1. Section 299b-21 defines key terms, and how information becomes patient safety information (PSWP);
2. Section 299b-22 sets out the confidentiality and privilege protections for patient safety work product, how patient safety work product may be disclosed, and the penalties for disclosures in violation of the protections;
3. Section 299b-23 describes the network of patient safety databases; and
4. Section 299b-24 outlines the requirements and processes for the listing and delisting of PSOs.

These provisions are discussed in this chapter.

The Federal Regulations

The federal regulations, proposed in February 2008 and finalized in November 2008, became effective on Jan. 19, 2009, and implemented the Patient Safety Act in a way that provides flexibility to meet the needs of various providers and institutions within the bounds of the statute, and encourages providers to participate in the program. The quality improvement system is technically voluntary (but see next paragraph) and not federally funded, so the regulations minimize direct federal involvement and yet ensure there are processes and procedures in place to certify PSOs with the appropriate government oversight. The regulations are found at 42 C.F.R. Part 3.

However, the Affordable Care Act mandated that by January 1, 2017, qualified health plans in health insurance exchanges may not contract with a hospital of 50 beds or more unless that hospital has a PSES and reports to a PSO or "[i]mplements an evidence-based initiative, to improve health care quality through the collection, management and analysis of patient safety events[.]" *(45 C.F.R. Section 156.1110(a)(2)(ii) (as amended March 8, 2016); see Patient Protection and Affordable Care Act of 2010, P.L. 111-48, Section 1311(h)(1)(A), 1311(h)(2) (note that the Jan. 1, 2015 deadline was thereafter extended to Jan. 1, 2017).)* Thus, although reporting to a PSO started out as voluntary, reporting to a PSO or implementing an evidence-based quality improvement initiative is now mandatory for most hospitals.

Government Oversight

The Patient Safety Act creates a system to protect the confidentiality of reports about specific patient safety information in order to encourage rapid process quality improvements for implementation. With this broad concept in mind, there is very limited federal participation. Oversight of the Patient Safety Act is divided between two agencies: (1) the Agency for Healthcare Research and Quality (AHRQ) oversees listing of PSOs and their compliance with Patient Safety Act requirements; and(2) the Office for Civil Rights (OCR) enforces compliance with the Act's confidentiality provisions.

In order to identify protected patient safety information (which is called Patient Safety Work Product or PSWP), the statute and the regulations contain key definitions of essential terms. Understanding these definitions is critical.

The entities that collect protected PSWP are the PSOs. A PSO is listed only after self-certifying to AHRQ that it meets specific criteria that ensure it has the capabilities necessary to collect and analyze patient safety events and data, and offer expert advice, feedback and recommendations back to providers. Certifications can be revoked by AHRQ for failing to maintain compliance with requirements.

Strategies to Improve Patient Safety: Final Report to Congress

The Patient Safety Act requires the Secretary of the Department of Health and Human Services (HHS), in consultation with the Director of AHRQ, to prepare a report on effective strategies for reducing medical errors and increasing patient safety. The Secretary of HHS published a draft report for notice and comment on December 16, 2020, which detailed measures determined appropriate by the Secretary to encourage the appropriate use of effective strategies for reducing medical errors and increasing patient safety, including use in federally funded programs. 85 Fed. Reg. 81478 (Dec. 16, 2020). The draft report was submitted for review to the National Academy of Medicine (NAM, formerly known as the Institute of Medicine). NAM's review of the draft report was roughly concurrent with the public comment period, which closed April 5, 2021, following which NAM published its report, entitled "Peer Review of a Report on Strategies to Improve Patient Safety," on April 19, 2021, available at https://pso.ahrq.gov/resources/act. HHS submitted its final report, "Strategies to Improve Patient Safety: Final Report to Congress Required by the Patient Safety and Quality Improvement Act of 2005" to Congress in November 2021, also available at https://pso.ahrq.gov/resources/act.

B. Key Definitions

As with any law, there are defined terms that are important to understand. Providers should use these terms when designing a PSES. The following list contains definitions exactly as written in the Patient Safety Act and its implementing regulations (see 42 C.F.R. Section 3.20).

"Affiliated provider" means, with respect to a provider, a legally separate provider that is the parent organization of the provider, is under common ownership, management, or control with the provider, or is owned, managed, or controlled by the provider.

"Disclosure" means the release, transfer, provision of access to, or divulging in any other manner of patient safety work product by:

1. An entity or natural person holding the PSWP to another legally separate entity or natural person, other than a workforce member of, or a health care provider holding privileges with, the entity holding the patient safety work product; or
2. A component PSO to another entity or natural person outside the component PSO and within the legal entity of which the component PSO is a part.

"Patient safety activities" means the following activities carried out by or on behalf of a PSO or a provider:

1. Efforts to improve patient safety and the quality of health care delivery;
2. The collection and analysis of PSWP;
3. The development and dissemination of information with respect to improving patient safety, such as recommendations, protocols or information regarding best practices;

4. The utilization of PSWP for the purposes of encouraging a culture of safety and of providing feedback and assistance to effectively minimize patient risk;
5. The maintenance of procedures to preserve confidentiality with respect to PSWP;
6. The provision of appropriate security measures with respect to PSWP;
7. The utilization of qualified staff; and
8. Activities related to the operation of a PSES and to the provision of feedback to participants in a PSES.

"Patient safety evaluation system" means the collection, management or analysis of information for reporting to or by a PSO.

"Patient safety organization" (PSO) means a private or public entity or component thereof that is listed as a PSO by the AHRQ. A health insurance issuer or a component organization of a health insurance issuer may not be a PSO.

Except as otherwise provided, **"patient safety work product"** (PSWP) means any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements (or copies of any of this material):

1. Which could improve patient safety, health care quality or health care outcomes; and
    a. Which are assembled or developed by a provider for reporting to a PSO and are reported to a PSO, which includes information that is documented as within a PSES for reporting to a PSO, and such documentation includes the date the information entered the PSES; or
    b. Are developed by a PSO for the conduct of patient safety activities; or
2. Which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a PSES.

PSWP does not include a patient's medical record, billing and discharge information, or any other original patient or provider information; nor does it include information that is collected, maintained, or developed separately, or exists separately, from a PSES. Such separate information or a copy thereof reported to a PSO shall not by reason of its reporting be considered PSWP.

PSWP assembled or developed by a provider for reporting to a PSO may be removed from a PSES and no longer considered PSWP if:

1. The information has not yet been reported to a PSO; and
2. The provider documents the act and date of removal of such information from the PSES.

Nothing in the Patient Safety Act shall be construed to limit information that is not PSWP from being:

1. Discovered or admitted in a criminal, civil or administrative proceeding;
2. Reported to a federal, state, local or tribal governmental agency for public health or health oversight purposes; or

3. Maintained as part of a provider's record keeping obligation under federal, state, local or tribal law.

NOTE: The definition of PSWP includes information that is documented as being within a provider's PSES, but which has not yet been reported to a PSO. This definition allows providers to sequester or store information intended to be reported to a PSO (but not yet reported), and subsequently remove it in the event the information is necessary for another purpose. Once removed, however, the information is no longer PSWP.

"Provider" means:

1. An individual or entity licensed or otherwise authorized under state law to provide health care services, including:
    a. A hospital, nursing facility, comprehensive outpatient rehabilitation facility, home health agency, hospice program, renal dialysis facility, ambulatory surgical center, pharmacy, physician or health care practitioner's office (includes a group practice), long term care facility, behavior health residential treatment facility, clinical laboratory or health center; or
    b. A physician, physician assistant, registered nurse, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, psychologist, certified social worker, registered dietitian or nutrition professional, physical or occupational therapist, pharmacist, or other individual health care practitioner;
2. Agencies, organizations, and individuals within federal, state, local, or tribal governments that deliver health care, organizations engaged as contractors by the federal, state, local, or tribal governments to deliver health care, and individual health care practitioners employed or engaged as contractors by the federal state, local, or tribal governments to deliver health care; or
3. A parent organization of one or more entities described in paragraph (1)(a) of this definition or a federal, state, local or tribal government unit that manages or controls one or more entities described in paragraphs (1)(a) or (2) of this definition.

"Workforce" means employees, volunteers, trainees, contractors or other persons whose conduct, in the performance of work for a provider, PSO or responsible person, is under the direct control of such provider, PSO or responsible person, whether or not they are paid by the provider, PSO or responsible person.

C. Preemption

The Patient Safety Act and rules provide strong confidentiality protections by preempting any federal, state, tribal or local law that allows or requires disclosure of PSWP. The U.S. Department of Health and Human Services, in issuing regulations, went to great lengths to explain the policy behind preempting state or other laws that compel or allow disclosure of PSWP. Preemption and the federal protections that blanket PSWP are designed to "provide a mechanism for protection of sensitive information that could improve the quality, safety, and outcomes of health care by fostering a non-threatening environment in which information about adverse medical events and near misses can be discussed." [73 Fed. Reg. 70795 (Nov. 21, 2008)] To the extent the Patient Safety Act or its regulations are inconsistent with

any state law, including court decisions, the Patient Safety Act and its implementing rules take precedence over state laws or court orders that provide lesser protection.

Once information is identified as PSWP, it generally continues to be protected as privileged and confidential so long as it is maintained separately. The introductory language (preamble) to the final rule says that "[a] state may not require the patient safety work product be disclosed." In fact, the final rule further clarifies that "[f]or patient safety work product to be disclosed, even to a State entity, the discloser must have an applicable disclosure permission." [73 Fed. Reg. 70743 (Nov. 21, 2008))] As mentioned above, these protections afforded under the Patient Safety Act and rules preempt state or other laws that allow or require disclosure of information contained in patient safety work product. *(See 73 Fed. Reg. 70795 (Nov. 21, 2008).)*

However, the Patient Safety Act does not obviate mandatory reporting obligations under federal, state, tribal or local law *(See, e.g., 73 Fed. Reg. 70732, 70773, 70750 (Nov. 21, 2008))*. Hospitals should structure their systems so that information that is not PSWP can be used to fulfill mandatory reporting obligations.

II. HOW TO IMPLEMENT A PATIENT SAFETY EVALUATION SYSTEM

There are several elements that must be addressed when developing and structuring a PSES. The first step is to contract with an AHRQ-listed PSO. Other key elements of a PSES include creating and adopting new or revised hospital policies that address the type of information and data collected; the method of collecting the information and data; labeling the information as PSWP and time-stamping it; and the method of conducting patient safety activities. These steps are discussed below.

A. Contract With an AHRQ-Listed PSO

Each provider must execute a contract with an AHRQ-listed PSO to participate in confidential voluntary reporting under the Patient Safety Act and benefit from the legal protections that follow. The Patient Safety Act and rules limit participation to PSOs that are listed in the AHRQ's list of approved PSOs. These PSOs have certified to the AHRQ that they meet the necessary criteria to collect and protect patient safety and quality information, analyze the data, and generate best practices and quality recommendations. Only the PSOs listed on the AHRQ website can offer providers the legal protections afforded under the Patient Safety Act and rules. AHRQ periodically performs compliance surveys of listed PSOs. PSOs can also be delisted by voluntary relinquishment or for cause by failing to comply with AHRQ criteria. A hospital that contracts with a delisted PSO will no longer benefit from the confidentiality protections for information reported after the date of delisting. Therefore, hospitals should periodically verify that its contracted PSO remains AHRQ-listed.

Compliance Tip: Include in the hospital's PSES a mechanism to actively monitor and verify that its contracted PSO is listed with the AHRQ. Listed PSOs may be found at www.pso.ahrq.gov/listed.

B. Key Elements Necessary to Establish a PSES

The most common method of establishing a PSES is by way of hospital policies and procedures that provide robust descriptions of the components of the PSES, and the quality and patient safety goals it is designed to accomplish. Hospitals should address how patient quality and safety information is collected, managed, sequestered, and/or analyzed for reporting to the contracted PSO. The hospital's policy should address the high-level structure and purpose of the PSES. More detailed implementation processes would likely be contained in the hospital's procedures documents, and should describe how the PSES will be implemented and operated. Hospital policies and procedures should:

1. Describe the purpose of the PSES in terms of a system designed for quality improvement. Because the legal confidentiality protections may be challenged by state regulators and individuals (e.g., malpractice plaintiffs' attorneys), the PSES documentation should describe the PSES as being developed expressly for the purpose and goals identified by the Patient Safety Act and its implementing rules, and should incorporate key terms, definitions, and near or exact language used in the law.
2. Describe the full scope of activities and data that will be included in the PSES. The documents should specify:
    a. The types of activities and data that will be collected and how collection will be accomplished;
    b. The process for evaluation and analysis, by whom, and how it will be conducted;
    c. The investigatory activities and processes for implementing and documenting patient safety activities; and
    d. The process to formulate recommendations and conclusions.
3. Describe how information is entered into the PSES and quarantined or warehoused prior to reporting to the PSO. This should include a method that records the date and time the patient safety information is entered into the PSES.

Compliance Tips:

1. If information or data is intended to be reported, it need not actually be reported to the PSO to be considered PSWP. The regulations address the ability for information to be quarantined within the PSES, so long as at the time it is isolated, there is a good faith intent, and activity that supports it, that the information was intended to be reported to the PSO.
2. Hospitals may want to be expansive when designing the scope of information designated for its PSES. If there is a need to use the information for another purpose, hospitals have the ability to remove collected information (e.g., incident reports) from the PSES so long as it has not yet been reported to the PSO. Once removed, however, it is de-designated as PSWP.
3. Deliberations and analyses, such as root cause analyses, conducted within the PSES are PSWP even if not reported to a PSO and cannot be de-designated. When conducting deliberations and analyses destined for a use incompatible with PSWP rules (e.g., peer-review disciplinary hearings), the deliberations and analyses must occur outside the PSES.

As mentioned above, hospitals can likely redesign existing systems and protocols for quality and safety improvements.

C. Determine What is and is Not Patient Safety Work Product

As noted above, PSWP is patient safety, quality data, and information collected and maintained for reporting to a PSO. The ability to accurately identify the quality of safety data and information that constitutes PSWP and maintain it separately from non-PSWP, is essential to safeguarding PSWP confidentiality when defending a demand for production or access to confidential PSWP. In designing a PSES, hospitals should keep in mind that it can include as confidential PSWP information not yet reported to the PSO through the hospital PSES, so long as at the time it is collected, the hospital intends to report it to the PSO. The hospital must demonstrate, by its policies or procedures, that each part of the PSES is a necessary component of achieving patient safety and quality improvement purposes.

Compliance Tip: Each component part of the hospital PSES must demonstrate by policy or procedure the type of patient safety and quality data and information collected, the process for collecting it, how it is marked or designated as PSWP and reported through the hospital PSES, the method of segregating the PSES from non-PSES such as original records, and the process for assembling or developing the PSWP for reporting to a PSO. When designing the PSES, hospitals may want to consider its design broadly, knowing that if the information is necessary for other purposes such as mandated reporting or peer review, it can be de-designated PSWP and removed from the PSES. At minimum, hospitals should consider including the incident response and analysis activities within the PSES.

Distinguishing between PSWP and non-PSWP also entails maintaining quality and safety information separately within and as part of the PSES. Recall that the Patient Safety Act excludes from PSWP, original medical records, billing and discharge information, and any other original patient or provider information. Also excluded from PSWP is any information that is collected, maintained or developed separately, or exists separately, from a PSES. This includes patient safety information that is collected for external reporting, such as cancer registry data.

What is Patient Safety Work Product?

PSWP is any patient safety or quality information that is assembled or developed for reporting to a PSO, and deliberations and analyses conducted within the PSES.

What is NOT Patient Safety Work Product?

1. Information that must be reported through the various mandated reporting requirements (e.g., adverse events, surgical site infections, and provider preventable diseases). Note that information reported within the hospital PSES (PSWP) that is needed for mandated reporting obligations outside the PSES can subsequently be removed from the PSES and de-designated as PSWP so long as it has not yet been transmitted to the PSO.
2. Original patient or provider records.
3. Patient safety information originally collected for disclosure purposes other than for reporting to a PSO such as for disclosure to registries or accrediting bodies.

D. Structural Components of a Patient Safety Evaluation System

In designing or structuring a PSES, hospital policies and protocols should describe the quality and safety data and information collected as PSWP, the process of entering PSWP into the PSES, and the process of conducting patient safety activities within the PSES.

The date and time information and data were entered into the PSES must be clearly indicated because it becomes the presumptive date and time that the information becomes PSWP. Processes and forms including those already in use for quality and safety activities should be updated to include a designation marking the information “PSWP.”

Once PSWP is entered into the hospital’s PSES, the information and data may be used broadly; there are no restrictions on internal uses other than those uses that would violate the privilege provisions in the Patient Safety Act. Permitted uses include collecting and analyzing PSWP to develop and disseminate patient safety recommendations, protocols and best practices. Hospitals have significant discretion in designing the PSES broadly, including how information will be used within the PSES, storing information within the PSES, and the time at which the hospital will report PSWP to a PSO.

Compliance Tip:

1. Since most hospitals have existing risk management and quality improvement programs, it may be appropriate to restructure existing policies and protocols as a part of the hospital's PSES. Doing so would allow for quality data analysis and feedback to occur in a protected and safe environment so that the hospital can rapidly implement quality improvements and best practices from lessons learned.
2. If the hospital policy states that incident reports enter the PSES upon creation, then the report time field in the original report can be used to establish the time the report entered the PSES. This avoids adding another data field solely for the purpose of identifying PSES entry time.

E. Patient and Provider Identifiers, Restrictions and Security Requirements

Patient Identifiers

PSWP with patient identifiers is, at minimum, protected as it is under the Health Insurance Portability and Accountability Act (HIPAA). Hospitals face additional restrictions on disclosing PSWP with patient identifiers in one circumstance: disclosure for patient safety activities to another provider actively participating in the same PSO requires that the other provider must have reported at least one event to the PSO. In addition, the hospital must remove all direct patient identifiers as for a limited data set as defined in HIPAA *(see "Table 13-1: Direct Identifiers That Need to be Removed When One Provider Discloses PSWP to Another Provider," page 13.11)*.

PSOs are subject to additional restrictions regarding disclosures of PSWP containing patient identifiers, in that all direct identifiers (as for a limited data set as defined in HIPAA) must be removed prior to disclosing information to another PSO or provider. Information transmitted from the PSO to the Network of Patient Safety Databases (NPSD) must also have direct identifiers removed.

Provider Identifiers

When dealing with PSWP, provider identifiers are protected. Unless further restricted in a specific disclosure (e.g., to accrediting bodies), provider identifiers may be retained in PSWP except when disclosing PSWP for patient safety activities to another provider actively participating in the same PSO (that other provider must have reported at least one event to the PSO). In that circumstance, the hospital must remove all direct provider identifiers *(see "Table 13-1: Direct Identifiers That Need to be Removed When One Provider Discloses PSWP to Another Provider," page 13.11)*.

PSOs face further restrictions with regard to provider identifiers, in that all direct provider identifiers (as defined in Table 13-1) must be removed prior to disclosing information to another PSO or provider. Also, information transmitted from the PSO to the Network of Patient Safety Databases (NPSD) must first be stripped of all direct identifiers and all free-text fields, then processed by the PSO Privacy Protection Center (PSOPPC) to ensure de-identification prior to entry in the NPSD.

The Relationship with HIPAA and State Health Information Privacy Laws

PSOs are required to comply with HIPAA privacy and security rules, as well as the additional security rule adopted under the Patient Safety Act. Hospitals do not have new or additional security responsibilities, though it is highly recommended that hospitals undertake a careful evaluation of the restrictions and protections applicable to the new information use and disclosure possibilities that arise under the Patient Safety Act to ensure newly-identified risks are properly managed or mitigated.

Health care providers may also be subject to state health information privacy laws, such as California's Confidentiality of Medical Information Act. A disclosure of patient-identifiable medical information must comply with these laws also.

List of Direct Identifiers

The following table provides a list of direct patient and provider identifiers that may be helpful when distinguishing permitted from unpermitted disclosures of patient safety activities.

Table 13-1: Direct Identifiers That Need to be Removed When One Provider Discloses PSWP to Another Provider

The following are direct identifiers of any providers and of affiliated organizations, corporate parents, subsidiaries, practice partners, employers, members of the workforce, or household members of such providers	The following are direct identifiers of the patient or of relatives, employers, or household members of the patient
PSQIA	**HIPAA**
Names	Names
Postal address information, other than town or city, state and zip code	Postal address information, other than town or city, state and zip code
Telephone numbers	Telephone numbers
Fax numbers	Fax numbers
Email addresses	Email addresses
Social security numbers or taxpayer identification numbers	Social security numbers
Provider or practitioner credentialing or DEA numbers	Medical record numbers
National Provider Identification Number	Health plan beneficiary numbers
	Account numbers
Certificate/license numbers	Certificate/license numbers
	Vehicle identifiers and serial numbers, including license plate numbers
	Device identifiers and serial numbers
Web Universal Resource Locators (URLs)	Web Universal Resource Locators (URLs)
Internet Protocol (IP) address numbers	Internet Protocol (IP) address numbers
Biometric identifiers, including finger and voice prints	Biometric identifiers, including finger and voice prints
Full face photographic images and any comparable images	Full face photographic images and any comparable images

III. CONFIDENTIALITY OF PATIENT SAFETY WORK PRODUCT

PSWP cannot be disclosed, except in very specific circumstances and subject to very specific restrictions. The most relevant exceptions for health care providers and PSO workforce members are listed below. The Patient Safety Activities exception is the most common applicable exception that providers and PSOs will work with and utilize. The Patient Safety Act contains additional permitted disclosures, but use or reliance on other exceptions should have prior review by legal counsel or another knowledgeable individual before permitting any disclosure.

A. Permitted Disclosures

The Patient Safety Act lists several categories of patient safety activities that provide permissive authority to disclose PSWP. In addition, the Patient Safety Act is enforced by the Secretary of Health and Human Services. Therefore, PSWP may be disclosed to the Secretary, and the Secretary may require disclosure of PSWP, to investigate or determine compliance with the Patient Safety Act or with HIPAA.

Patient Safety Activities

PSWP may be disclosed:

1. Between the provider and the PSO, i.e., from the provider to the PSO for Patient Safety Activities and from the PSO to the disclosing provider for Patient Safety Activities.
2. To a contractor of a provider or a PSO for contracted Patient Safety Activities. (The contractor may not further disclose the PSWP, except back to the contracted provider or the PSO.)
3. Among affiliated providers, for Patient Safety Activities.
4. From one PSO to another PSO or another provider if:
    a. Direct identifiers (which are defined in the regulations) of any providers, affiliated organizations, corporate parents, subsidiaries, practice partners, employers, members of the workforce, or household members of such providers are removed *(see Table 13-1)*; and
    b. With respect to any individually-identifiable health information within the PSWP, direct patient identifiers (a limited data set, defined by HIPAA) are removed *(see "Table 13-1: Direct Identifiers That Need to be Removed When One Provider Discloses PSWP to Another Provider," page 13.11)*.

Business Operations

A provider or PSO may disclose PSWP to attorneys, accountants or other professionals for business operations purposes. Further disclosure (except back to the contracting entity) is prohibited.

Authorized by Identified Providers

Disclosure of PSWP is permitted if all identified providers authorize the disclosure. Authorization must be in writing, signed by the provider, and must state the nature and scope of the disclosure.

Accrediting Bodies

PSWP may be (but is not required to be) disclosed to an accrediting body (such as The Joint Commission) if any identified provider agrees to the disclosure; or direct identifiers of any provider (or affiliated organizations, corporate parents, subsidiaries, practice partners, employers, members of the workforce, or household members) are removed *(see "Table 13-1: Direct Identifiers That Need to be Removed When One Provider Discloses PSWP to Another Provider," page 13.11)*.

Nonidentifiable PSWP

Nonidentifiable PSWP may be disclosed. The regulations set out specific requirements for "nonidentification" *(see 42 C.F.R. Section 3.212)*.

Research

This exception allows disclosure of PSWP to researchers conducting certain types of research projects. If protected health information is involved, HIPAA also applies.

Food and Drug Administration

PSWP may be disclosed to the FDA by a provider concerning an FDA-regulated product or activity; by an entity required to report to the FDA about the quality, safety, or effectiveness of an FDA-regulated product or activity; or by a contractor acting on behalf of the FDA or entity for these purposes.

Law Enforcement

PSWP may be disclosed to law enforcement personnel if the PSWP contains evidence of a criminal act; is material to the proceedings; and it is not reasonably available from any other source. Note that this exception requires all three component parts to permit disclosure.

Criminal Proceedings

PSWP may be disclosed in a criminal proceeding, but only after a court makes an *in camera* (in closed chambers) determination that the information relates to an event that either constitutes the commission of a crime, or for which the disclosing person reasonably believes constitutes the commission of a crime, provided that the disclosing person reasonably believes under the circumstances, that the PSWP disclosed is necessary for criminal law enforcement purposes.

Disclosure to Permit Equitable Relief for Reporting Individuals

This exception allows use of PSWP by individuals who claim they have been the victim of an adverse employment action because the individual reported information to a PSO (either directly to the PSO or with the intent of having it reported to the PSO). Note that this permitted disclosure is subject to a "protective order" issued by the court or administrative tribunal to protect the confidentiality of PSWP used in the proceeding.

Compliance Tip: Disclosure of patient-identifiable medical information must also comply with the Confidentiality of Medical Information Act and other state laws.

B. Required Reporting, Root Cause Analyses and Medical Staff Peer Review

PSWP may not be used to comply with state or other mandated reporting. As a result, whenever there is a patient safety concern or event that is also a reportable event or unusual occurrence (as defined in California hospital licensing regulations), PSWP should not be provided as part of the required report — that is, the hospital's analyses, deliberations, and conclusions should not be reported. Only the original non-PSWP records such as medical records, billing records, discharge information and other information maintained or developed separately from the PSES may be provided as part of the required reporting.

Most root case analyses (RCAs) are deemed PSWP. RCAs conducted in anticipation of litigation at the direction of legal counsel are not PSWP unless they are specifically designated as such. Similarly, RCAs conducted by a medical staff peer review committee do not constitute PSWP unless that specific designation is made. PSWP may be voluntarily disclosed to an accreditation organization (such as The Joint Commission) as a permitted disclosure, subject to the specific criteria under the PSA (individually identified providers agree to the disclosure, all identifiers are removed, and all applicable authorizations are obtained).

C. De-Designating PSWP

If PSWP collected for reporting to a PSO, such as an incident report, is needed outside the PSES for hospital activities or operations such as peer review, employee records, personnel actions, or other hospital operations, PSWP not yet reported to a PSO may be removed from the PSES and de-designated as PSWP. This allows the information to be used as necessary to support the required action or activity, without violating the confidentiality requirements. This ability to remove PSWP and de-designate the information reinforces the benefit of having a time-delay between entry into the PSES and reporting to the PSO. It affords sufficient time to identify any patient safety concerns that may require de-designation of PSWP. Once the required activities are conducted, hospitals may re-enter duplicate copies of the information into the PSES for reporting to a PSO. Deliberations and analysis conducted within the PSES in response to an original record or incident report are PSWP and remain so, even when not reported to a PSO.

D. Violations of the Confidentiality Requirements and Enforcement

PSWP may not be disclosed except as permitted or required by law or unless authorized by the patient. Any person (defined broadly to include hospitals) who knowingly or recklessly violates the confidentiality provisions is subject to a civil money penalty of up to $10,000 for each act constituting a violation.

Safe Harbor

A provider whose workforce member discloses confidential PSWP is deemed not to have violated the Patient Safety Act if the workforce member disclosure does not include written or oral statements that assess the quality of care of an identifiable provider and does not describe or pertain to one or more actions or failures to act by an identifiable provider. The safe harbor does not apply, however, if the disclosure is knowing or reckless. Nor does the safe harbor apply to the PSO organization or the PSO workforce. Any PSO workforce member's disclosure is attributable to the PSO.

E. Training for Employees and Hospital Medical Staff

Hospital workforce training is a critical component of establishing a PSES and coordinating patient safety activities within the auspices of a PSES. Training is also vital to assert and defend the protections afforded under the Patient Safety Act. Training should be targeted to hospital workforce and medical staff members who create, access or handle PSWP and must address appropriate criteria for disclosing PSWP to an outside provider for patient safety activities. Workforce members must understand and acknowledge their obligations to maintain the confidentiality of PSWP.

Since many hospitals will be modifying existing policies and procedures to design and implement patient safety activities under a PSES, it is essential to highlight the differences between the pre-PSES system and the post-PSES system. Any unauthorized disclosures will not only expose the hospital and its workforce to civil penalties, but will also taint the ability to keep that PSWP confidential going forward. Therefore, training must address any changed systems and protocols under the PSES and reinforce revised patient safety policies and procedures as necessary to secure, maintain and report patient safety activities conducted within the PSES.

Patient safety systems and protocols will likely differ from hospital to hospital, but the responsibilities and obligations of the hospital workforce and medical staff accessing PSWP are the same. Training curriculum should include permitted uses of PSWP and appropriate measures necessary to maintain confidentiality in accordance with hospital policies and procedures. Some suggested participants to include in developing your PSES and training are as follows:

1. Risk Management, Safety and Quality Leaders/Staff
2. Chief Medical Officer and Physician Leaders
3. Chief Nursing Officer and Nursing Leaders
4. Ambulatory Care Administration
5. Executive Team and Board Members
6. Environmental Safety Officer
7. Radiation Safety Officer
8. Laboratory and Blood Bank Director
9. Pharmacy Director
10. Legal Counsel

IV. ASSERTING AND DEFENDING THE PROTECTIONS UNDER THE PSA

A. Asserting the Protections and Privileges

Once a PSES is established, PSWP within the PSES is privileged, and therefore protected from discovery or access by subpoena, court order, administrative order, inspection processes and other demands for access. Asserting the privilege requires documentation to demonstrate and defend that patient safety information and activities are conducted within the PSES and designated as PSWP. Just as in keeping appropriate medical records,

documentation is required to establish and defend the component parts and processes that constitute the PSES and the patient safety activities or PSWP maintained for the purposes of reporting to a PSO. Once established, the privilege is hard to break because it cannot be waived by conduct.

However, there has been significant confusion in the courts over what to do when data relating to medical errors is "assembled or developed" both for the purpose of reporting to a PSO and for some other purpose, particularly state law requiring the development of this data. Federal district courts have been split on this issue and the United States Supreme Court has denied review of the matter *(see C. "Case Law," page 13.17).*

In May of 2016, HHS issued guidance (the Guidance) for PSOs and providers that was intended to clarify what information qualifies as PSWP [81 Fed. Reg. 32655 (May 24, 2016)]. This Guidance purports to "clarify" that records kept by providers for more than one purpose — i.e., records kept by a hospital both in its ordinary course of business or under a state law requirement as well as for purposes of reporting to a PSO — do not count as PSWP, and thus are not protected from discovery. The Guidance explained that "[t]he intent of the system established by the Patient Safety Act is to protect the *additional information created* through voluntary patient safety activities, not to protect records created through providers' mandatory information collection activities" [81 Fed. Reg. 32655, 32655 (emphasis added)]. Thus, according to HHS, the PSWP privilege applies only to records created solely for reporting to a PSO. Records collected or created for any other purpose are not PSWP.

HHS's Guidance does not have the force and effect of law, as it was not issued through the notice and public comment rulemaking process. Further, it is at odds with the position taken by The Joint Commission, the American Hospital Association, the Alliance for Quality Improvement and Safety, and various PSOs concerning "dual purpose" documents. However, the Guidance can be considered an interpretive instrument.

If a governmental agency, individual or organization requests or demands access to PSWP, hospitals should immediately consult with legal counsel and assert the PSWP privilege. To assist with defending the privilege, all documents containing PSWP should be labeled to identify them as confidential and privileged PSWP. This also helps to safeguard PSWP.

As described above, several narrow and limited exceptions permit disclosure of PSWP under the specific criteria described in the Patient Safety Act and implementing regulations. Requests or demands for PSWP by others must be declined, unless all identified providers supply written consent for release, or the information has been rendered non-identifiable, or the request can be satisfied through original records such as the medical record.

Compliance Tips:

1. If a hospital wishes to provide information protected by the PSWP privilege, the hospital can reconstruct the information outside the PSES using sources outside the PSES. As an example, this may take the form of a root cause analysis, with re-interviews of participants in the original analysis, along with re-review of the original records, such as the medical record.
2. The Patient Safety Act is a fairly recent law that preempts state and other laws that provide lesser protections. As a result, some regulatory agencies and accreditation organizations may not be familiar with the confidentiality requirements and protections in the Patient Safety Act. There is tremendous value to having a written description of the confidentiality requirements under the Patient Safety Act that includes legal citations.

B. Defending the Privilege

In defending the confidentiality of PSWP, hospitals must be able to demonstrate establishment of a PSES and a contract with a PSO. In a way, a PSES is virtual — it is established by policies, procedures and protocols that constitute patient safety activities and data, collected either physically, electronically or functionally, and then backed by evidence of the system. Documentation is critical and will be necessary to defending PSWP as confidential. Thus, policies and procedures will likely be discoverable or will have to be produced to defend the privilege.

Since PSWP does not require immediate reporting to the PSO, hospitals must also be able to defend and justify any delay in doing so. The PSES policy should reflect the practice or standard for retention prior to reporting to the PSO, the type and scope of information that is protected PSWP, circumstances under which patient safety information and activities are conducted for other purposes outside the PSES, and the types of information subject to mandatory reporting. The contract with the PSO will also be an important element in defending the privilege, as will a board resolution approving the development of the PSES and PSO contract.

If patient safety information was collected for another purpose (such as at the request of legal counsel in anticipation of litigation) and subject to the attorney-client privilege or other privilege, there is nothing to prevent hospitals from also asserting and defending the patient safety activities and information as privileged and confidential PSWP. Defending the confidentiality afforded PSWP may result in litigation, and with relatively few cases having been decided under the Patient Safety Act, the lessons learned are limited. However, they are informative and so are described below.

C. Case Law

The Patient Safety Act is fairly recent, so state regulatory agencies, other oversight entities, and courts may not completely understand the protections afforded under the Patient Safety Act or recognize the impact that federal preemption may have on state and other confidentiality and disclosure laws. To date, litigation challenging the confidentiality of PSWP highlights the critical value of documentation. Protecting PSWP must be supported by documentation evidencing:

1. Establishment of a PSES system,
2. A signed and dated contract with a PSO,
3. The date on which the PSES was implemented or "went live," and
4. That the types of data and information collected and created are patient safety and quality related and were collected for the purpose of reporting to the PSO.

The most significant case addressing the Patient Safety Act and the protections afforded PSWP is *Illinois Dept. of Financial and Professional Regulation v. Walgreens,* 970 N.E.2d 552 (Ill. App. Ct. 2012). In this case, Walgreens was served with subpoenas requesting "all incident reports of medication errors" by three specific pharmacists between October 2007 and June 2010. Walgreens, which had established a PSO in January 2009, refused to produce the incident reports because they were collected and maintained as part of its PSES, and thus were privileged and confidential PSWP. The state agency sued Walgreens. The state court ruled in favor of Walgreens, determining that the incident reports were PSWP and therefore confidential, privileged and protected from discovery under the Patient Safety Act, which preempts contrary state law seemingly giving the agency authority to access the reports. The state agency appealed and after significant briefing by both sides and vigorous oral argument, the appellate court affirmed the trial court's decision and upheld the lower court's dismissal. In the appellate decision, the court referred to the sweeping evidentiary protections, and the purpose of the Patient Safety Act as documented in the Senate record — that being to provide for "broad confidentiality and legal protections of information collected and reported voluntarily for the purposes of improving the quality of medical care and patient safety."

Additional key points noted in the decision are as follows:

1. The Patient Safety Act "announces a more general approval of the medical peer review process and more sweeping evidentiary protections for materials used therein" [*KD ex rel. Dieffebach v. United States*, 716 F.Supp.2d 587, 595 (D. Del. 2010)].
2. The Patient Safety Act provides that "patient safety work product shall be privileged and shall not be subject to discovery in connection with a Federal, State, or local civil, criminal, or administrative proceeding" [42 U.S.C. Section 299b-22(a) (2006)].
3. PSWP includes any data, reports, records, memoranda, analyses, or written or oral statements that are assembled or developed by a provider for reporting to a PSO and are reported to a PSO [42 U.S.C. Section 299b-21(7) (2006)].
4. Excluded as PSWP is "information that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system" [42 U.S.C. Section 299b-21(7)(B)(ii) (2006)].

Dual Purpose Documents

There has been significant case law in recent years concerning "dual purpose" documents. Courts have split on this issue, with some finding that dual purpose documents are privileged under the PSQIA and others finding that they are not. Three cases out of the Kentucky Supreme Court have received national attention, as there is no nationally-binding precedent on the matter.

First, the Kentucky Supreme Court held in *Tibbs v. Bunnell*, 448 S.W.3d 796, 801 (2014) — a medical malpractice case — that because Kentucky regulations require health care facilities to maintain administrative reports, including "incident investigation reports," this information could not be privileged from discovery even if the incident reports were stored in the hospital's PSES. The hospital filed a petition with the United States Supreme Court for a writ of certiorari in this case, but the petition was denied on June 27, 2016.

However, in *Baptist Health of Richmond, Inc. v. Clouse, et al.*, 427 S.W.3d 759 (2016), the Kentucky Supreme Court was again asked whether documents sought in a medical malpractice case were protected from discovery by the PSQIA. The *Baptist* court vacated the trial court's discovery order compelling production of "any and all incident reports, investigation reports, sentinel event reports, root cause analysis reports, Joint Commission reports, Medicare reports, Medicaid reports, peer review reports and reports of any nature relating to [the decedent]," and remanded the matter.

With *Baptist*, the Kentucky Supreme Court added several new components to the dialogue. First, the Court explained that its prior *Tibbs* decision had no precedential effect because it was a plurality decision, and concluded that "the correct result in this case lies in the middle ground between the plurality and dissenting opinions in *Tibbs*." The court then held that:

> ... a provider who participates in the [PSQIA] may collect information within its patient safety evaluation system that complies with the [PSQIA] and that also complies with *state statutory and regulatory requirements*. However, doing so does not relieve the provider from complying with those state requirements and, to the extent information collected in the provider's internal patient safety evaluation system is needed to comply with those state requirements, it is not privileged.

The court explained that "[a]s long as a provider fulfills those obligations [under state law], the trial court has no reason to review the information in the provider's [PSES]." This test is notably different from prior tests because it includes only information collected pursuant to "statutory and regulatory requirements," not information arising from activities (such as peer review) that a state, federal or accreditation standard may require the hospital to perform. Finally, although the court addressed and arguably agreed with HHS's Guidance in part in reaching its holding, it did not reference the "sole purpose" standard; indeed, the holding vacates the trial court's order applying this standard. Thus, the court arguably rejected this standard as the determinant for whether documents qualify as PSWP.

In *University of Kentucky v. Bunnell*, Case No. 2017-CA-000543-OA (Oct. 20, 2017), the Kentucky Court of Appeals attempted to reconcile *Tibbs* and *Baptist*, and found that the "event report" sought in that medical malpractice matter was privileged from production because:

> it was created within the PSES for submission to a PSO, and it was submitted to a PSO. It was not a patient record, it was not prepared for, nor needed to satisfy, any external obligation or condition of participation in any government-sanctioned program; and it was not created for a business purpose such as internal risk management or voluntary submission to a voluntary program.

The Illinois Appellate Court reached a similar finding in *Daley v. Teruel*, 2018 IL App (1st) 170891, a medical malpractice action, reversing a ruling compelling the production of documents that had been collected within the hospital's PSES and reported to its PSO. The documents at issue were two incident reports concerning the patient and a record of a

complaint made by the patient's daughter concerning care provided to the patient on the date at issue. Relying on *Walgreens*, supra, the only other Illinois case to have examined the PSQIA, and the recent HHS Guidance, the court held that the documents at issue were privileged from production because they were "the very type of information that is by definition patient safety work product;" because the documents were assembled and prepared "solely" for submission to the hospital's PSO; because the documents, were, in fact submitted to the hospital's PSO; and because "the information contained in the documents had the ability to improve patient safety and the quality of health care." The court also rejected the plaintiff's argument that the documents were not privileged because they contained information that also was in the patient's medical record, and found that no state law required the hospital to compile the documents at issue. Finally, the court found that the PSQIA expressly preempts Illinois's discovery statute for any documents that meet the definition of PSWP.

In a similar vein, a Florida appeals court held in *Charles v. Southern Baptist Hospital*, Case No. 1D15-0109 (Oct. 28, 2015) — also a medical malpractice case — that, even though Florida law purported to give patients the right to "any records made or received in the course of business by a health care facility or provider relating to any adverse incident," this law was preempted by the PSQIA to the extent that it included documents that "met the definition of PSWP." The Florida appeals court held that the patient's interpretation of the PSQIA — that is, that state law requiring the creation of the same information created for reporting to a PSO takes away PSWP protections from such reporting — "would render [the PSQIA] a 'dead letter' and is contrary to Congress's intent to cultivate a culture of safety to improve and better the healthcare community as a whole."

However, this case was appealed to the Florida Supreme Court, and although the parties ultimately settled the case before the appeal was heard, the state Supreme Court still ordered oral argument and briefing in the case. The Florida Supreme Court thereafter reversed the appellate court's ruling. The court relied on HHS's Guidance and held that the documents at issue did not constitute PSWP because the hospital was required by Florida law to create and maintain those records. The United States Supreme Court denied the hospital's petition for a writ of certiorari on October 2, 2017.[1]

Similarly, in *Edwards v. Thomas*, Case No. SC15-1893 (Oct. 26, 2017), the Florida Supreme Court reversed an appellate court decision that had protected an external peer review report from production as PSWP. *Edwards*, like the other cases discussed in this chapter, was a medical malpractice case. Different from some of the other cases, however, the external peer report at issue in *Edwards* was created at the direction of the hospital's attorney. The *Edwards* court, however, held that this was a distinction without a difference. The court

1 More recently, the United States District Court for the Middle District of Florida held that PSQIA protects documents determined to be PSWP and preempts demands under state laws, such as Florida's law, to turn such records over in medical malpractice litigation discovery [Fl. Health Sci.Ctr., Inc. d/b/a Tampa General Hospital v. Azar, 420 F. Supp. 3d 1300 (M.D. Fla. 2019)]. However, on appeal by HHS, the Eleventh Circuit Court of Appeals vacated the district court's decision for lack of Article III standing by Tampa General Hospital following the state trial court's dismissal of the initial malpractice suit [Fl. Health Sci.Ctr., Inc. d/b/a Tampa General Hospital v. Azar, 844 F. App'x 217 (11th Cir, 2021)]. Additionally, the Middle District of Florida also recently held that it did not have jurisdiction to address the question of whether the PSQIA preempts Florida law where there was no injury or damages to seek compensation for. HHS has never imposed a penalty on a healthcare provider for producing PSWP, and thus the hospital would have no injury if it were compelled to produce such documents. [*Shands Jacksonville Med. Ctr., Inc. v. Azar*, No. 3:19-CV-579-J-32MCR (M.D. Fla. June 10, 2020)]

explained that Florida law gives its citizens access to "any records made or received in the course of business by a health care facility or provider relating to any adverse medical incident," and does not distinguish between reports created by "risk management committees" and those created by other peer review committees, which are clearly discoverable under Florida law. Thus, the court held that the peer review report was not protected as PSWP.[2]

The question of whether incident information is, in fact, PSWP that is protected from discovery also has been heard by courts in Pennsylvania, Rhode Island, Illinois, and California, with each court using a slightly different analysis to reach a slightly different conclusion. In *Carron v. Rosenthal,* No. NC 2013-0479, the plaintiffs alleged that the negligence of a physician employed by the hospital during an emergency delivery caused the death of a newborn infant. Plaintiffs sought the production of two Medical Event Reporting System (MERS) reports relating to the event, which were prepared and submitted to a PSO, relying on *Tibbs* to argue that the reports were not privileged because they were required to be developed, collected and maintained by Rhode Island state law. The hospital distinguished *Tibbs* by noting that the MERS reports were not required by state law (Rhode Island state law did not require the preparation and/or maintenance of patient incident records) and that the hospital collected state-law mandated report information in a different form. Following a motion to compel production of the MERS reports, the trial court, without written analysis, but appearing to rely on *Tibbs*, ruled in plaintiffs' favor. The hospital filed a petition for issuance of a writ of certiorari on June 29, 2015 that was granted by the Rhode Island Supreme Court on January 21, 2016. However, the case was settled before oral argument.

In *Johnson v. Cook County*, No. 15 C 741, 2015 WL 5144365 at *1 (N.D. Ill. Aug. 31, 2015), plaintiff, the estate administrator of Rex Johnson, brought a Section 1983 action against Cook County for alleged constitutional violations relating to Johnson's death while he was a jailed inmate. Plaintiff brought a motion to compel production of the Mortality and Morbidity Report (Report) prepared following Johnson's death. Cook County asserted that the Report was privileged under state law and PSQIA. The trial court concluded that Cook County "ha[d] not met its burden of establishing that either statutory privilege applies." First, the trial court concluded that Cook County had failed to demonstrate the Report was actually reported to a PSO. The trial court continued that, even if Cook County had adequately demonstrated the Report was functionally reported to a PSO, the Report would still not be privileged because "that information is privileged only if it is specifically generated or assembled for the purpose of reporting to a PSO or patient safety evaluation system," and Cook County had failed to show that "the Report was generated with a PSO or patient safety evaluation system in mind." Similarly, the United States District Court for the Western District of Pennsylvania held in *Crawford v. Corizon Health, Inc.*, No. 17-113, 2018 WL 3361147 at *5-*6 (W.D. Pa. July 10, 2018) that information submitted by a prison health system to its PSO, but not "assembled or developed for reporting" was not privileged under the PSQIA, and therefore compelled production of the information.

2 Although we discuss case law from Florida here for the purpose of providing a complete analysis, and because Florida's courts have been especially active in deciding cases relating to PSWP protections, it is important to note that Florida may be an outlier with respect to PSWP. This is because each Florida case relies on the same law, "Amendment 7" to Florida's constitution. This amendment gives Florida citizens the "right to have access to any records made or received in the course of business by a health care facility or provider relating to any adverse medical incident." Art. X, Section 25(a), Fla. Const. This law is unique to Florida and weighs heavily in each Florida PSWP decision. Thus, judicial decisions from Florida may be of limited utility and application to other jurisdictions.

In *Schlegel v. Kaiser Health Plan*, No. CIV 07-0520 MCE KJM, 2008 WL 4570619 at *1 (E.D. Cal. Oct. 14, 2008), the plaintiff brought suit against Kaiser Health Plan and other defendants "alleging claims for breach of the duty of good faith and fair dealing, breach of contract, negligence, fraud, negligent misrepresentation, and intentional and negligent infliction of emotional distress" with respect to Kaiser's kidney transplant program. The plaintiff sought to compel Kaiser to produce documents related to the "overall operation of Kaiser's transplant program, including documents relating to any investigation and audits of the transplant center by Kaiser, [California's Department of Managed Health Care (DMHC), the Federal Department of Health and Human Services Centers for Medicare and Medicaid Services ("CMS"), and the United Network for Organ Sharing (UNOS)]." Defendants argued that these documents were protected from discovery under state law (California Evidence Code Section 1157) and PSQIA. The United States District Court for the Eastern District of California held in *Schlegel* that ERISA preempted state law because the claims related to an employee benefit plan and thus the state law peer review protection did not apply. With respect to PSQIA, the court held that:

> [T]he unique and narrow privilege created by the [PSQIA] was not intended to apply to the materials requested ... There is no indication that the investigations conducted by Kaiser, UNOS, CMS and DMHC were prepared for and reported to a patient safety organization ... None of these entities themselves is a patient safety organization.

The United States District Court for the Middle District of Pennsylvania likewise refused to insert a "sole purpose" requirement into the PSQIA, and protected PSWP from disclosure in *Rumsey v. Guthrie Medical Group, P.C.*, Case No. 4:18-cv-01605-MWB (Sept. 26, 2019). In that case, the court analyzed both the PSQIA and Pennsylvania's Medical Care Availability and Reduction of Error ("MCARE") Act as potential bases for protecting information pertaining to the hospital's infection-prevention procedures from discovery in a medical malpractice action. The court explained that "The MCARE Act's protection is similar to the PSQIA's but narrower in that [information] must be 'solely' prepared for that purpose." With this understanding, the court held that documents produced by the hospital's PSO for the purpose of patient safety activities were protected from discovery under the PSQIA. The court further held that the "[a]gendas, notes, and other written records" of the hospital's quality committee meetings discussing infection prevention or control likewise were protected as the "'deliberations or analysis of' a patient safety evaluation system" under the PSQIA, the MCARE Act, and Pennsylvania's Peer Review Protection Act. However, the court refused to protect from disclosure correspondence with governmental agencies relating to infection prevention, reporting, and management, and also refused to protect the hospital's infection policies, noting that "information available outside of the [PSES] does not become privileged merely by virtue of its use in the evaluation process." In addition to being notable for rejecting a "sole purpose" standard for protecting documents under the PSQIA, the *Rumsey* decision also is notable because it is one of the first decisions (along with *Daley*, discussed above) to uphold PSQIA protections for "deliberations or analysis" rather than only for information directly reported to a PSO.

However, the Superior Court of Pennsylvania reached a different decision in *Ungurian v. Beyzman*, 2020 Pa. Super 105, 232 A.3d 786, reargument denied (June 30, 2020). There, the hospital asserted that an event report and root cause analysis were PSWP because they were prepared for the purpose of improving patient safety and quality and were maintained

within its PSES for reporting to its PSO. In rejecting the hospital's attempt to protect the documents from discovery under the PSQIA, the court held that the documents were not privileged because they were not developed for the purpose of reporting to a PSO and because they were not maintained solely in the hospital's PSES. (Id. at 796.)

As the above survey of case law makes clear, unless and until further guidance is issued by the United States Supreme Court, providers should be wary of relying on the PSQIA's protection for maintaining the confidentiality of their PSWP, at least to the extent that it consists of data assembled or developed for purposes other than reporting to a PSES.

Other than the *Schlegel* case concerning dual purpose documents, there have been no significant California appellate cases reported to date.[3]

3 But *see Doe v. Pasadena Hosp. Ass'n, Ltd.*, No. 218-CV-08710ODWMAA, 2021 WL 4557221 (C.D. Cal. June 7, 2021) (holding that "the PSQIA privilege" applied to the hospital's documents labeled as "event reports" which "identify or reflect deliberation or analysis of information being reported, allow for the identification of providers that are a subject of the work product and/or providers that participate in activities that are a subject of the work product[.]")

14 **Other Laws**

I. Introduction 14.1

II. Antitrust Laws 14.1

A. Overview of Antitrust Laws 14.1

Purpose of Antitrust Laws 14.1

Who is a Competitor? 14.1

Anti-Competitive Activities 14.2

Federal Antitrust Policy Statements 14.2

Accountable Care Organizations 14.3

California Antitrust Law 14.3

B. Enforcement and Penalties 14.3

C. Policies 14.4

III. Emergency Medical Treatment and Labor Act (EMTALA) 14.5

A. Overview of the Law 14.5

B. Enforcement and Penalties 14.6

C. Resources for More Information 14.6

IV. Health Information Privacy, Security and breach notification Laws 14.6

A. Consent for Medical Treatment 14.7

V. Record Retention 14.8

A. Steps to Take in Developing Effective Record Retention Policies and Procedures 14.8

B. Record Retention Periods 14.9

C. Legal Requirements and Considerations 14.9

D. Electronic Records 14.9

E. Legal Hold 14.9

F. CHA Resources 14.10

VI. How to Obtain CHA Publications 14.10

14 Other Laws

I. INTRODUCTION

The purpose of this chapter is to highlight major laws that impose significant compliance obligations on hospitals — and therefore should be included in a hospital's compliance program — that are not described elsewhere in this manual. These laws are considered high-risk areas because of the complexity of the laws, the impact on the day-to-day operations of hospitals, and the consequences of noncompliance (both in terms of impact on patient care and imposition of fines and penalties).

A detailed discussion of these laws is beyond the scope of this manual. This chapter provides a brief overview, intended to alert compliance officers to the importance of these issues. Because of the complexity of the laws, CHA has published separate manuals on these issues with the exception of antitrust laws.

Topics highlighted in this chapter include:

1. Antitrust Laws
2. Emergency Medical Treatment and Active Labor Act (EMTALA)
3. Health Information Privacy and Security Laws
4. Consent for Medical Treatment
5. Records Retention

II. ANTITRUST LAWS

This section provides an overview and general understanding of antitrust laws. Because antitrust law is extraordinarily complex, compliance officers and others should contact appropriate legal counsel when antitrust issues arise.

A. Overview of Antitrust Laws

Purpose of Antitrust Laws

The primary purpose of the antitrust laws is to foster a competitive, free market economy. While there are multiple federal antitrust laws addressing various types of anti-competitive activities, the general thrust of those laws is to prohibit agreements or other arrangements that unreasonably restrain free and open competition. The federal antitrust laws also prohibit monopolization or the attempt to monopolize, where significant control of a market is used to exclude or otherwise harm competitors or potential competitors. California also has antitrust laws on the books; they are very similar to the federal laws.

Who is a Competitor?

Although health care providers usually don't think of themselves as "businesses" competing for "customers" (patients), this is how the law may view them. In general, a hospital's competitors will be other hospitals and health care facilities. Ambulatory surgery centers, imaging centers, and other types of outpatient providers may also be competitors.

Anti-Competitive Activities

Ordinarily, the determination that an activity or business arrangement is anti-competitive is made after an extensive analysis of the activity in question, where both the pro-competitive effects and the anti-competitive effects are examined to determine if, on balance, the activity unreasonably harms competition. It is often difficult to determine in advance whether a proposed action will be found to be anti-competitive under this analysis.

However, certain types of activities have been determined to be so inherently harmful to competition that they are *per se* illegal, meaning that engaging in the activity violates federal antitrust law, regardless of whether the activity has any harmful effects on competition. Some of the types of activities that are *per se* violations are:

1. Agreements among competitors that affect or influence the prices competitors charge for items or services (commonly referred to as "price fixing").
2. Agreements among competitors to "divide markets," meaning agreements not to compete in certain markets or not to offer competing services. An example of market division in the health care context may include two competing hospitals agreeing that one of them will provide neurosurgery services, and the other will provide orthopedic services, and they won't complete with each other in these services lines. This is prohibited conduct. Each hospital must make its own independent determination about the services it will provide.
3. Agreements among competitors to boycott, or refuse to deal with, another competitor, or a customer or supplier. An example of a refusal to deal in the health care context may include two competing hospitals agreeing not to contract with a particular health plan. This is prohibited conduct. Each hospital must make its own independent determination about whether it will contract with a particular health plan.
4. Selling a product or service only on condition that another product or service is purchased as well (commonly referred to as a "tying arrangement").

Probably the most frequently prosecuted of the *per se* violations listed above is price fixing. Any agreement of any nature among competitors regarding price can constitute *per se* price fixing. However, one of the safety zones (described below) protects joint negotiations or agreements among competing health care providers regarding price if the competitors are financially or clinically integrated and do not control a significant portion of the relevant market. Financial integration can be achieved through significant financial risk-sharing among the competitors, such as through capitation payments or significant withholds from fee-for-service payments with distribution of the withholds tied to achieving cost containment goals. Clinical integration involves establishing a common program of clinical management among the practices of competing providers that is likely to influence the clinical practice patterns of those providers.

Federal Antitrust Policy Statements

The U.S. Department of Justice and the Federal Trade Commission are the federal agencies responsible for enforcement of federal antitrust laws. These agencies have issued statements of their antitrust enforcement policies regarding activities in the health care area. These policy statements contain "safety zones" regarding health care provider conduct that they generally

will not challenge under the federal antitrust laws. The Department of Justice and Federal Trade Commission Statements of Antitrust Enforcement Policy in Health Care may be found at www.justice.gov/atr/public/guidelines/1791.htm. They include:

- Statement 1: Mergers Among Hospitals
- Statement 2: Hospital Joint Ventures Involving High Technology or Other Expensive Health Care Equipment
- Statement 3: Hospital Joint Ventures Involving Specialized Clinical or Other Expensive Health Care Services
- Statement 4: Providers' Collective Provision of Non-Fee-Related Information to Purchasers of Health Care Services
- Statement 5: Providers' Collective Provision of Fee-Related Information to Purchasers of Health Care Services
- Statement 6: Provider Participation in Exchanges of Price and Cost Information
- Statement 7: Joint Purchasing Arrangements Among Health Care Providers
- Statement 8: Physician Network Joint Ventures
- Statement 9: Multiprovider Networks

Accountable Care Organizations

In October 2011, the Centers for Medicare & Medicaid Services (CMS) issued a final rule establishing a shared savings program for accountable care organizations (ACOs). Simultaneously, the U.S. Department of Justice and the Federal Trade Commission issued a Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program. The statement and related information may be found at www.justice.gov/atr/public/health_care/aco.html.

California Antitrust Law

California's principal antitrust law is the Cartwright Act [Business and Professions Code Sections 16700-16770]. While the Cartwright Act is not identical to federal antitrust law, the principles discussed above regarding federal antitrust law are generally applicable under California law as well.

B. Enforcement and Penalties

As mentioned above, responsibility for enforcement of federal antitrust laws lies with the U.S. Department of Justice and the Federal Trade Commission. The federal antitrust laws are criminal statutes and provide for substantial and severe penalties. For example, violations of the Sherman Act, the fundamental federal antitrust law, are felonies punishable by imprisonment for up to 10 years and/or fines up to $1 million for an individual and up to $100 million for a corporation. Alternatively, fines may be imposed amounting to double the gain to the violator or the loss to the victim. The current federal sentencing guidelines provide for mandatory jail sentences for certain antitrust violations. The enforcement agencies may also bring civil lawsuits for enforcement of these statutes.

Private parties may also enforce the antitrust laws through civil lawsuits. In general, any person or company injured by an antitrust violation may recover three times the amount of any actual damage to the injured person or company.

Additional damages and penalties are available under California law.

C. Policies

A hospital may wish to develop the following policies to promote compliance with federal and state antitrust laws in its business activities:

1. Joint ventures with other hospitals regarding the purchase and/or operation of major medical equipment should comply with the federal antitrust safety zone for hospital high technology joint ventures. This safety zone generally requires that the joint venture include only the number of hospitals whose participation is needed to support the equipment.
2. Participation with other hospitals in collectively providing fee-related information to purchasers of health care services should comply with the federal antitrust safety zone for such activities. This safety zone generally requires that the collection of the information be managed by a third party, and that any information made available to competing providers be provided in a manner that does not allow recipients to identify the prices of individual providers.
3. Participation in price surveys for services, or wages, salaries or benefits of health care personnel, should comply with the federal antitrust safety zone for such activities. This safety zone generally requires that the survey be managed by a third party, and that any information is provided in a manner that does not allow recipients to identify prices charged or compensation paid by particular providers.
4. Joint purchasing arrangements with other hospitals should comply with the antitrust safety zone for such activities. This safety zone generally requires that the purchases account for less than 35 percent of the total sales of the items in the relevant market, and that the cost of the items purchased jointly account for less than 20 percent of the total revenues from all items sold by each competing participant in the joint purchasing arrangement.
5. The hospital should participate in multi-provider networks that jointly market their health care services to health plans and other purchasers only where it has been determined that the providers' integration in the network is likely to produce significant efficiencies in the health care market, and where it has been determined that any price agreements among network providers are reasonably necessary to realize those efficiencies.
6. No hospital representative should engage in any discussions or agreements with competitors regarding prices for services, how prices are determined, the terms of vendor relationships, the allocation of markets for goods or services, or the refusal to do business with particular vendors or suppliers.
7. The hospital should not engage in any activity that is likely to have an anti-competitive effect on a market in which the hospital participates unless either:
    a. The activity falls within a federal antitrust safety zone;

b. The effects of the activity on competition in the market have been thoroughly analyzed and a determination has been made, with the approval of hospital legal counsel, that the activity will not have an overall anti-competitive effect; or

c. The activity has been reviewed and approved by federal antitrust agencies pursuant to the business review or advisory opinion request process.

8. Marketing and advertising on behalf of the hospital should contain only truthful, informative and nondeceptive information, and should accurately reflect services available and the licensure and certification of hospital programs.

9. No response should be made to an oral or written inquiry regarding antitrust or unfair trade matters without prior consultation with the hospital's legal counsel.

10. No restrictive covenant that limits the hospital's ability to compete should be entered into without prior consultation with the hospital's legal counsel.

III. EMERGENCY MEDICAL TREATMENT AND LABOR ACT (EMTALA)

A. Overview of the Law

The Emergency Medical Treatment and Labor Act (EMTALA) was enacted to ensure that all Americans have access to emergency services without regard to insurance status or ability to pay. Often referred to as the "patient anti-dumping" law, EMTALA imposes significant obligations on Medicare-participating hospitals.

In general, EMTALA requires hospitals to provide an appropriate medical screening examination to any individual who comes to the hospital seeking emergency services. To the extent such a medical screening examination reveals that the individual has an emergency medical condition, the hospital must:

1. Provide stabilizing treatment; or

2. Transfer the patient, within very narrow and specifically-defined circumstances, to another hospital that has the capability and capacity to treat the patient. The transferring hospital must obtain the approval of both the receiving hospital and a physician at the receiving hospital in advance of the transfer.

In addition, EMTALA requires specified documentation, the maintenance of a central log of emergency patients, posting of specified signage regarding patients' rights to emergency services, and maintenance of a list of physicians who are on call to come to the hospital and provide stabilizing treatment. EMTALA also requires receiving hospitals to accept transfer patients under certain circumstances, and to report to the Centers for Medicare & Medicaid Services (CMS) or the state survey agency (in California, this is the California Department of Public Health (CDPH)) if it believes it received an individual transferred with an unstable emergency medical condition from another hospital in violation of EMTALA requirements.

The EMTALA statute was initially enacted in 1986, and amended several times since then. CMS adopted regulations to interpret the statute. In addition, CMS has published *Interpretive Guidelines* as guidance to surveyors who are assessing hospitals' compliance with EMTALA. Despite more than three decades of experience with EMTALA, there is still considerable confusion by hospitals, physicians, state survey agencies and even CMS officials on the

scope and application of the law. EMTALA regulations have been amended frequently and the courts have established their own body of law in applying EMTALA, sometimes in ways that differ from the EMTALA regulations or the *Interpretive Guidelines*.

B. Enforcement and Penalties

Generally, enforcement actions under EMTALA are triggered by complaints from patients, receiving hospitals, physicians, hospital employees, and ambulance or other emergency services agencies. EMTALA investigations may also originate from routine licensing surveys or during the accreditation process.

CMS has the authority to conduct complaint and enforcement surveys for EMTALA compliance, and to terminate a hospital's Medicare provider agreement upon confirming one or more violations of EMTALA.

The OIG has the authority to impose civil money penalties against hospitals and physicians, and/or to exclude a hospital or physician from the Medicare and Medicaid (Medi-Cal) programs for violations of EMTALA that are "gross and flagrant or repeated." The maximum amount of the fines is subject to annual adjustment for inflation.

There may also be Quality Improvement Organization (QIO) review of the violation. Finally, CDPH may impose additional fines and penalties.

C. Resources for More Information

For an in-depth discussion of hospital and physician obligations under EMTALA, hospitals should consult legal counsel, CHA's *EMTALA: A Guide to Patient Anti-Dumping Laws*, or both. In addition to federal EMTALA laws, the CHA manual addresses California laws governing patients seeking emergency services. Written in a question-and-answer format, the manual answers the most frequently asked questions and is approximately 500 pages in length. Information about the manual may be found at www.calhospital.org/emtala-manual.

Topics include: when and where EMTALA begins and ends, medical screening exams, financial considerations, patient transfers, refusal of treatment, EMTALA and psychiatric emergency patients, obligations of receiving hospitals, central logs and signage requirements, physician on-call responsibilities, reporting requirements, enforcement and private actions, quality improvement, and application of EMTALA to disasters and public health emergencies.

IV. HEALTH INFORMATION PRIVACY, SECURITY AND BREACH NOTIFICATION LAWS

Health care providers in California must comply with many health information privacy, security, and breach notification laws. At the state level, there is the Confidentiality of Medical Information Act (CMIA), the Lanterman-Petris-Short (LPS) Act, special provisions regarding HIV test results, the Patient Access to Health Records Act (PAHRA), the California Consumer Privacy Act, and other laws. At the federal level, there is the Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rules (including special restrictions for psychotherapy notes), the Health Information Technology for Economic and Clinical Health (HITECH) Act, special provisions for federally-assisted substance abuse programs, and other

laws. There are also laws related to the confidentiality of Social Security numbers, driver's license Information, and information collected when accepting payment by check or credit card.

Many state and federal agencies have the authority to enforce and punish the laws listed above, and aggrieved individuals may bring a lawsuit alleging violations of some of these laws. Noncompliance with these laws has serious potential implications. HIPAA, for example, provides for fines in 2020 of $119-$1,785,651 per violation, depending on the level of culpability, and criminal penalties of up to 10 years in prison. The penalties are adjusted for inflation each year. The penalties for use or disclosure of medical information in violation of CMIA can be even higher. A California hospital is subject to both state and federal penalties.

CHA has published a separate manual, the *California Health Information Privacy Manual*, that describes the requirements of these laws as well as other privacy, security and breach notification laws in detail and contains many sample forms that hospitals may use to achieve compliance. The manual answers the most frequently asked questions and is approximately 450 pages in length. Information about the manual may be found at www.calhospital.org/publications/california-health-information-privacy-manual.

A. Consent for Medical Treatment

State and federal laws grant patients certain rights. Foremost among these is the right for a competent adult to make his or her health care decisions. A person does not give up the right to control what is done with his or her body when seeking care at a hospital. Indeed, a physician has both a legal and an ethical duty to obtain the patient's consent, or the consent of the patient's legal representative, to medical treatment.

Individuals who are unable to exercise this right, such as minors and incapacitated adults, have the right to be represented by another person who will protect their interests and preserve their basic rights.

Failure to obtain the proper consent to treatment in accordance with applicable legal standards may result in a charge of battery, professional negligence (malpractice), and/or unprofessional conduct against the physician, nurses, or other health care providers, for even the simplest of procedures. If the nature of the treatment involved is complicated, the recognition of the patient's right to self-determination may require that "informed" consent be obtained. In addition, if a patient refuses recommended treatment, obtaining an "informed refusal" from the patient may be required.

In very limited circumstances, a hospital and physician may treat a patient without his or her consent. For the most part, such circumstances are limited to emergency situations or to mental health patients who are a danger to themselves or others, or gravely disabled.

So that patients will know and understand their rights, both state and federal law require hospitals to post signs and provide handouts informing patients of their rights when hospitalized — for example, the right to confidentiality and privacy, to an interpreter, to have visitors, to refuse treatment, and more.

CHA's *Consent Manual* contains a complete discussion of patients' rights and, in particular, consent laws, including when informed consent is required, who may consent on behalf of a minor or an adult lacking capacity to consent, what factors to consider in determining whether a patient lacks capacity to consent, and when patients may be treated without

their consent. The manual details consent requirements for specific treatments (sterilization, hysterectomy, abortion, reuse of hemodialysis filters, vaccines, antipsychotic medications, organ transplants, etc.) and for different patient types (adults under conservatorship, adults with an advance health care directive, minors who may legally consent to specific treatments, minors who lack the ability to consent, patients in the custody of law enforcement, etc.).

Broader consent-related issues such as release of information, mandatory signage and handouts, and mandatory reporting requirements are also addressed. The nearly 1,000-page manual contains more than 100 forms that hospitals can adapt to meet their own needs; many of the forms are translated into Spanish.

Information about the manual may be found at www.calhospital.org/consent.

V. RECORD RETENTION

Hospitals create volumes of records dealing with a variety of matters. In order to demonstrate that legally required standards are being met, hospitals and health care facilities must document compliance with the law in all areas of operations. A thorough record retention policy is a critical element of an effective compliance plan. The policy should address all types of records: corporate and administrative, business and finance, dietary, engineering, environmental services, human resources, imaging, laboratory, medical records, pharmacy, purchasing, etc. The policies and procedures should be followed consistently to dispute any allegation that the provider withheld, hid, altered or destroyed evidence relevant to a legal proceeding ("spoliation of evidence"). Spoliation of evidence is a crime in California and at the federal level.

A. Steps to Take in Developing Effective Record Retention Policies and Procedures

CHA recommends that hospitals take the following steps:

1. Designate an employee to be responsible for implementing and updating record retention policies and procedures, as well as training and monitoring employees to ensure consistent compliance throughout the organization.
2. Consider establishing a records management committee with representation from throughout the organization to update the policies and procedures as necessary, and to assist in implementation, training and monitoring/auditing.
3. Establish a comprehensive record retention and disposal/destruction policy. Such a policy should contain at least the following elements:
    a. A statement as to the purpose of the policy;
    b. Whether the policy covers the entire organization or only certain departments;
    c. A statement that the destruction of relevant records will be suspended upon receipt of legal process or other notice of pending or reasonably foreseeable investigations or litigation, whether government or private ("legal hold" or "litigation hold," discussed below);
    d. A list of employees and/or departments responsible for maintaining and updating the policy;

e. A list of employees and/or departments responsible for moving documents to long-term storage and destroying documents in accordance with the policy; and

f. A retention period for each type of record generated or maintained by the hospital.

4. Train affected employees.

5. Monitor and audit for compliance with the hospital's policies.

B. Record Retention Periods

The retention period for each type of record maintained by the hospital should be based on legal requirements and policy considerations (discussed below), frequency of use of a record, space constraints, and historical or research uses for the records.

C. Legal Requirements and Considerations

Many state and federal government agencies have promulgated regulations that specify how long hospitals and other health care providers must keep certain documents. Providers are required to comply with these retention periods. However, in many cases, compliance with these minimum retention requirements is inadequate to protect the health care provider in all situations. Additional considerations in determining an optimal record retention period include accreditation requirements, contractual obligations, and statutes of limitations.

Sometimes hospitals and other health care providers will want to be able to produce records to defend themselves in a lawsuit. It is helpful to understand the time period during which various types of lawsuits may be brought in order to develop an effective retention policy. The time period during which a lawsuit may be brought is called the "statute of limitations." After the statute of limitations has run, it is too late for a plaintiff to bring a lawsuit, and related records will thus not be needed to defend any such suit.

Statutes of limitations commonly applicable in the California health care industry include actions for medical malpractice; personal injury (such as slip-and-fall injuries on hospital premises, car accidents by employees in hospital-owned vehicles, etc.); breach of contract; fraud and abuse; and Internal Revenue Service/tax actions.

D. Electronic Records

Retention policies for electronic records should focus on both transferring information for longer-term storage and on purging information from the system. Transfer to longer-term storage is the inevitable result of the limited online capacity of any system. Once information is fully transferred, it is no longer available to any terminal user and can be retrieved only through operator intervention. Providers must store the disks in a safe and secure place, and establish a system of access similar to that used in hard copy storage.

The question of purging information from an electronic system is identical to that of discarding or destroying hard copy. The same record retention periods apply irrespective of whether a record is electronic, paper, microfiche, microfilm, etc.

E. Legal Hold

If a hospital has reason to believe that it may be sued or may be the subject of an audit or investigation, legal counsel should be consulted immediately to determine whether to initiate

a legal hold. If a legal hold (also called a "litigation hold") is initiated, the usual retention and disposal policies are suspended with respect to records relevant to the potential claim, dispute, lawsuit, audit or investigation. All potentially relevant records should be retained in their original form until legal counsel authorizes their destruction or deletion in accordance with the usual record retention schedule. This includes paper records as well as electronic data and documents (including e-mails). If a medical device, product, equipment, drug, other supply, or patient specimen may be involved, it should be sequestered. Employees and other personnel should be notified to suspend destruction of potentially relevant records, and all steps related to compliance with the legal hold should be documented.

The occurrence of any of the following should provoke the hospital to consider a legal hold:

1. Service of legal process (subpoena, summons, or the like)
2. Learning of an investigation or audit by a government agency, government contractor, or private entity
3. Receipt of a claim (formal or informal)
4. Receipt of a patient complaint (not including minor complaints)
5. A dispute

F. CHA Resources

CHA has developed a guide, the *Record and Data Retention Schedule*, that discusses in detail the legal requirements and considerations regarding record retention policies and lists the required and recommended time periods for the retention of various classes of records.

The first section of the *Record and Data Retention Schedule* discusses why hospitals and other health care providers need a record retention policy and the pertinent factors that should be considered when determining how long to keep various documents. The second section is a Recommended Retention Schedule. It contains tables listing typical records, provider types, any applicable legal citations, and recommended retention periods. The information in the guide applies to all records, regardless of media (paper, electronic, microfiche, microfilm, video/audio recording, magnetic tape, CDs, etc.).

Information about the manual may be found at www.calhospital.org/publications/record-and-data-retention-schedule.

VI. HOW TO OBTAIN CHA PUBLICATIONS

The California Hospital Association publishes numerous legal manuals, forms, posters and other documents to help hospitals understand and comply with the law. To learn more about CHA's publications, or to order a manual, please visit our website at www.calhospital.org/publications.

15 Repayment and Self-Disclosure

I. Introduction 15.1

II. Criminal Disclosure Statutes 15.1

III. Regulatory 60-Day, or Cost Report Due Date, Deadline for Refunding Medicare/Medicaid Overpayments 15.2

A. Requirement to Report and Return Identified Overpayments 15.2

False Claims Act Implications 15.3

B. Level of Knowledge Triggering Disclosure Obligation or Duty to Investigate 15.3

C. Timing and Process for Overpayment Refunds 15.6

D. How Far Back Must Disclosure Go? 15.7

Overpayments 15.7

False Claim 15.8

Investigation 15.9

IV. OIG Self-Disclosure Protocol 15.9

A. The Original 1998 Protocol 15.10

B. The Updated OIG Disclosure Protocol 15.11

C. The Basic Elements of the Updated Protocol 15.12

D. Requirements for Conduct Involving False Billing 15.13

E. Requirements for Conduct Involving the Anti-Kickback Statute and Physician Self-Referral Law 15.14

F. Financial Inability to Pay 15.15

G. Overpayment Reconciliation 15.15

V. CMS Self-Referral Disclosure Protocol 15.16

A. Eligible Parties and Matters 15.16

B. Basic Elements 15.17

C. Financial Analysis and Report 15.18

D. CMS Processing of Disclosure 15.19

E. CMS Criteria for Settlement 15.19

F. Consequences of Self-Disclosure 15.20

G. Hospitals with CIAs or CCAs 15.21

H. Relationship to Other Federal Authorities 15.21

VI. Determining Which Self-Disclosure Protocol to Use 15.21

15 Repayment and Self-Disclosure

I. INTRODUCTION

Under federal and state law, hospitals and other providers can be criminally prosecuted for knowingly failing to refund overpayments that have been received by them from federal and state health care programs and by private insurers. In addition, federal law requires a hospital to report and refund a Medicare or Medicaid overpayment to the applicable payer by the later of 60 days after the date on which the overpayment was identified or the date any corresponding cost report is due. A violation of this 60-day deadline can subject a hospital to a civil monetary penalty (CMP), exclusion from federal health programs, and liability under the federal or state False Claims Act (FCA) for the knowing concealment or retention of an overpayment. This is true even if the original claims leading to the overpayment were not actionable because, for example, they were originally caused by an innocent billing error. *(See chapter 3 for a detailed discussion of the FCA laws, and chapter 11 for information about excluded providers.)*

This chapter provides an overview of:

1. Federal and California criminal disclosure statutes.
2. The deadlines and requirements for reporting and returning Medicare and Medicaid overpayments.
3. The procedures for disclosing and seeking settlement of overpayment liabilities that may involve violations of the Physician Self-Referral Law (Stark Law) or fraud, including under the Office of the Inspector General's (OIG) Provider Self-Disclosure Protocol and the Center for Medicare & Medicaid Services' (CMS) Self-Referral Disclosure Protocol.

In the face of severe potential criminal and civil penalties, hospitals should ensure that any known overpayments from Medicare, Medi-Cal or other federal health care program, or private insurer, are promptly disclosed and repaid to the relevant program or insurer. However, as described below, a hospital's proper handling of the disclosure process can also significantly influence the nature (e.g., criminal or civil) and extent (e.g., fines, treble damages, civil penalties or exclusion) of its potential liability for any improper claims to government and private health care programs and plans.

II. CRIMINAL DISCLOSURE STATUTES

Under the federal disclosure statute, concealing or failing to disclose overpayments that have been received by a hospital under any federal health care program, including Medicare and Medi-Cal, may be a felony crime punishable by up to ten years in prison and/or a fine of up to $100,000 [42 U.S.C. Section 1320a-7b(a)(3)]. Under California's disclosure statute, the

same conduct with respect to any benefit payable under a private insurance contract may be a felony punishable by up to five years in state prison and/or a fine of up to $50,000, or double the amount of the fraud, whichever is greater [Penal Code Section 550(b)(3)].

In order to be criminally liable under the federal disclosure statute, a hospital or one of its employees must:

1. Know of an event affecting the hospital's initial or continued right under a federal health care program to any payment received on a claim; and
2. Knowingly conceal, or fail to disclose, the event with a fraudulent intent to secure the payment either in a greater amount than was due or when no payment at all was authorized.

Under California's disclosure statute, a hospital (and potentially its responsible employees) is criminally liable for knowingly concealing, or failing to disclose the occurrence of, an event that affects:

1. Any person's initial or continued right or entitlement to any insurance benefit or payment, or
2. The amount of any such benefit or payment.

While these criminal disclosure statutes are always a serious concern when an overpayment from a government or private health care plan is at issue, there are few court cases describing the circumstances under which these statutes could be used to prosecute a hospital for knowingly retaining or concealing an overpayment. Indeed, the application of California law in this situation is unclear, and attorneys have differing opinions as to when such law does and does not apply, with some taking the position that it applies only when the relevant claims were known to be wrongful when they were first submitted. However, at a minimum, a hospital must ensure that it is complying with any regulatory requirements regarding the disclosure and refund of overpayments — including the 60-day or cost report due date deadline discussed below — because any violation of such requirements could be viewed by the government as evidence of a fraudulent intent to retain the overpayments at issue. In addition, hospitals should consult their legal counsel to ensure that compliance with regulatory requirements is carefully implemented and documented before, during, and after making any overpayment disclosure to the federal or state government or a private insurer.

III. REGULATORY 60-DAY, OR COST REPORT DUE DATE, DEADLINE FOR REFUNDING MEDICARE/MEDICAID OVERPAYMENTS

A. Requirement to Report and Return Identified Overpayments

Since 2010, federal law has required hospitals and other providers to "report and return" any Medicare or Medicaid overpayment to the applicable payer by the later of "60 days after the date on which the overpayment was identified" or "the date any corresponding cost report is due, if applicable." For purposes of this deadline, an **"overpayment"** means any Medicare or Medicaid funds that a hospital "receives or retains ... to which the [hospital], after applicable reconciliation, is not entitled." In addition, the hospital must notify the applicable payer in writing of the reason for the overpayment, and, if an overpayment is calculated using a statistical sampling methodology, the hospital must describe the statistically valid sampling and extrapolation methodology. Under implementing regulations for Medicare Part A and B

overpayments, the report and return obligations are satisfied in cases that do not Implicate the OIG Self-Disclosure Protocol or the CMS Voluntary Self-Referral Disclosure Protocol by using an applicable claims adjustment, credit balance, self-reported refund, or other reporting process set forth by the applicable Medicare Administrative Contractor (MAC) to report an overpayment and, if a statistical sampling methodology is used, by also describing the methodology for sampling and extrapolation. Noridian provides instructions on submitting a voluntary refund through claim adjustments or check accompanied by a voluntary check form at https://med.noridianmedicare.com/web/jea/topics/overpayment-recoupment/voluntary-refunds.

The deadline for returning overpayments is suspended when:

1. The OIG acknowledges receipt of a submission to the OIG Self-Disclosure Protocol;
2. CMS acknowledges receipt of a submission to the CMS Voluntary Self-Referral Disclosure Protocol; or
3. A hospital requests an extended repayment schedule.

The suspension of the deadline ends when a settlement agreement is entered, the hospital withdraws or is removed from the OIG Self-Disclosure Protocol or the CMS Voluntary Self-Referral Disclosure Protocol, the extended repayment schedule is rejected, or the hospital fails to comply with the terms of the extended repayment schedule, as applicable.

[42 U.S.C. Section 1320a-7k(d); 42 C.F.R. Section 401.305]

In February 2016, CMS issued final regulations to implement the statutory 60-day or cost report due date deadline for reporting and refunding overpayments under Medicare Part A and Part B [81 Fed. Reg. 7654 (Feb. 12, 2016)]. These regulations are described in this portion of the manual.

False Claims Act Implications

An identified overpayment retained by a hospital past the applicable deadline for reporting and refunding it is an "obligation" within the meaning of the federal FCA provision imposing liability on a hospital that "knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the government." *(See chapter 3, "Federal and State False Claims Acts.")* A hospital's violation of the 60-day, or cost-report due date, deadline does not automatically transform an overpayment into a false claim subject to treble damages (three times the amount of the false claim) and a mandatory civil penalty, which, as of June 19, 2020, ranges from $11,665.00 to $23,331.00 per false claim. However, it increases the likelihood that the federal government will view the violation as being actionable under the FCA as a knowing concealment or improper avoidance of an "obligation" to refund an overpayment. A hospital's violation of the deadline can also result in a CMP of up to $21,113 per overpayment in 2021. In addition, the Secretary may make a determination in the same proceeding to exclude the person from participation in the federal health care programs (as defined in 42 U.S.C. Section 1320a-7b(f)(1)) and to direct the appropriate state agency to exclude the person from participation in any state health care program.

Voluntarily disclosing certain identified overpayments can have implications on potential False Claims Act settlements as well. In 2019, the Department of Justice (DOJ) issued guidance to its False Claims Act litigators that cooperation credit may be earned by hospitals voluntarily

disclosing misconduct, as well as those hospitals cooperating in an ongoing investigation, or undertaking remedial measures in response to a violation. For a more detailed discussion of this recent guidance see E. "Remedies for Violations of the FCA," page 3.18.

B. Level of Knowledge Triggering Disclosure Obligation or Duty to Investigate

CMS regulations define an **"identified"** overpayment to mean that a hospital, other provider or supplier, "has, or should have through the exercise of reasonable diligence, determined that the person has received an overpayment and quantified the amount of the overpayment. A person should have determined that the person received an overpayment and quantified the amount of the overpayment if the person fails to exercise reasonable diligence and the person in fact received an overpayment" [42 C.F.R. Section 401.305(a)(2)]. Thus, the 60-day time period begins when either the hospital completes its reasonable diligence or on the day the hospital received credible information of a potential overpayment if it failed to conduct reasonable diligence and an overpayment was in fact received.

It is important to note that the final rule clarifies that "identification" of an overpayment requires both the determination that an overpayment was received as well as quantification of the amount of the overpayment. That quantification may be accomplished by a statistically valid sampling and extrapolation methodology. In the final rule, CMS noted that hospitals should not report and return overpayments on specific claims from a probe sample until the full overpayment is identified.

CMS stated in the preamble to the final rule that a hospital demonstrates reasonable diligence through the "timely, good faith investigation of credible information, which is at most six months from receipt of the credible information, except in extraordinary circumstances." CMS believes a total of eight months (six months for investigation and sixty days for reporting and returning) is a reasonable amount of time, absent extraordinary circumstances. CMS states that what constitutes extraordinary circumstances may include unusually complex investigations, natural disasters or a state of emergency. (These are examples, not necessarily an exhaustive list.) Thus, CMS expects hospitals to exercise reasonable diligence in determining whether an overpayment exists through proactive self-audits and other internal compliance investigations, as well as timely reactive investigations in response to credible information of a potential overpayment.

The foregoing suggests that a hospital should initiate further investigation whenever there is a reasonable suspicion of an overpayment. A reasonable suspicion is a belief, based on specific objective facts and reasonable inferences drawn from those facts in light of experience, sufficient to lead a prudent or reasonable person to suspect that an overpayment has occurred.

In the 2012 proposed regulations, CMS gave the following examples of "identified" overpayments:

1. Based on its review of billing or payment records, a hospital learns that it incorrectly coded certain services, resulting in an overpayment.
2. A hospital learns that a patient death occurred before the service date on a claim that has been submitted for payment.
3. A hospital learns that services were provided on its behalf by an unlicensed or excluded individual.

4. A hospital performs an internal audit that reveals overpayments.
5. A government agency informs a hospital that its audit discovered a potential overpayment, but the hospital fails to make a reasonable inquiry about whether the overpayment exists.
6. A hospital experiences a significant increase in Medicare revenue for no apparent reason, but fails to make a reasonable inquiry to determine whether an overpayment exists.

Note that two of CMS' examples reflect the agency's position that a hospital's failure to make a reasonable inquiry after obtaining information that gives it a reason to believe that an overpayment occurred can result in the hospital identifying an overpayment for purposes of triggering the 60-day or cost report due date deadline.

In the case of claims to government programs, using a reasonable suspicion standard is prudent because this increases the likelihood that a hospital will discover and disclose overpayments before the government learns of them — a clear benefit for the hospital, because if the government first identifies improperly paid claims, the negative consequences for the hospital may be severe. At a minimum, the government is likely to be skeptical that a hospital did not know of a significant overpayment discovered by a government audit, and the hospital runs the risk that its internal compliance and audit programs will be viewed as insufficient by virtue of their having failed to discover the billing error before an outside auditor did. A hospital's failure to take a proactive view of its disclosure obligations also is likely to negatively impact the government's assessment of whether the overpayment was the result of inadvertent billing errors versus knowing false claims.

A lawsuit by the federal government against a provider for failing to investigate credit balances is illustrative. On Aug. 4, 2015, the U.S. Attorney's Office for the Southern District of Georgia announced that Pediatric Services of America Healthcare, Pediatric Services of America, Inc., Pediatric Healthcare, Inc., Pediatric Home Nursing Services (collectively, PSA), and Portfolio Logic, LLC agreed to pay $6.88 million to resolve allegations that PSA, a provider of home nursing services to medically fragile children, knowingly:

1. Failed to disclose and return overpayments that it received from federal health care programs such as Medicare and Medicaid;
2. Submitted claims under the Georgia Pediatric Program for home nursing care without documenting the requisite monthly supervisory visits by a registered nurse; and
3. Submitted claims to federal health care programs that overstated the length of time their staff had provided services, which resulted in PSA being overpaid.

This was the first settlement under the FCA involving a health care provider's failure to investigate credit balances on its books to determine whether they resulted from overpayments made by a federal health care program.

PSA had been maintaining numerous credit balances on its books that related to claims it had submitted to various federal health care programs, some of which had been on PSA's books for several years. Additionally, PSA wrote off and absorbed credit balances that had resulted from overpayments into their revenue because they had not investigated the reason

for the credit balances before doing so. At the government's request, PSA cooperated with a joint audit of the credit balances on its books in order to identify all outstanding overpayments. As part of the settlement, PSA also agreed to enter into a corporate integrity agreement.

The settlement resolved allegations that had been filed by Yvette Odumosu and Sheila McCray, former employees of PSA, under the *qui tam* provisions of the FCA. Ms. Odumosu's lawsuit was filed in the Northern District of Georgia and was captioned *U.S. ex rel. Yvette Odumosu v. Pediatric Services of America Healthcare*, No. 1:11-CV-1007-AT and Ms. McCray's lawsuit subsequently was filed in the Southern District of Georgia and was captioned *United States ex rel. Sheila McCray, et al. v. Pediatric Services of America, Inc., Pediatric Services of America, Pediatric Healthcare, Inc., Pediatric Home Nursing Services, collectively d/b/a PSA Healthcare; and Portfolio Logic, LLC*, No. CV413-12. For a similar decision, see *Kane v. Healthfirst, Inc. et al.,* No. 1:11-cv-02325 (S.D.N.Y. 2015).

In a more recent decision, however, Judge Rosemary M. Collyer of the United States District Court for the District of Columbia called into question the extent to which an analogous report and return rule pertaining to overpayments by Medicare Part C and Part D plans unlawfully applies a negligence standard. In *UnitedHealthCare Insurance Co. v Azar*, 330 F. Supp. 3d 173 (D.D.C. 2018), the court concluded that the adoption of a negligence standard in the 2014 final rule on Medicare Part C and Part D overpayments "extends far beyond the False Claims Act and, by extension, the Affordable Care Act. Not being Congress, CMS has no legislative authority to apply more stringent standards to impose FCA consequences through regulation." The court also went on to conclude that CMS' 2014 final rule on Medicare Part C and Part D overpayments impermissibly adopted a "proactive compliance" requirement that was not set forth in the proposed rule. Although *UnitedHealthCare Insurance Co. v Azar* was appealed to the United States Court of Appeals for the District of Columbia Circuit, the appeal did not challenge either of these two holdings regarding the Part C and Part D overpayment rule's negligence standard, [*UnitedHealthCare Insurance Co. v Becerra, 16 F.4th 867 (D.C. Cir. 2021)*] Analogous arguments might be made concerning the February 2016 final report and return rule for Medicare Part A and Part B overpayments, but, at the time of this printing, there are no decisions directly addressing the analogous provisions in the February 2016 final rule.

C. Timing and Process for Overpayment Refunds

A hospital may rely on the Medicare cost report due date deadline only for overpayments resulting from the cost report reconciliation process — such as a reconciliation of interim payments to costs for cost-based providers, outlier, disproportionate share hospital, capital, graduate medical education, and new technology payments — and is subject to the 60-day deadline for identified overpayments involving separate hospital claims (using the CMS-1450 form) for inpatient services, even though such claim payments are ultimately reconciled in the cost report with the interim payments received by the hospital during each annual cost reporting period. In addition, hospitals should consider reporting and potentially refunding overpayments resulting from an error identified in interim or claims-based payments even where the error would ultimately be addressed in the cost report, such as an error in the disproportionate share hospital (DSH) add-on to interim payments, in order to avoid ambiguity as to whether the overpayment would be considered to be tied to the cost report for purposes of the 60-day rule. Where the cost report due date deadline is applicable, CMS

will require the hospital to "reconcile" any known cost report-related overpayments in its submitted cost report, subject to exceptions for overpayments resulting from:

1. Updated supplemental security income ratios used to calculate disproportionate share hospital payments, which may be refunded at the time of the final reconciliation of the cost report; and
2. Exceeding the relevant thresholds governing outlier payments. Which may be refunded when the final settlement of the cost report occurs.

In terms of methodology, CMS regulations permit hospitals to use an applicable claims adjustment, credit balance, self-reported refund, or other reporting process set forth by the applicable Medicare contractor to report an overpayment, unless the hospital makes a disclosure under the OIG Self-Disclosure Protocol or the CMS Voluntary Self-Referral Disclosure Protocol that results in a settlement agreement. *(See IV. "OIG Self-Disclosure Protocol," page 15.10.)* If the amount of the overpayment is calculated using a statistical sampling methodology, the hospital must describe the statistically valid sampling and extrapolation methodology when reporting and returning the overpayment.

Under the federal civil FCA, a hospital can decrease its liability from treble to double damages if, among other things, the hospital provides the appropriate government officials with all information known to the hospital about the false claim(s) within 30 days after the date on which the hospital first obtained the information. *(See chapter 3, "Federal and State False Claims Acts.")* This 30-day deadline under the FCA indicates that the government expects cooperative hospitals to disclose information about potential false claims within a month of discovery. A hospital's best practice should be to rely only on the 60-day deadline for reporting Medicare or Medi-Cal overpayments in cases where there is no reason to be believe that false claims liability exists.

If the hospital believes that the overpayment is the result of an inadvertent or isolated billing error, then an initial disclosure to the government may not be necessary so long as the hospital investigates, reports, and refunds the overpayment in a reasonable period of time, which, in the case of Medicare and Medicaid overpayments, means the later of the applicable 60-day or cost report due date deadline after the overpayment is identified and quantified.

In the case of private insurers, the above federal rules do not apply. To satisfy an obligation that it may have under the California criminal disclosure statute, a hospital is not required to provide a detailed disclosure of any overpayment, but may simply return the overpayment to the insurer in accordance with the insurer's overpayment procedures and with a clear, but brief, explanation of the reason for the overpayments.

D. How Far Back Must Disclosure Go?

When a hospital discovers that an overpayment relating to a particular claim or claims has occurred, the inevitable question arises of how far back in time the hospital must investigate to determine the extent to which the cause of that overpayment resulted in other improper claims being submitted and paid by federal health care programs.

The hospital may not arbitrarily limit its disclosure of any overpayment — whether by time or type of claimed service, supply, or other cost — if the objective facts regarding the cause of

the overpayment would lead a reasonable and prudent person to conclude that the improper claims were being submitted in other time periods or the cause of the overpayment also resulted in similar improper claims for different types of services, supplies, or other costs. However, some outside limits are set by law.

Overpayments

Medicare

Prior to the effective date of the final regulations implementing the 60-day rule (March 13, 2016), in the case of simple Medicare billing errors where a hospital has not committed "fraud or similar fault," a hospital arguably had no duty to identify incorrect claims that were paid more than four years ago or to identify incorrect cost reports that have Notices of Program Reimbursement that are more than three years old, because these are the current regulatory time limitations on the reopening by CMS of Medicare claims and cost reports.

However, effective March 13, 2016, a hospital or other provider must look back six years at least with respect to overpayments (whether or not arising from fraud) resulting from claims as opposed to cost report matters. Accordingly, CMS has revised the claims reopening rules to allow Medicare contractors to reopen claims upon a provider's request to accommodate the six-year look-back period [42 C.F.R. Section 405.980(c)(4)]. Curiously, although it appears from the commentary that CMS intended for the six-year period to apply to cost report matters as well, CMS did not revise the cost report reopening provisions. Accordingly, there remains an open question whether a hospital has an obligation to report and repay with respect to a Medicare cost report for which an overpayment has been received within six years of the identification of the overpayment which is otherwise closed because the Notice of Program Reimbursement (NPR) was received more than three years prior to the identification of the overpayment.

The six-year "look-back" period adopted by CMS is also longer than the four-year look-back period previously applied by CMS for Physician Self-Referral Law (Stark law)self-disclosures under the Self-Referral Disclosure Protocol (SRDP). CMS continued to apply the four-year look-back period for self-disclosures that had been resolved through the SRDP or were pending with CMS under the SRDP as of the effective date of the final rule (March 14, 2016). However, CMS has indicated that providers and suppliers reporting overpayments under the SRDP on or after March 14, 2016, are now subject to the 6-year lookback period specified in the final overpayment rule.

Medi-Cal

In the case of Medi-Cal billing errors, the time limitations on the hospital's disclosure obligation are less clear. Again, state limitations on the recovery of overpayments arguably also limit a hospital's disclosure and refund obligations. These limits depend on the nature of the proceeding through which repayment of such overpayments is sought. The time limitation may range from an equitable "laches" defense of unreasonable delay (in the case of administrative recoupment actions) to three years (for actions based upon liability created by statute or for relief on the grounds of mistake or known fraud [Code of Civil Procedure Section 338]) to four years (for actions on an open book account or a written provider agreement [Code of Civil Procedure Section 337]). In addition, a hospital may be able to claim that a three-year limitations period applies because cost reports and other payment data are deemed true and correct if not audited within three years [Welfare and Institutions

Code Section 14170].

Others

With respect to private insurers, the hospital's disclosure obligation likely extends to claims by noncontracted hospitals that are no more than three years old based on the limitations period for known fraud [Code of Civil Procedure Section 338], or potentially four years for claims submitted by hospitals under a written provider agreement [Code of Civil Procedure Section 337], although certain limitation periods may not begin to run until the payer knew or should have known of the overpayment. In addition, the provision of the Knox-Keene Act requiring health plans to seek overpayment refunds within 365 days of the date of payment [28 C.C.R. Section 1300.71(b)(5)] and a similar provision of the Insurance Code may further limit the look-back period, particularly where such provisions are included in the provider agreement. Moreover, the provider agreement itself may further limit overpayment obligations to a managed care organization by, for example, providing that claims payments (including overpayments and underpayments) become final after a certain amount of time.

False Claim

With respect to any Medicare or Medi-Cal claims that might be viewed by the government as arguably false, the federal FCA statute of limitations (discussed in greater detail in chapter 3, "Federal and State False Claims Acts") can reach back as far as 10 years. Depending on the specific facts, a hospital that suspects false claims may wish to investigate for the full 10 years. *(For more information, see "The Statute of Limitations on FCA Actions," page 3.11.)* However, this is not part of a hospital's obligation to report and refund identified overpayments.

Investigation

Regardless of how far a hospital must look back, depending on the type of claimed services, supplies or other costs, the hospital may be able to conduct a reasonable investigation for the purposes of disclosure by conducting a statistically-reliable probe sample of older claims to determine whether the same billing errors or false claims actually occurred. In this manner, a hospital can avoid the expense of a full scope audit unless the probe sample indicates that such an audit is necessary.

Compliance Tip: Avoiding Opinions in Disclosures

Disclosures of overpayments to the federal government should be comprehensive, objective and factual; including only those facts the government needs to determine the nature, extent, cause, and amount of the overpayment. Hospitals should avoid including opinions in an overpayment disclosure, especially the following:

- Do NOT include the hospital's opinion about whether the claims violated the FCA or any other law (except to the extent required by the Self-Referral Disclosure Protocol discussed on page);
- Do NOT include the hospital's view about the credibility of any witness who was interviewed as part of its internal investigation; and
- Do NOT offer the hospital's position about the appropriate FCA damages multiplier or per-claim penalties.

Hospitals make their best argument for minimizing the negative consequences of any overpayment by providing a factual, complete investigation and disclosure of the nature, extent, and cause of the overpayment.

IV. OIG SELF-DISCLOSURE PROTOCOL

The OIG's Self-Disclosure Protocol provides hospitals with a detailed road map for how they are to disclose various types of overpayments and other irregularities in their claims to federal health care programs, including Medicare and Medi-Cal. It should be kept in mind that an OIG settlement resolves only the civil claims for which the OIG has authority. The OIG does not settle potential criminal or false claims exposure, although, as a practical matter, it would be very unusual for any such other sanctions to be imposed if there has been an OIG settlement. While this protocol was originally developed to provide a vehicle for completely voluntary disclosures, it would be incorrect to continue to think of these disclosures as being a voluntary process. This is because the disclosure of overpayments is now mandatory as a result of the previously discussed report and refund rules under the ACA. While providers are to make disclosure and repayment to the relevant Medicare contractor rather than to the OIG if the facts surrounding the overpayment are not suggestive of fraud, the OIG's protocol provides the only mechanism outside of various forms of litigation for resolving overpayments that may be tainted by fraud. In addition, the OIG's disclosure protocol was developed before significant changes in case law and statutory law clarified that billings resulting from services that are induced by kickbacks are actionable as false claims. This change in the law strongly suggests that such billings are also overpayments falling within the scope of the ACA report and refund rules, thereby potentially converting another category of what were formerly voluntary disclosures into mandatory disclosures. The OIG maintains a website for its disclosure protocol at http://oig.hhs.gov/compliance/self-disclosure-info/protocol.asp and some related materials are posted there as well.

A. The Original 1998 Protocol

The OIG initially announced its Provider Self-Disclosure Protocol in October 1998 [63 Fed. Reg. 58399 (Oct. 30, 1998)]. A copy of the 1998 publication may be found at https://www.oig.hhs.gov/compliance/self-disclosure-info/protocol.asp. This document provided detailed information about the OIG's thinking regarding its Self-Disclosure Protocol, the steps that hospitals must take to avail themselves of the benefits of self-disclosure, the information that hospitals must provide to the OIG, and how the OIG may respond.

After the initial protocol was published in 1998, the OIG published four Open Letters clarifying as well as modifying the Self-Disclosure Protocol. These letters, dated Nov. 20, 2001, April 24, 2006, April 15, 2008, and March 24, 2009, may be found at https://oig.hhs.gov/compliance/open-letters/index.asp.

While a disclosure that is made pursuant to the OIG's Self-Disclosure Protocol does not protect a hospital from civil FCA actions or criminal health care fraud prosecutions, the OIG has emphasized that self-reporting of wrongdoing can be a mitigating factor in its recommendations to prosecuting agencies and also provides numerous other benefits.

Self-reporting therefore offers providers the opportunity to minimize the potential cost and disruption of a full-scale audit and investigation, to negotiate a fair monetary settlement,

and to avoid an OIG-permissive exclusion preventing the entity from doing business with the federal health care programs, such as Medicare and Medi-Cal. Because a provider's disclosure can involve a very wide range of misconduct, the OIG will not make any commitments as to how a particular disclosure will be resolved or the specific benefit that will ensure to the disclosing entity. Nevertheless, as a practical matter, it appears that the government would choose to make conduct that has been affirmatively disclosed to it by a provider the subject of civil litigation or its full arsenal of penalties in only very unusual circumstances.

In the Open Letter dated March 24, 2009, the OIG informed providers that it would no longer accept them into the Self-Disclosure Protocol based solely on a violation of the Stark self-referral law. However, the OIG confirmed that it would continue accepting providers based on a "colorable" violation of the anti-kickback statute — whether or not a Stark violation was also involved — but would require a minimum settlement of $50,000 for any disclosure based on a kickback. Therefore, matters involving only a violation of the Stark law may not be disclosed to the OIG. However, the OIG's narrowing of the protocol's scope does not in any manner mitigate a hospital's legal duties that may arise under the federal and state FCAs, the Federal Disclosure Statute, the 60-day rule and the Stark law itself to disclose overpayments of claims resulting from Stark violations. Rather, matters involving only a violation of the Stark law must be disclosed to CMS under its Self-Referral Disclosure Protocol (which is discussed in VI. "Determining Which Self-Disclosure Protocol to Use," page 15.22). *(See also chapter 6, "Physician Self-Referral Laws" and chapter 7, "Federal and State Anti-Kickback Laws" for more information.)*

B. The 2013 OIG Disclosure Protocol Update

After 15 years (and the resolution of more than 800 disclosures, with recoveries to the federal government totaling more than $280 million), the OIG released a substantially updated version of its Self-Disclosure Protocol on April 17, 2013. While the scope of conduct to be addressed through the protocol did not materially change, this update provided disclosing parties with a much more detailed understanding of timeframes under the protocol and of the requirements that must be satisfied for a disclosure to be considered complete. In addition, the update was intended generally to streamline and expedite the disclosure process. Importantly, although the OIG cautioned that a higher payment may be required based on particular facts, settlement based on an amount determined by multiplying the "single damages" (i.e., the amount of a single overpayment or, in some cases, the excessive remuneration paid to a physician) by 1.5 is indicated as being appropriate in most instances (at least where DOJ does not become involved). The 2013 protocols also indicated that the OIG will generally settle violations of the anti-kickback statute or the Stark law based upon a multiplier of the remuneration conferred by the referral recipient upon the source of the referral.

The OIG observed that it receives many submissions disclosing the employment of, or contracting with, individuals who appear on OIG's List of Excluded Individuals and Entities. The OIG therefore provided very specific guidance (not further detailed herein) on the requirements for a complete disclosure of this type of misconduct and specified the method for calculating damages in such cases.

The 2013 protocol also provided guidance as to how disclosed matters were to be resolved. In addition to adopting a $50,000 minimum settlement amount for violations involving

the anti-kickback statute, the OIG used the 2013d protocol to set a minimum settlement amount of $10,000 for other conduct. In addition, OIG made it clear that it may coordinate with CMS and/or DOJ in resolving disclosed matters. Importantly, the OIG stated that DOJ will be involved in a disclosure if a disclosing party seeks a release under the False Claims Act or if DOJ otherwise chooses to become involved in a settlement. In such instances, the protocol stated that "the matter will be resolved as DOJ determines is appropriate consistent with its resolution of FCA cases, which could include a calculation of damages resulting from violations of the anti-kickback statute based on paid claims." The protocol thus outlined an important caveat to the OIG's position, that, if it is the sole agency representing the government in a settlement, it will settle the matter under the OIG's applicable CMP authority (implicitly providing no settlement of potential liability under the FCA) on the basis of a multiple of the remuneration that was improperly paid to the physician. The OIG's further statement that DOJ determines the approach in cases in which it is involved clearly signaled that DOJ may function as a wild card in the disclosure process.

The protocol also explained that OIG suspends a provider's obligation to report and return identified overpayments within 60 days until such time as a settlement agreement is entered into, or the provider withdraws or is suspended from the OIG's protocol.

There are potential disadvantages to a provider that makes a disclosure under the 2013 OIG's protocol — for example, the potential waiver of Fifth Amendment privileges (where otherwise applicable) as well as any applicable statute of limitations, laches or similar defenses. However, the 2013 protocol left unclear how providers may otherwise address the fact that the ACA has in many instances effectively made disclosure to the OIG mandatory.

C. The 2021 OIG Health Care Fraud Self-Disclosure Protocol

After resolving 2,200 disclosures and recovering over $870 million, on November 8, 2021, the OIG issued an amended self-disclosure protocol, renaming the program the "OIG's Health Care Fraud Self-Disclosure Protocol." A copy of this 2021 protocol may be found at https://oig.hhs.gov/compliance/self-disclosure-info/protocol.asp. For an explanatory video on this OIG self-disclosure protocol, please see www.youtube.com/watch?v=QKUOzbV1zSU#t=142.

The most significant amendment included in the 2021 protocol is that now, for kickback-related submissions, OIG will require a $100,000 minimum settlement amount (increased from the 2013 protocol's $50,000) to resolve the matter. The settlement amounts to resolve non-kickback-related matters were also increased from a $10,000 minimum to a $20,000 minimum.

The updated protocol also clarified that:

1. Any "individual, trust or estate, partnership, corporation, professional association or corporation, or other entity, public or private" as outlined in 42 C.F.R. section 1003.110 could engage in the self-disclosure protocol.
2. While persons subject to a Corporate Integrity Agreement ("CIAs") may use the self-disclosure protocol, the hospital has a mandatory duty to reference the CIA in the disclosure, as well as a mandatory duty to send a copy of the disclosure to the disclosing party's OIG monitor.
3. The protocol should not be used for conduct that would more appropriately be disclosed through the OIG's Grant Self-Disclosure Program or the Contractor

Self-Disclosure Program. (More Information on those programs may be found at available at https://oig.hhs.gov/compliance/self-disclosure-info/grant.asp and https://oig.hhs.gov/compliance/self-disclosure-info/contractor.asp respectively.)

4. In some instances, the DOJ may choose to actively participate In the settlement. In these circumstances, the disclosing parties may also request a release under the FCA. To the extent any criminal activity Is disclosed, such matters will be referred out to the DOJ for resolution.

D. The Basic Elements of the OIG Health Care Fraud Self-Disclosure Protocol

Under the OIG's Health Care Fraud Self-Disclosure Protocol, the disclosing party is expected to conduct an internal investigation and report its findings to OIG in its submission. If the disclosing party is unable to complete its internal investigation before sending its submission, the disclosing party must certify in its submission that it will complete the internal investigation within 90 days of the date of its initial submission. A narrative submission must be made which includes the following elements:

1. The name, address, type of health care provider, provider identification number(s), and tax identification number(s) of the disclosing party and the government payors (including Medicare contractors) to which the disclosing party submits claims or a statement that the disclosing party does not submit claims.
2. If the disclosing party is an entity that is owned or controlled by or is otherwise part of a system or network, an organizational chart, a description or diagram describing the pertinent relationships; the names and addresses of any related entities; and any affected corporate divisions, departments, or branches.
3. The name, street address, phone number and email address of the disclosing party's designated representative for purposes of the voluntary disclosure.
4. A concise statement of all details relevant to the conduct disclosed, including, at minimum, the types of claims, transactions, or other conduct giving rise to the matter; the period during which the conduct occurred; and the names of entities and individuals believed to be implicated, including an explanation of their roles in the matter.
5. A statement of the federal criminal, civil, or administrative laws that are potentially violated by the disclosed conduct.
6. The federal health care programs affected by the disclosed conduct.
7. An estimate of the damages, as described in the applicable section below, to each federal health care program relevant to the disclosed conduct, or a certification that the estimate will be completed and submitted to OIG within 90 days of the date of submission. This estimate should identify the total estimated damages amount for each affected federal health care program and the sum of estimated damages for all affected federal health care programs. When a disclosing party can determine the amount of actual damages to federal health care programs, the actual damages amount must be provided instead of an estimate.
8. A description of the disclosing party's corrective action upon discovery of the conduct.

9. A statement of whether the disclosing party has knowledge that the matter is under current inquiry by a government agency or contractor. If the disclosing party knows of a pending inquiry, it must identify any involved government entity and its individual representatives. The disclosing party must also disclose whether it is under investigation or other inquiry for any other matters relating to a federal health care program and provide similar information relating to those other matters.
10. The name of an individual authorized to enter into a settlement agreement on behalf of the disclosing party.
11. A certification by the disclosing party, or, in the case of an entity, an authorized representative on behalf of the disclosing party, stating that to the best of the individual's knowledge, the submission contains truthful information and is based on a good faith effort to bring the matter to the government's attention for the purpose of resolving potential liability to the government.

For those wishing to use it, an online disclosure portal is available at https://forms.oig.hhs.gov/forms/Self-Disc-Form-Protocol.aspx.

E. Requirements for Conduct Involving False Billing

When a disclosure involves the submission of improper claims to federal health care programs, the disclosing party must conduct a review to estimate the improper amount paid by the federal health care programs and prepare a report of its findings. The disclosing party's estimation of damages must consist of a review of either:

1. All the claims affected by the disclosed matter; or
2. A statistically valid random sample of the claims that can be projected to the population of claims affected by the matter.

A disclosing party may not extend the time to resubmit claims to federal health care programs through the protocol; therefore, the damages estimation must not include a reduction, or "netting," for any underpayments discovered in the review.

When using a sample to estimate damages, the disclosing party must use a sample of at least 100 items and use the mean point estimate to calculate damages. If a probe sample was used, those claims may be included in the 100-item sample if statistically appropriate. To avoid unreasonably large sample sizes, the protocol does not require a minimum precision level for the review of claims. As a result, the disclosing party may select an appropriate sample size to estimate damages as long as the sample size is at least 100 items. As a general rule, smaller sample sizes (closer to 100) will suffice where the population has a high level of homogeneity, and larger sample sizes will be necessary where the population contains a more diverse mixture of claim types. The disclosing party should keep in mind that a careful and complete definition of the population will assist in making accurate findings.

The disclosing party's report must include, at a minimum, the following information:

1. A statement clearly articulating the objective of the review.
2. A description of the group of claims about which information is needed, an explanation of the methodology used to develop the population, and the basis for this determination.

3. A full description of the source of the data reviewed and the information upon which the review was based, including the sources of payment data, and the documents that were relied upon.

4. The names and titles of the individuals who conducted the review. The review should be conducted by qualified individuals, e.g., statisticians, accountants, auditors, consultants and medical reviewers, and the review report should describe their qualifications.

5. The review report should identify the characteristics used for testing each item. For example, in a review designed to estimate the value of overpayments due to duplicate payments, the characteristics used are those that must exist for an item to be a duplicate. The amount of the duplicate payment is the measurement of the overpayment. The report must also explain the method for determining whether an item entirely or partially meets the criterion for having the characteristics measured.

If the financial review was based upon a sample, the review report must also include a description of the sampling plan that was followed which includes detailed information as specified by the protocol.

F. Requirements for Conduct Involving the Anti-Kickback Statute and Physician Self-Referral Law

Another large category of submissions relates to potential violations of the anti-kickback statute (including conduct that violates both the anti-kickback statute and the Stark law). With respect to such violations, any disclosure must clearly acknowledge that in the disclosing party's reasonable assessment of the information available at the time of the disclosure, the subject arrangement(s) constitute potential violations of the anti-kickback statute and, if applicable, the Stark law. The OIG will not accept any disclosing party into its protocol that fails to acknowledge clearly that the disclosed arrangement constitutes a potential violation of the anti-kickback statute and, if applicable, the Stark law.

As with other self-disclosed conduct, OIG needs to understand the precise nature of the disclosed conduct that creates potential anti-kickback statute liability or both anti-kickback statute and Stark law liability. Therefore, the disclosing party must include in its narrative submission (not by reference to attachments or other documents) a concise statement of all details directly relevant to the disclosed conduct and a specific analysis of why each disclosed arrangement potentially violates the anti-kickback statute and Stark laws. The description should include the participants' identities, their relationship to one another to the extent that the relationship affects their potential liability (e.g., hospital-landlord, referring physician-tenant); the payment arrangements; and the dates during which each suspect arrangement occurred. Further, the disclosure should explain the relevant context and the features of the arrangement that raise potential anti-kickback statute or both anti-kickback statute and Stark law liability. Below are examples of the type of information OIG finds helpful in assessing and resolving disclosed conduct involving potential anti-kickback statute and, if applicable, Stark law violations:

1. How fair market value was determined and why it is now in question.

2. Why required payments from referral sources, under leases or other contracts, were not timely made or collected or did not conform to the negotiated agreement and how long such lapses existed.

3. Why the arrangement was arguably not commercially reasonable (e.g., lacked a reasonable business purpose).
4. Whether payments were made for services not performed or documented and, if so, why.
5. Whether referring physicians received payments from designated health service entities that varied with, or took into account, the volume or value of referrals without complying with a Stark law exception.

Finally, the submission must describe the corrective action taken to remedy the suspect arrangement(s), as well as any safeguards implemented by the disclosing party to prevent the conduct from recurring.

With respect to calculating damages, the OIG observed that anti-kickback statute compliance is a condition of payment of the federal health care programs. Under Section 1128B(g) of the Act, claims that include items or services resulting from an anti-kickback statute violation constitute false or fraudulent claims for purposes of the FCA [42 U.S.C. Section 1320a-7b(g)]. Stark law compliance is also a condition of payment under Section 1877 of the Act [42 U.S.C. Section 1395]. Thus, a disclosing party must submit an estimate of the amount paid by federal health care programs for the items or services associated with potential violations of the anti-kickback statute and, if applicable, the Stark law. A disclosing party may use the sampling methodology discussed above to calculate the estimate. Alternatively, a disclosing party may identify another reliable methodology to calculate this claims-based estimate and explain that methodology in its submission.

A disclosing party must include the total amount of remuneration involved in each arrangement without regard to whether the disclosing party believes a portion of the total remuneration was offered, paid, solicited, or received for a lawful purpose. A disclosing party may also explain what it believes is the value of the financial benefit conferred under the arrangement and whether it believes any portion of the total remuneration should not be considered by OIG in determining an appropriate settlement of OIG's CMP authorities. Given the various legal authorities at issue, OIG has broad discretion in determining an appropriate resolution in these cases. For purposes of resolving disclosed matters, the OIG observed that it will generally exercise this discretion by compromising its CMP authorities for an amount based upon a multiplier of the remuneration conferred by the referral recipient to the individual or entity making the referral. While this is the OIG's general approach, the OIG's determination of the appropriate settlement amount depends on the facts and circumstances of each matter. It will generally use this remuneration-based methodology as an incentive to encourage disclosure of potential anti-kickback statute violations.

G. Financial Inability to Pay

The OIG recognizes that in some situations, disclosing parties may be unable to pay otherwise appropriate settlement amounts. In preparing the disclosure, disclosing parties should determine whether an inability to pay may be an issue. If a disclosing party asserts that it cannot pay a proposed settlement amount (i.e., damages plus a multiplier or penalty amount), OIG will require extensive financial information, including audited financial statements, tax returns, and asset records. Disclosing parties must certify to the truthfulness and completeness of the financial disclosure. In addition to submitting the financial forms, disclosing parties should include an assessment of how much they believe they can afford

to pay. Disclosing parties should raise potential inability-to-pay issues at the earliest possible time. Doing so enables OIG to promptly send the disclosing party the financial disclosure forms and consider that information in determining an appropriate resolution.

H. Overpayment Reconciliation

If, prior to resolving a disclosed matter, a disclosing party refunds an overpayment related to the same conduct disclosed under the disclosure protocol, OIG will credit the amount paid toward the ultimate settlement amount. However, OIG is not bound by any amount that is repaid outside the disclosure process. OIG may question the methodology of the overpayment calculation, particularly if the disclosing party estimated the overpayment amount by some method other than as described in the disclosure protocol. If OIG disputes the methodology used to calculate the overpayment, OIG may require the disclosing party to redo the review or conduct an independent damages review, which may result in a damages or overpayment amount that is higher than the disclosing party's estimate. Moreover, even if OIG agrees with the methodology used to calculate the overpayment, the disclosing party should expect to pay a multiplier on the damages under the disclosure protocol.

V. CMS SELF-REFERRAL DISCLOSURE PROTOCOL

In 2010, the Patient Protection and Affordable Care Act (ACA) of 2010 directed CMS to establish a protocol to enable hospitals and other providers to disclose an actual or potential violation of the Stark law. ACA also authorized CMS to reduce the overpayment resulting from a disclosed Stark violation to less than the amount of all paid claims resulting from the violation. CMS released its Stark Self-Referral Disclosure Protocol on Sept. 23, 2010. On March 28, 2017, in an effort to "reduce the burden on providers and suppliers submitting disclosures to the Self-Referral Disclosure Protocol and facilitate CMS' review of the disclosures," CMS released a revised, standardized Self-Referral Disclosure Protocol. Beginning June 1, 2017, providers must use the specific forms provided by CMS for all disclosures. These standardized forms and instructions are available at https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/CMS-Voluntary-Self-Referral-Disclosure-Protocol-Original.pdf. *(See chapter 6 for a complete discussion of state and federal physician self-referral laws, including the Stark law.)* A listing of the settlements that have been reached under the protocol can be found at https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfreferral/Self-referral-Disclosure-Protocol-Settlements.html.

CMS' Self-Referral Disclosure Protocol provides detailed instructions to hospitals for submitting a disclosure. Like the OIG's protocol, CMS' protocol originally was intended to provide a vehicle for voluntary disclosures, but the disclosures that it addresses are now typically mandatory as a result of the previously discussed mandatory report and repay rules under the ACA (although, again, there may be discretion as to the exact procedure to be used for the disclosure). The details of the Stark Self-Referral Disclosure protocol are explored below.

A. Eligible Parties and Matters

All Medicare hospitals may use the Self-Referral Disclosure Protocol to disclose and resolve actual or potential violations of the Stark law. A hospital may be accepted into the protocol even if it is already the subject of a government inquiry, whether an investigation, audit, or

routine oversight activity, so long as its disclosure is made in good faith and does not attempt to circumvent an ongoing inquiry.

A hospital cannot use the Self-Referral Disclosure Protocol to obtain a CMS determination as to whether a Stark violation occurred and will not be accepted into the protocol for conduct that is concurrently the subject of a request for an advisory opinion under the Stark law. Instead, the hospital should use the protocol only to facilitate the resolution of conduct that the hospital reasonably believes is an actual or potential Stark violation that has resulted in an overpayment.

The Self-Referral Disclosure Protocol reminds hospitals that conduct creating potential liability under the federal anti-kickback statute, whether or not a Stark violation was also involved, should be disclosed through the OIG's self-disclosure protocol. A hospital should disclose an overpayment under either the OIG or CMS protocol, but not under both.

B. Basic Elements

Under CMS' revised Self-Referral Disclosure Protocol, a hospital's self-disclosure must now include the following revised forms:

1. Disclosure Form;
2. Physician Information Form(s);[1]
3. Financial Analysis Worksheet; and
4. Certification.

A hospital may also submit an optional cover letter, including information that may be relevant to CMS' evaluation of the disclosure.

The Self-Referral Disclosure Protocol requires a hospital's disclosure to include the following (items 9 through 12 were added in the 2017 revisions to the Self-Referral Disclosure Protocol):

1. A description of the nature of the matter being disclosed, including the type of financial relationship(s), the parties involved, the specific time periods the hospital may have been out of compliance (and, if applicable, the dates (or a range of dates) when the conduct was cured), the type of Medicare claims at issue, the type of transaction or other conduct giving rise to the matter, and the names of entities and individuals believed to be implicated and an explanation of their roles in the matter;
2. A statement indicating why the hospital believes a Stark violation may have occurred, including a complete legal analysis of the application of the Stark self-referral law to the conduct and any physician self-referral exception that applies to the conduct and/or that the hospital attempted to use, including an explanation of which elements of the applicable exception were met and which were not and a description of the potential causes of the incident or practice, e.g., intentional conduct, lack of internal controls, circumvention of corporate procedures or government regulations;
3. A description of the circumstances under which the hospital discovered the disclosed matter, and the measures the hospital took upon discovery to address it and prevent future abuses;

1 One for each physician included in the disclosure who made referrals in violation of the Stark law.

4. A statement indicating whether the hospital has a history of "similar conduct," or was the subject of any prior criminal, civil, and regulatory enforcement actions (including payment suspensions);

5. A description of the existence and adequacy of the hospital's pre-existing compliance program, the hospital's efforts to prevent a recurrence of the incident or practice in the affected department and in any related health care entities — including, for example, implementation of new accounting or internal control procedures, increased internal audit efforts, increased supervision by higher management or through training — and the hospital's actions to restructure the arrangement or noncompliant relationship;

6. A description of any appropriate notices the hospital provided to other government agencies (e.g., the Securities and Exchange Commission or Internal Revenue Service) in connection with the disclosed matter;

7. An indication of whether the hospital has knowledge that the matter is under current inquiry by a government agency or contractor and, if it does have knowledge of a pending inquiry, the identity of the government entity or individual representatives involved; and

8. If the hospital is under investigation or other inquiry for any other matters relating to a federal health care program (including matters it disclosed to other government entities), the identity of the government entity or individual representatives involved.

9. A report of the pervasiveness of noncompliance, which, for purposes of the disclosure, means how common or frequent the disclosed noncompliance was in comparison with similar financial relationships between the disclosing party and physicians;

10. The date range of the noncompliance and the exact date of discovery, described in the form as the date the party determined that it received an overpayment because it failed to comply with the physician self-referral law;

11. For each physician included in the disclosure, a separate Physician Information Form providing details of the noncompliant financial relationship between the physician and the disclosing party; and

12. For each noncompliant financial relationship, either (a) a certification that the financial relationship was noncompliant (or that the services failed to satisfy an applicable exception), or (b) a statement that, because the hospital cannot confirm that the financial relationship complied with the physician self-referral law, it is certifying noncompliance with the law.

Finally, the hospital must also submit identification information and specified organizational information, as well as a signed certification from the CEO, CFO, or other authorized representative.

C. Financial Analysis and Report

As part of its self-disclosure, the hospital must also conduct a financial analysis confirming that it conducted a full examination of the disclosed conduct. The revised Self-Referral Disclosure Protocol now provides a specific Excel format financial analysis report worksheet for hospitals to use. The worksheet must include:

1. For each physician included in the disclosure, the physician's name, NPI number, and the date that the overpayment associated with the physician was identified;
2. The total overpayment amount arising from each physician's prohibited referrals, itemized by year, based upon the entire time period during which the hospital may not have been in compliance with the Stark law; and
3. A description of the methodology used to determine the overpayment amount, including whether estimates were used, and, if so, how they were calculated.

D. CMS Processing of Disclosure

After reviewing and verifying the information in a hospital's disclosure submission, CMS will send a letter either accepting or rejecting the hospital's entry into the Self-Referral Disclosure Protocol. CMS' processing and resolution of the hospital's self-disclosure includes the following:

1. CMS will review the circumstances surrounding the matter disclosed to determine an appropriate resolution, but is not bound by any conclusions made by the hospital under this protocol and is not obligated to resolve the matter in any particular manner;
2. To facilitate its review, CMS must have access to all financial statements, notes, disclosures, and other supporting documents, "without the assertion of privileges or limitations on the information produced," but with the understanding that CMS will not normally request production of written communications subject to the attorney-client privilege. CMS will discuss with the hospital's attorney ways for CMS to obtain information covered by the work product doctrine that it deems "critical to resolving the disclosure" without the hospital waiving "the protections provided by an appropriately asserted claim of privilege";
3. CMS may request additional information from the hospital needed for its review, including financial statements, income tax returns, and other documents. CMS will give the hospital at least 30 days to furnish the requested information; and
4. During its review, if CMS discovers other hospital overpayments or violations outside the scope of the hospital's self-disclosure, CMS may treat them as matters outside the protocol.

Upon review of the hospital's disclosure submission, CMS will also coordinate with the OIG and DOJ and, if appropriate, may use the hospital's submission to refer the hospital to these law enforcement agencies for further action under other civil and/or criminal laws, including the False Claims Act, CMP authorities, and anti-kickback statute. Accordingly, a hospital should carefully consult with its attorney about the decision to apply to enroll in CMS' Self-Referral Disclosure Protocol.

E. CMS Criteria for Settlement

In deciding whether to reduce the overpayment below the amount of all paid claims resulting from the disclosed Stark violation, CMS may consider the following factors:

1. The nature and extent of the improper or illegal practice;
2. The timeliness of the self-disclosure; and
3. The cooperation in providing additional information related to the disclosure.

Although CMS may consider these factors in determining whether reduction in an overpayment is appropriate, it is not required to reduce any amounts due. Instead, CMS will make an individual determination as to whether a reduction is appropriate based on the particular facts and circumstances of each disclosed actual or potential Stark violation. The protocol provides no real guidance about whether CMS will in fact reduce overpayments resulting from what have been historically characterized by the OIG as technical Stark violations, such as unsigned or expired hospital-physician agreements. The protocol's ultimate utility for hospitals will therefore depend on how CMS applies the protocol to specific disclosures.

It is therefore helpful that CMS discloses summaries of protocol settlements, including information about the violation, the settlement amount, and the type of disclosing provider. CMS' settlement descriptions have been too general regarding the nature of the violation to allow for meaningful analysis of how the agency is applying the protocol to different factual scenarios. Anecdotally, however, it appears that many of the matters that have been disclosed have been viewed by CMS to have involved only technical or other minor noncompliance with the Stark law, and that CMS has been willing to settle these minor types of matters for only a small fraction of the single damages amounts that would exist as exposure under the Stark law. CMS' practice has thus somewhat alleviated the concerns of practitioners who had felt that their matters might be disposed of more favorably through disclosures to the OIG.

F. Consequences of Self-Disclosure

Once a hospital is accepted into CMS' Self-Referral Disclosure Protocol, no payment relating to the disclosed Stark violation may be made to Medicare or its contractors without CMS' prior consent. If CMS consents to a payment, the hospital will be required to acknowledge in writing that CMS' acceptance of the payment:

1. Does not constitute its agreement as to the amount of applicable loss resulting from the disclosed Stark violation;
2. Does not relieve the hospital of any criminal, civil, or civil monetary penalty liability; and
3. Does not provide a defense to any further administrative, civil, or criminal actions against the hospital.

However, pending resolution of the hospital's self-disclosure, the Self-Referral Disclosure Protocol encourages the hospital to place any overpayment owed "in an interest-bearing escrow account to ensure adequate resources have been set aside to repay amounts owed."

The hospital's receipt of a CMS email confirmation that its protocol disclosure of an overpayment has been received suspends the hospital's regulatory obligation to report and refund an overpayment within 60 days of its identification until a settlement agreement is executed, or the hospital withdraws or is removed from the protocol. As drafted, the protocol does not mention the alternative cost report due deadline for overpayments subject to the cost reporting process, and therefore facially would not protect a hospital that discloses an overpayment from a Stark violation more than 60 days after identification and quantification, but before the due date of the applicable cost report.

A hospital that resolves a Stark violation under the Self-Referral Disclosure Protocol through a settlement agreement has no appeal rights for claims relating to the disclosed conduct.

However, if the hospital is not accepted into, or withdraws or is removed from, the protocol, the hospital may appeal any CMS overpayment demand letter in accordance with applicable regulations, but agrees that CMS' reopening rules apply from the date of its protocol submission [42 C.F.R. Sections 405.980-405.986]. As a practical matter, this agreement may require that a provider consent to reopen claims that would otherwise not be subject to reopening.

Finally, the Self-Referral Disclosure Protocol reminds hospitals that any amounts collected from patients that were billed in violation of the Stark law — including deductible, copayment or coinsurance amounts that have been paid (or that secondary insurers have paid on their behalf) — must be timely refunded to such patients, but does not indicate whether patient refunds can be reduced if CMS determines that a reduction in the claims overpayment amount to be paid by the hospital is appropriate. A hospital should therefore consult with its attorney about the handling of patients' funds as part of the protocol disclosure process because such patient refunds can materially increase the hospital's overall liability for the Stark violation and create liability under the CMP law if not timely made.

G. Hospitals with CIAs or CCAs

Hospitals that have corporate integrity agreements (CIAs) or certification of compliance agreements (CCAs) with the OIG should also comply with any disclosure or reportable event requirements under such agreements. A reportable event solely related to a Stark issue should be disclosed to CMS using the requirements set forth in the Self-Referral Disclosure Protocol with a copy to the hospital's OIG monitor.

H. Relationship to Other Federal Authorities

CMS will coordinate with the OIG and the U.S. DOJ, and may refer a disclosure to the OIG and DOJ for consideration under other federal authorities. CMS may also make a recommendation to the OIG and DOJ for resolution of False Claims Act, civil monetary penalty or other liability. It is not clear whether a settlement agreement with CMS of potential Medicare overpayment liability under the Stark law will release the hospital from potential liability under other federal authorities in cases where the disclosure has not been referred to the OIG and DOJ.

VI. DETERMINING WHICH SELF-DISCLOSURE PROTOCOL TO USE

If a hospital concludes that it has been overpaid, it must then determine which process is most appropriate. This will depend on whether the conduct at issue is:

1. A simple overpayment;
2. A violation of the Stark law that is not potentially associated with a violation of the anti-kickback statute; or
3. An overpayment that may involve fraud, including, but not limited to, a violation of the anti-kickback statute.

With respect to simple overpayments, the OIG's annual work plans have repeatedly emphasized that the OIG does not investigate individuals, facilities, or entities that merely commit errors or mistakes on claims submitted to the Medicare or Medicaid programs. Consequently, if an overpayment is clearly the result of an inadvertent and isolated billing

error, a hospital should simply reverse the improper claim(s) and return the overpayment to the Medicare fiscal intermediary, Medi-Cal or other federal contractor with a one-line minimal explanation of the nature and cause of the billing error (e.g., duplicate, corrected CPT code, services not rendered, not our patient(s), medical necessity, insufficient documentation, billed in error, etc.). If an overpayment is calculated using a statistical sampling methodology, the hospital must describe the statistically valid sampling and extrapolation methodology [42 C.F.R. Section 401.305(d)(1)].

Regardless of the amount at issue, overpayments that may involve fraud are proper subject matter for disclosure to the OIG. Therefore, if a hospital has a reasonable suspicion that an overpayment from a federal health care program (including Medi-Cal) was the result of a false claim(s), and not merely an innocent mistake, then its disclosure should ordinarily be made to the OIG in accordance with the OIG's Self-Disclosure Protocol. Such a disclosure to the OIG provides a hospital with the best chance of receiving the benefits that are available under that protocol, including reduced FCA civil damages and per-claim penalties.

Further, the OIG will ordinarily contact and coordinate with the local U.S. Attorney's office or the U.S. DOJ in Washington D.C. (representing the Medicare/Medicaid programs and the Centers for Medicare & Medicaid Services) and/or the California DOJ (representing Medi-Cal and the California Department of Health Care Services) regarding any resulting FCA settlement agreement, thereby saving significant time and expense for the hospital. By contrast, if a hospital discloses only to the local federal or state law enforcement agency, the hospital will not formally qualify for the benefits available under the OIG's Self-Disclosure Protocol and typically will also be responsible for ensuring that the OIG is added as a party to any resulting FCA settlement.

In the absence of facts putting a hospital on notice of potential fraud, a hospital's disclosure and repayment of overpayments of relatively low dollar amounts can safely be made to the Medicare contractor. However, even in the absence of facts otherwise suggesting fraud, it may be advantageous for significant overpayments to be disclosed by the hospital to the OIG for the simple reason that the government may view a high dollar overpayment as potentially the result of false claims until the hospital proves otherwise. Indeed, under Medicare rules, fiscal intermediaries and contractors must periodically report all hospital refunds to the local Medicare benefit integrity unit for further review.

Violations of the Stark law or the anti-kickback law are not appropriate subjects for disclosure to Medicare contractors. This is because additional penalties beyond simple repayment of overpayments can be assessed in connection with such violations. Because the OIG does not accept providers into its Self-Disclosure Protocol based solely on a violation of the Stark self-referral law, if a hospital overpayment was solely the result of a Stark violation, the hospital's disclosure and refund should be made directly to CMS pursuant to its Self-Referral Disclosure Protocol. However, the OIG protocol is intended to address overpayments involving fraud. Therefore, although the issue is not explicitly addressed by the OIG protocol, it may be appropriate for violations of the Stark law that suggest fraud to be disclosed to the OIG, even when there is no associated violation of the anti-kickback statute.

The OIG's Self-Disclosure Protocol is appropriate both for overpayments that may involve fraud and for all violations of the anti-kickback statute, including violations of the Stark law where the anti-kickback statute is implicated. The OIG protocol provides hospitals with a

detailed road map on how to voluntarily disclose overpayments or other irregularities in their claims to federal health care programs, including Medicare and Medi-Cal. Hospitals may also use the protocol to report prohibited employment of excluded individuals. *(See chapter 11, "Screening for Excluded Providers," for more information.)* Use of the OIG protocol can be very helpful when kickbacks are involved. Under the OIG's protocol, for services induced by kickbacks (which constitute overpayments), claims can be resolved on the basis of a multiple of the remuneration paid to the physicians, rather than a multiple of the tainted claims. When Stark violations (which also normally result in overpayments) can be resolved with associated kickback claims under the OIG protocol, those claims also will be resolved favorably as part of the same payment to resolve the kickback claims, which again, is determined on the basis of the remuneration to the physicians.

In cases where there is clearly only one type of violation, the decision regarding which disclosure protocol to use is relatively straightforward. In cases in which it is clear that only the Stark law is implicated, a hospital may only make a disclosure to CMS using the Self-Referral Disclosure Protocol. In cases involving more than simple overpayments in which it is clear that the conduct does not implicate the Stark law, a provider may only make a disclosure to the OIG using the OIG Self-Disclosure Protocol. For conduct which clearly implicates both the Stark law as well as other laws, a provider should make its disclosure to the OIG, and not CMS, using the OIG Self-Disclosure Protocol.

It may be difficult to determine with certainty whether the conduct in question implicates only the Stark law, or whether such conduct also involves the potential violation of other laws. In these cases, the potential may exist to make a good faith argument that either the OIG Self-Disclosure Protocol or the CMS Self-Referral Disclosure Protocol is appropriate. In such instances, hospitals may wish to consider other factors when deciding which disclosure protocol to use. In addition to the features addressed in the table below, hospitals should consider the particular facts of a given case, such as the duration of the conduct, the number and degree of potential violations, evidence of the parties' intent (such as emails or other communications between the parties or changes in referral patterns), and other facts and circumstances, as appropriate.

Hospitals may also wish to consider the amount of Medicare collections or the amount of compensation paid to physicians when choosing which disclosure protocol to use. In the typical cases that involve Medicare collections higher than the compensation paid to physicians, it may be advantageous to use the OIG Disclosure Protocol because, as stated above, the OIG will settle such cases based upon a multiple of the compensation paid to physicians. Of course, a colorable violation of the anti-kickback statute is a predicate to utilizing the OIG Disclosure Protocol, the absence of which will likely result in a referral of the disclosure by the OIG to CMS. In contrast, if the conduct involves high compensation paid to physicians with relatively low Medicare collections, then hospitals may wish to consider disclosing to CMS, rather than the OIG. This could settle overpayment liability but, in itself, would not resolve the civil kickback liability. It must be kept in mind, moreover, that CMS has been willing to make settlements on a very favorable basis in situations it views to involve only technical non-compliance under the Stark law (for example, missing signatures as opposed to payments to physicians that are above fair market value). There is therefore no advantage to settling technical non-compliance claims by bundling them with anti-kickback claims under the OIG protocol.

The following table outlines several key differences between the two disclosure protocols, and is intended to serve as the starting point to determine which disclosure protocol is most appropriate.

KEY CONSIDERATIONS	STARK DISCLOSURE PROTOCOL	OIG DISCLOSURE PROTOCOL
Applies to Stark law only violations	Yes	No
Applies to non-Stark law violations (e.g., violations of the Anti-Kickback Statute)	No	Yes
Applies to "mixed facts" situations implicating both the Stark law and Anti-Kickback law	No	Yes
Submission tolls 60-day requirement to report and return overpayments	Yes	Yes
Disclosing party must provide a complete legal analysis, including which elements of applicable exception are not met	Yes	No
Government given access to attorney-client privilege material	Yes	No
Disclosing party must provide a detailed financial analysis of the scope of potential noncompliance with initial disclosure	Yes	Optional
Settlement amount based on multiple of compensation paid to physician(s)	Not addressed by protocol	Yes

The decision to disclose a potential violation of the law to the government is never an easy one. With the development of the Self-Referral Protocol, providers now have another potential disclosure tool at their disposal. However, use of the Self-Referral Disclosure Protocol is not without its risks, and providers should carefully weigh the benefits and costs before deciding to make a disclosure to CMS which could otherwise be made to the OIG.

16 Responding to Government Audits and Investigations

I. Introduction 16.1

II. Government Entities With Oversight Authority Over Hospitals 16.1

A. Federal Agencies 16.1

Federal "Yellow Zone" Compliance Contractors 16.2

Medicare Administrative Contractor 16.2

Federal Review Contractors 16.3

Federal "Red Zone" Enforcement Agencies and Contractors 16.4

U.S. Department of Justice and the Federal Bureau of Investigation 16.5

United Program Integrity Contractors 16.7

B. State Agencies 16.12

California Compliance and Enforcement Agencies 16.12

DHCS Audits and Investigations 16.12

California Department of Consumer Affairs 16.14

California State Controller's Office (SCO) 16.14

III. Government Investigation Tools 16.14

A. Letter Request 16.14

B. Civil Investigative Demand 16.15

C. Administrative Subpoena 16.15

D. Grand Jury Subpoena 16.16

E. Search Warrant 16.16

IV. Responding to Government Request for Information 16.17

A. Notification of Hospital In-House Counsel, Compliance Officer and Outside Attorneys 16.17

B. Internal Preservation of Potentially Responsive Information 16.18

C. Written Notice to Key Hospital Employees 16.18

D. Appointment of Custodian of Records 16.19

V. Internal Investigation 16.19

A. Communicate with the Government 16.20

B. Evaluate and Assemble Investigation Team 16.21

C. Identify Relevant Custodians and Data Sources 16.22

D. Review Documents and Evidence 16.22

E. Conduct and Document Interviews 16.22
F. Synthesize the Evidence and Follow Up 16.24
G. Waiver of Privilege and Self-Disclosure 16.24
H. Using the Results of the Investigation 16.25

16 Responding to Government Audits and Investigations

I. INTRODUCTION

This chapter offers practical guidance to hospitals about responding to a government audit or investigation, including important steps that can be taken to ensure that any response to an agency's request for information is comprehensive, accurate, and presented in a manner that ensures the best possible outcome for the facility.

When a hospital first receives a government request for information, there are important facts about the nature of the request that can be determined based on the identity of the requesting agency or contractor, the form of the request, and the types of information being requested. Most critically, a hospital's general knowledge about government entities, the various methods available to such entities to obtain information, and the significance of various information categories that may be requested can assist the facility in determining whether the request is part of a "routine" civil audit versus a far more serious civil false claim or criminal fraud investigation.

A hospital's response to any government request for information should be timely, complete, and well-documented. In addition, the hospital should usually conduct a thorough internal investigation into the subject matter of the underlying audit or investigation. The hospital should also send a document retention notice to all relevant employees and work with their IT department to preserve all documents and information as the internal investigation proceeds.[1] Taking a proactive approach will put the hospital in the best position to respond to the investigation and, if necessary, negotiate an appropriate and reasonable resolution or settlement of the government's audit or investigation. The important components of an effective response and internal investigation are detailed below.

II. GOVERNMENT ENTITIES WITH OVERSIGHT AUTHORITY OVER HOSPITALS

Hospitals are faced with an ever-increasing number of government agencies and contractors (accompanied by a bewildering sea of acronyms) that have oversight authority over them. When a request for information is received, a hospital's knowledge of the requesting agency's or contractor's specific mission and oversight authority can provide particularly useful information about the nature of the request and the likely course of the underlying audit or investigation.

A. Federal Agencies

In recent years, federal agencies and contractors have been far more active in investigating California hospitals for potential legal violations associated with their claims to the Medicare

1 This includes turning off all auto-delete functions and ensuring documents and information are preserved on facility-issued cell phones, laptops, and other devices.

program than their counterpart state agencies have been with respect to their Medi-Cal claims.[2]

While similar state laws exist, federal enforcement activity relating to hospital compliance with the federal False Claims Act *(see chapter 3, "Federal and State False Claims Acts")*, anti-kickback statute *(see chapter 7, "Federal and State Anti-Kickback Laws")* and the Stark law *(see chapter 6, "Physician Self-Referral Laws")* has been higher than that of the state. This is partly because whistleblowers have historically been more likely to file false claims lawsuits (including those involving Medi-Cal claims) in federal court and California agencies have focused their compliance resources on providers other than hospitals.[3]

As a result, a hospital is more likely to receive a request for information from a federal agency or contractor. For risk management purposes, these federal entities can be divided into compliance ("yellow zone") contractors and enforcement ("red zone") agencies or contractors.

Federal "Yellow Zone" Compliance Contractors

With respect to the Medicare and Medicaid programs, the Centers for Medicare & Medicaid Services (CMS) has delegated significant administrative and compliance responsibilities to private contractors. These CMS compliance contractors generally have oversight authority over hospital compliance with Medicare and Medicaid coverage rules, but no direct responsibility for enforcing civil and criminal laws (including penalties) applicable to fraud and other misconduct in government health care programs. However, compliance contractors are usually required to refer possible fraud or false claims cases to an enforcement agency or contractor.

Medicare Administrative Contractor

The Medicare Administrative Contractor (MAC) is a private contractor responsible for performing Medicare claims processing and payment functions on behalf of the government in A/B MAC Jurisdiction E, the region covering California. The current California MAC is Noridian Healthcare Solutions, LLC.

The MAC administers both Medicare Part A and Part B claims, replacing the fiscal intermediaries and carriers who separately administered these two claim categories in the past. In particular, MAC functions include determination of payment amounts, making payments, beneficiary education and assistance, provider consultative services, communication with providers, and provider education and technical assistance.

In addition, the MACs are responsible for pre- and post-payment medical review of hospital claims to ensure that they are for covered, reasonable and necessary services. This function replaces the Hospital Payment Monitoring Program handled by Quality Improvement Organizations (QIOs) until approximately July 2008. QIOs are still responsible for handling quality-of-care issues.

The MACs rely on Comprehensive Error Rate Testing (CERT) contractors and Recovery Audit Contractors (RACs) to identify potential claim errors. If an error is identifiable on the face of

2 In an October 2021 memorandum (the "Monaco Memo"), the DOJ also announced a renewed commitment to combatting corporate crime.

3 In recent years, some attorneys representing whistleblowers have been renewing focus on California state law-based theories of recovery, including the Insurance Frauds Prevention Act (Insurance Code Section 1871 et seq.)

the claim and any submitted documentation, the MAC will usually notify the hospital of the claim denial on the remittance advice.

However, in order to verify a potential error, the MAC may also send an Additional Documentation Request (ADR) form to a hospital requesting the supporting medical records for a claim or for a sampling of claims. Usually, the hospital will have 30 days to respond and if it fails to do so after 45 days, the MAC will deny the claim(s) as not reasonable and necessary with RA Code N102/56900 ("This claim has been denied without reviewing the medical record because the requested records were not received or were not received timely").

The MACs do not directly investigate or develop possible fraud cases against hospitals and have no authority to enforce criminal or civil penalties against hospitals for false claims or other misconduct, including kickback and Stark law violations. However, the MACs are required to refer possible fraud cases to a Zone Program Integrity Contractor (ZPIC) for development, as well as a Unified Program Integrity Contractor (UPIC). UPICs were established in 2016 and will eventually replace the regional MICs and ZPICs. Qlarant Integrity Solutions, LLC, was selected by CMS as the UPIC for the Western Jurisdiction in 2017. It was formerly known as MEDIC or Health Integrity, LLC. Qlarant performs fraud, waste and abuse detection, deterrence and prevention activities for Medicare and Medicaid claims within the Western Jurisdiction, which includes California.

Federal Review Contractors

Federal Review Contractors (FRCs), are private contractors currently tasked with detecting and recovering past improper payments of Medicare claims that were paid between one and three years before. The RAC for California in RAC Region 4 is Cotiviti.

RACs search for incorrectly paid claims through:

1. Automated claims history reviews (often referred to as "data mining") that identify clear payment errors without the need to look at underlying medical records, and
2. Complex reviews where data mining establishes a high probability of a payment error, but the underlying medical records are required to confirm that an overpayment actually occurred.

Typically, the first indication for a hospital that its claims are being reviewed by a RAC will be the receipt of a remittance advice from the MAC for an old claim with Code N432 ("Adjustment Based on Recovery Audit") or, in the case of complex reviews, an ADR form from the RAC requesting the complete patient medical record underlying an old claim. The hospital has 45 days from the date of the ADR, plus 10 additional calendar days for mailing, to submit the medical records, although extensions can be requested. RACs will accept imaged medical records on CD/DVD or, alternatively, will reimburse hospitals for copying fees at 12 cents per page. The RAC then has up to 60 days to review the medical records and then make a determination whether the old Medicare claim was incorrectly paid. Generally, for each hospital campus (defined as one or more facilities under the same Tax Identification Number (TIN) located in the same area based on the first three positions of the ZIP code), the annual baseline limit for the number of RACs is one-half of one percent (0.5%) of the provider's total number of paid Medicare claims from a previous 12-month period. The RAC ADRs every 45 days is limited to 2 percent of all claims submitted for the previous calendar

year divided by eight. However, the 45-day limit is subjected to recalculation (both increasing and decreasing) depending on a hospital's denial/success rate or risk-based adjustments. Thus, the more success a hospital has (i.e., the lower the denial rate), the lower the threshold goes.

The MAC (rather than the RAC) will send the hospital an automated demand letter identifying the overpayment and notifying it of its rebuttal and appeal rights with due dates. The date of this letter is deemed to be day one for calculating appeal due dates. On day 41, the MAC will recoup the overpayment by offset if the hospital has not already paid it by check.

There are five Medicare RAC regions in the United States — four Medicare Part A/B RACs and one national durable medical equipment (DME), home health and hospice RAC. Cotiviti GOV Services (formerly HMS) is the Medicare RAC for region 4, which includes California and covers Medicare Parts A and B.

Initially, RACs were focusing on areas where CMS and Medicare coverage criteria have been clear and in place for several years, such as inappropriate chest pain admissions. In the past, RACs have reopened and denied old Medicare claims that were for medically unnecessary, duplicate, or otherwise non-reimbursable services, were incorrectly coded, or lacked sufficient supporting documentation.

However, a RAC must now receive prior CMS approval for the recovery issues that it intends to audit. As of Dec. 14, 2021, Cotiviti, the RAC for California, received approval to audit over 200 reimbursement issues. Cotiviti's website is useful for seeing the list of issues.[4]

Compliance Tip: In responding to a request for medical records from any government agency, a hospital should have procedures in place to ensure the following:

- A complete medical record for the patient is submitted, including both sides of every page and both hard copy and electronic records;
- The entire medical record is bates stamped[5] with page numbers and a copy of the exact record sent to the agency is maintained by the hospital;
- The medical record is sent to the agency using a trackable delivery method such as certified mail or overnight mail that includes a return receipt; and
- A hospital employee is responsible for submitting requested medical records and monitoring any related mail, due dates, and appeal deadlines.

Federal "Red Zone" Enforcement Agencies and Contractors

Numerous federal agencies are directly responsible for the investigation and prosecution of health care providers, including hospitals, for civil false claims and criminal fraud and other misconduct, that may violate criminal and civil laws. In addition, under CMS's organization

4 https://racinfo.hms.com/Public1/NewIssues.aspx,

5 **"Bates stamping"** (or bates numbering) is used to label and identify documents by placing unique identifiers on each page of each document for reference and retrieval. Such "numbering" may be solely numeric or may contain a combination of letters and numbers (alphanumeric). Pre-printed self-adhesive labels may also be used, as well as electronic document discovery software that can electronically "stamp" documents stored as computer files by superimposing numbers onto them.

chart, detection of fraud and abuse by Medicare providers has been primarily delegated to a private contractor called a Unified Program Integrity Contractor (UPICs). Previously, there were also Zone Program Integrity Contractors (ZPICs), which have been primarily transitioned to UPICs, though ZPICs are still continuing to function in a legacy role in limited circumstances.

Any request for information or other contact with the law enforcement agencies and CMS contractor described below should never be treated as a routine administrative audit. Instead, the hospital should always assume that it is being investigated for false claims, fraud, or other potential misconduct subject to serious criminal and civil penalties. The hospital may wish to consult experienced legal counsel in these situations.

U.S. Department of Justice and the Federal Bureau of Investigation

The U.S. Department of Justice (DOJ) is the chief law enforcement agency of the federal government and is exclusively responsible for prosecuting health care providers for health care fraud, kickbacks, and other federal crimes, and for filing and litigating civil lawsuits against them for violating the federal False Claims Act (FCA).

Federal criminal cases and investigations against California health care providers are handled and supervised by Assistant United States Attorneys (AUSAs) assigned to the Criminal Division of the U.S. Attorney's Office (USAO) located in the judicial district in which the case is filed.

These offices are located in the Northern District (San Francisco), Eastern District (Sacramento), Central District (Los Angeles), and Southern District (San Diego).

Civil FCA actions against hospitals are also usually handled by local AUSAs in the USAO's Civil Division, but often in coordination with trial attorneys in the DOJ Civil Division's Commercial Litigation Branch (Fraud Section) in Washington D.C. More often than not, such actions are filed in court under seal (that is, confidentially and without notice to the hospital) on behalf of the United States by whistleblowers, known as relators, and are then initially investigated by USAO and DOJ analysts and investigators using administrative subpoenas and civil investigative demands (CIDs) to determine whether the government will "intervene" and take over prosecution of the false claims lawsuit *(see C. "Administrative Subpoena," page 16.15)*.[6] Once the FCA lawsuit is unsealed and served on the hospital, either the USAO or the relator will obtain information from the hospital using the civil discovery tools available in any lawsuit, including document requests, depositions, interrogatories, and requests for admission.

6 Pursuant to the False Claims Act, private whistleblowers may initiate civil actions and collect a portion of any judgment issued against entities found to have submitted false claims to the U.S. government. The DOJ retains certain rights under the law for these actions, including the ability to intervene and proceed with relator-initiated cases, as well as the right to move to dismiss an action. A January 2018 DOJ memorandum (the "Granston Memo") directs prosecutors to more seriously consider dismissing certain qui tam actions brought pursuant to the False Claims Act. The memo lays out seven factors federal attorneys should consider as grounds for moving to dismiss qui tam actions, and expressly admonishes them to consider doing so in appropriate cases. On their face, the factors suggest that one of the Granston memo's primary goals was to curb scenarios where qui tam litigation threatens the DOJ's ability to effectively control enforcement of the False Claims Act. Although the DOJ has incorporated the Granston Memo's policy into its practices in the year since its release, there has not been a spree of dismissals. Some attribute this to the fact that a number of circuits have held that the government does not have "unfettered" discretion to dismiss FCA actions. Instead these circuits have held that the government must demonstrate that its decision to dismiss an FCA action has a "rational relationship to a government interest."

Federal criminal actions are all prosecuted by the DOJ, but are investigated by a variety of law enforcement agencies, some of which are part of the DOJ, but others are not.[7] It is not uncommon for the federal government to conduct parallel criminal and civil investigations within DOJ using the exact same special agents.

The FBI, which is part of the DOJ, is by far the most active law enforcement agency with respect to criminal health care fraud investigations. The FBI dedicates numerous special agents throughout the United States to such white collar investigations, which rank behind only public corruption and corporate/securities fraud in terms of priority. The FBI staffs health care fraud investigations with special agents assigned to field offices in every major California city. Most FBI investigations currently involve fraud committed against Medicare, Medicaid, and other government health care programs, but the agency also investigates fraud against private insurance companies.

In a criminal investigation of a hospital for health care fraud, the first contact with the DOJ is likely to be a federal administrative subpoena or a grand jury subpoena personally served on the hospital by an agent of the FBI or other agency participating in the investigation. As further detailed in the next section, an administrative subpoena can request documents and the authenticating testimony of a records custodian only, but a grand jury subpoena can also compel the testimony of a witness before the grand jury. *(See C. "Administrative Subpoena," page 16.15, and D. "Grand Jury Subpoena," page 16.16.)*

Further DOJ investigative contacts relating to a criminal investigation may include special agents contacting current and former hospital employees and contractors (e.g., physicians and vendors) for voluntary questioning and interviews. Very rarely, agents may obtain and execute a search warrant for documents at the hospital.

Office of Inspector General, U.S. Department of Health and Human Services

The Office of Inspector General (OIG) for the U.S. Department of Health and Human Services (DHHS) bears the principal responsibility for the regulatory oversight of federal health care program waste, fraud, and mismanagement. This oversight responsibility includes monitoring the Medicare, Medicaid and U.S. Public Health Service (PHS) programs (such as the Indian Health Service).

The OIG has concurrent authority with the DOJ to civilly enforce the FCA, the anti-kickback statute, the Stark law, and other fraud and abuse statutes. By agreement with

7 In late 2017, the DOJ also released the Sessions memorandum, which announced a broad policy statement prohibiting the use of agency guidance documents as the basis for proving legal violations in civil enforcement actions, including actions brought under the FCA. It has also been followed up by the Brand Memo in 2018. The Brand Memo guides civil DOJ attorneys to avoid use of guidance documents from other administrative agencies. **"Guidance documents"** are "any agency statement of general applicability and future effect, whether styled as guidance or otherwise, that is designed to advise parties outside the federal executive branch about legal rights and obligations." The extent to which these policy changes ultimately create relief for health care defendants in FCA actions is unclear at this time. That said, the memo provides defendants with a valuable tool in defending FCA actions, either brought by DOJ or relator's counsel, that attempt to use alleged noncompliance with agency sub-regulatory guidance as support for an FCA theory. At least one court has held that such guidance may not be used as a basis for a FCA action based on the Supreme Court's decision in *Azar v. Allina Health Svcs.*, 139 S. Ct. 1804 (2019). *See United States ex rel. Polansky v. Exec. Health Resources, Inc.*, 422 F. Supp. 3d 916,934 (E.D. Pa., 2019), appeal pending. For more information regarding the impact of agency guidance in light of the *Allina* decision *see* HHS-OIG, Kelly M. Cleary & Brenna E. Jenny, Memorandum Regarding Impact of *Allina* on Medicare Payment Rules, Oct. 31, 2019; HHS-OGC, Advisory Op. 20-05 on Implementing *Allina* (Dec. 3, 2020), *available at* https://www.hhs.gov/sites/default/files/allina-ao.pdf.

the OIG, however, the DOJ is primarily responsible for enforcing the FCA. With respect to civil remedies and penalties, OIG has the authority to recover Medicare and Medicaid overpayments; exclude providers from the Medicare and Medicaid programs for fraud, false claims, and other criminal and civil misconduct [42 U.S.C. Section 1320a-7]; impose civil monetary penalties (CMPs) for false claims, kickbacks, improper retention of an overpayment, false statements, and other program-related misconduct [42 U.S.C. Section 1320a-7a]; and suspend payments to a provider "pending an investigation of a credible allegation of fraud." [42 C.F.R. Section 405.370]

In order to discharge its duties, the OIG has established an organizational structure with offices responsible for audits, evaluations and inspections, management and policy, investigations, and legal counsel.

The OIG's Office of Counsel handles and supervises civil proceedings involving false claims, CMPs, and exclusions. It also negotiates, approves, and monitors compliance with Corporate Integrity Agreements (CIAs) with providers as a condition of settlement in FCA cases. However, OIG counsel have no authority to file and prosecute criminal charges.

The OIG's Office of Investigations is the principal investigative arm of the agency. OIG special agents, investigators, and auditors conduct administrative audits and criminal and civil investigations of Medicare and Medi-Cal providers for a wide range of conduct, ranging from routine overpayments to intentional fraud. OIG special agents may demand to inspect any hospital documents or records relating to federal health care programs.

If an OIG investigation determines that a provider has committed fraud or other crimes, the case is referred to the DOJ, usually via the local U.Ss. Attorney's Office, for criminal prosecution.

An OIG investigation of a hospital will usually be initiated by a letter or administrative subpoena request for medical and other records.

With respect to federal health care fraud and false claims investigations, the OIG has the regulatory authority to issue administrative subpoenas for documents and/or sworn testimony [42 C.F.R. Section 1006.1 *et seq.*]. In California, however, the OIG rarely uses such subpoenas to compel testimony by witnesses. *(For more information on administrative subpoenas, see C. "Administrative Subpoena," page 16.15.)*

United Program Integrity Contractors

As a component of CMS's efforts to strengthen and consolidate its program integrity efforts, in 2016 CMS began shifting from three regional Medicaid Integrity Contractors (MICs) focused on Medicaid to five new regional UPICs responsible for a range of Medicare and Medicaid program integrity activities previously performed by other contractors. UPICs are intended to fully Integrate the previous functions of ZPICs, Program Safety Contractors (PSCs), the Medicare-Medicaid data match program (Medi-Medi) and Medicaid Integrity Contractors (MICs).

The UPIC program is likely to go a long way towards streamlining the audit process and reducing the number of duplicative audit requests received from competing CMS program integrity contractors. In any event, the consolidation of these program integrity duties is yet

another clear indication that the government intends to improve its efficiency in scrutinizing questionable Medicare and Medicaid billings. CMS believes that the UPIC program integrity strategy will greatly enhance the ability of the agency to identify aberrant billing patterns and practices, especially those that involve both Medicare and Medicaid claims. According to CMS, the purpose of the UPICs is to coordinate provider investigations across Medicare and Medicaid; improve collaboration with states by providing a mutually beneficial service; and increase contractor accountability through coordinated oversight. According to CMS officials, aspects of the UPIC program — such as the goal of having contractors work collaboratively with states — reflect their prior experiences with the collaborative audits.

UPICs perform fraud, waste, and abuse detection, deterrence and prevention activities for Medicare and Medicaid claims processed in the United States. Specifically, the UPICs perform integrity related activities associated with Medicare Parts A and B, durable medical equipment, home health, hospice, Medicaid, and the Medicare-Medicaid data match program.The UPIC contractors operate in five (5) separate geographical jurisdictions in the United States.

UPICs develop investigations early and take immediate action to ensure Medicare Trust Fund monies are not inappropriately paid. They also identify any improper payments to be recouped by the MAC. When receiving a request from a UPIC, providers are often given 15 days to respond, though generally requests for additional time are readily granted. As with other program integrity audits, most reviews (and claims reopenings) by UPICs are generated as a result of data mining. In these cases, a UPIC often restricts its review efforts (at least initially) to the claims being assessed, along with relevant, associated medical, coding, billing records and related materials.

In addition to the claims-related documents listed above, a UPIC may also seek documents related to a provider's business practices and/or business relationships. Requests for this type of information may signal that the UPIC has received other information about the facility that suggests that it may be engaging in unlawful business practices. To the extent a UPIC finds evidence that a provider is engaging in wrongdoing, the contractor is required to make a referral to law enforcement (i.e., OIG or DOJ).

If a small set of postpayment claims are being reviewed, the UPIC may be conducting a "Probe Sample" of the provider's claims. The purpose of the probe sample is to see if there appears to be a potential problem with the provider's medical necessity, documentation, coding or billing practices. If few problems are found, the UPIC will likely issue an "Education Letter" to the provider, with information on how to correct the observed issues. If, however, a significant number of errors are identified, the UPIC will likely expand its audit and issue a subsequent request for the supporting documentation associated with a larger number of claims.

If the UPIC's initial request for records asks for records associated with a larger number of claims over a longer period of time, there is a high likelihood that the UPIC has pulled these claims as part of a "Statistically Relevant Sample." Increasingly, government entities have been seeking to extrapolate the error rate found across the entire universe of claims for a facility.

Qlarant is performing fraud, waste and abuse detection, deterrence and prevention activities for Medicare and Medicaid claims within the Western Jurisdiction, including California.

CMS Zone Program Integrity Contractor

While UPICs are intended to fully replace ZPICS, PSCs, the Medicare-Medicaid data match program, and MICs, these prior contractors still have some involvement in the investigation of potential fraud, particularly for past claims for which investigation and/or appeals are still ongoing. For instance, a few legacy ZPICs are still working on CMS projects, but for the most part, all of their program integrity duties have been transferred over to UPICs. This section describes the prior functioning and responsibilities of the ZPICs as background information to the extent a facility receives an inquiry still being handled by a ZPIC in its legacy role.

A ZPIC was a private CMS contractor responsible for investigating and preventing potential Medicare fraud by reviewing past and pending claims and comparing a provider's billings with those of similarly situated providers. ZPICs also investigated fraud allegations referred by Medicare beneficiaries, providers, and other CMS contractors (e.g., MACs and RACs). The prior duties of ZPICs have been transitioned and consolidated into the duties of a UPIC. As noted above, the assigned UPIC for the Western region of the United States is Qlarant. Hospitals are not likely to see further audit activity from the ZPICs, but the process still remains for a few legacy ZPICs which continue to work on CMS projects.

Medicaid Integrity Contractor

Medicaid Integrity Contractors (MICs) were private contractors that analyzed Medicaid paid claims data to identify high risk providers with aberrant or suspect billing practices ("Review MICs") and also audit such providers to recover overpayments ("Audit MICs"). The MICs were overseen by CMS's Medicaid Integrity Program (MIP). The role of the MICs has also been subsumed by the UPICs, though similar to ZPICs, MICs may continue to appear on rare occasions in a legacy role.

In such an instance, the first notice to a hospital of a MIC audit will usually be its receipt of a Notification Letter requesting records and identifying a primary Audit MIC point of contact. The hospital must be given at least 30 business days to produce the requested Medi-Cal claim records, although the time period may be as short as two weeks in some situations. The Audit MIC can authorize an extension of 15 business days if requested and justified by the hospital. The Audit MIC will accept imaged or facsimile medical records, but does not reimburse for copying costs. The Audit MIC will also contact the provider to schedule an entrance conference to explain the purpose of the audit and, in some cases, a field audit to review Medi-Cal claim records and interview staff at the hospital. Most MIC audits are desk audits performed by auditors who review hospital records at CMS offices. Audit MICs are prohibited from auditing Medi-Cal claims that are more than five years old as of the date of the notification letter. At the end of the audit, the Audit MIC will also schedule an exit conference to discuss its findings with the hospital.

The Audit MIC will review the Medi-Cal claims information that it received from CMS and the hospital. There is no specific time period within which the MIC's audit must be completed. If the Audit MIC determines that any Medi-Cal overpayments occurred, it will prepare a draft audit report that is sent to the MIP. This report will also be sent to the California Department of Health Care Services (DHCS) and the hospital for comments, but the MIP has the final decision-making authority on any proposed changes to the report. The final MIC audit report is then sent to DHCS for collection of the identified Medi-Cal overpayments in accordance with state law, including all available appeal rights.

The MIC may also refer a suspect hospital to federal and state law enforcement agencies if the MIC's review or audit reveals potentially fraudulent billing practices. As noted above, while this process may still occasionally arise, the role of MICs has been nearly completed transitioned to the UPICs.

Other Federal Law Enforcement Agencies

California hospitals may sometimes be contacted by other federal law enforcement agencies with oversight authority over specific federal health care programs other than Medicare or Medi-Cal, or specific aspects of hospital operations not necessarily related to billing. Such agency contact will usually be initiated or accompanied by an administrative subpoena (usually issued by the DOJ) or grand jury subpoena seeking hospital records. *(See C. "Administrative Subpoena," page 16.15, and D. "Grand Jury Subpoena," page 16.16.)*

However, if a criminal investigation is being conducted, these investigative agencies must, just like the FBI and the OIG, present their cases to the DOJ for criminal prosecution. In addition, such agencies conduct criminal and civil investigations of providers in conjunction with the FBI or the OIG, sometimes as part of a national or local health care fraud task force.

The Office for Civil Rights, U.S. Department of Health and Human Services. The Office for Civil Rights (OCR) for the DHHS is responsible for enforcing the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule and related Security Rule, which protects the personal health information of patients from unauthorized access, use and disclosure. OCR also enforces federal laws regarding discrimination and language access (deaf/foreign language interpreter and translation requirements).

OCR investigates HIPAA complaints filed with the agency and also conducts compliance reviews to determine if covered entities, including hospitals, are in compliance with these laws.

Ordinarily, a hospital's first contact with OCR will be a letter notifying the facility that a complaint about a possible violation has been received and requesting production of information about the incident or other problem described in the complaint. The hospital is legally required to cooperate with these complaint investigations and OCR usually requires the hospital to respond to its information request within 30 days of the letter's date.

If OCR determines that a complaint describes a possible criminal HIPAA violation *(see 42 U.S.C. Section 1320d-6)*, it will normally refer the complaint to DOJ for further investigation.

After conducting its investigation, OCR will notify the hospital of its findings. If the hospital violated either the Privacy Rule or the Security Rule, OCR may attempt to resolve the case by obtaining voluntary compliance, corrective action, and/or a resolution agreement. In some cases, OCR may also impose CMPs, especially if the hospital does not otherwise resolve the matter to OCR's satisfaction.

Defense Criminal Investigative Service. The Defense Criminal Investigative Service (DCIS) is the investigative branch of the OIG. Its special agents investigate criminal health care fraud relating to the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), the civilian indemnity-type health care program for military personnel and their families, and TRICARE, a managed health care insurance program for the same beneficiaries.

A hospital's first contact with DCIS will usually be through service of an administrative subpoena or grand jury subpoena. *(See C. "Administrative Subpoena," page 16.15, and D. "Grand Jury Subpoena," page 16.16.)*

Office of Inspector General for the Office of Personnel Management. Special agents of the OIG for the Office of Personnel Management investigate fraud committed against Federal Employee Health Benefits programs for federal civilian employees and their dependents administered through various plans, including Aetna HealthFund and Open Access, the American Postal Workers Union, Anthem Blue Cross, Blue Cross and Blue Shield Service Benefit, the Blue Shield of California Access, Foreign Service Benefit, Government Employees Health Association, Health Net of California, Kaiser Foundation of California, the Mail Handlers Benefit, the National Association of Letter Carriers, and Special Agents Mutual Benefit Association.

The Office of Personnel Management will usually initiate contact with a hospital under investigation through an administrative subpoena or grand jury subpoena for records. *(See C. "Administrative Subpoena," page 16.15, and D. "Grand Jury Subpoena," page 16.16.)*

U.S. Postal Inspection Service. The U.S. Postal Inspection Service (USPIS) is the investigative branch of the U.S. Postal Service. Its inspectors investigate the use of the U.S. mail and wires to commit health care fraud, usually with respect to private insurance companies.

A hospital's first contact with USPIS will usually be through service of an administrative subpoena or grand jury subpoena. *(See C. "Administrative Subpoena," page 16.15, and D. "Grand Jury Subpoena," page 16.16.)*

The Drug Enforcement Administration. The Drug Enforcement Administration (DEA) is part of the DOJ and investigates violations of the federal Controlled Substances Act, including the diversion (i.e., theft) of controlled substances from legitimate dispensing and distribution channels, including hospitals and pharmacies.

DEA diversion investigators are primarily responsible for conducting diversion investigations, but special agents will become involved if search and arrest warrants are needed because diversion investigators are not sworn peace officers.

The DEA will usually initiate contact with a hospital under investigation through an administrative subpoena or grand jury subpoena for records. *(See C. "Administrative Subpoena," page 16.15, and D. "Grand Jury Subpoena," page 16.16.)*

Food and Drug Administration. Special agents of the Food and Drug Administration (FDA) generally do not independently conduct fraud investigations against hospitals, but may become involved in an investigation by another agency involving claims for medical devices (e.g., EKGs, implantable cardiovascular defibrillators, blood pressure monitors, implants) which are at issue, and over which the FDA has regulatory jurisdiction.

A hospital's first contact with the FDA will typically be an administrative subpoena or grand jury subpoena for records. *(See C. "Administrative Subpoena," page 16.15, and D. "Grand Jury Subpoena," page 16.16.)*

Additional Federal Oversight Related to the COVID-19 Pandemic

In 2020, with the ongoing COVID-19 pandemic, healthcare providers became subject to additional scrutiny because of the trillions of dollars in funds released by the federal government to support providers on the frontlines of the pandemic. The significant funds

available to businesses and individuals through government programs in the CARES Act and Paycheck Protection Program (PPP) carry an inherent risk of fraud, waste, abuse, and mismanagement.

The DOJ is investigating and prosecuting cases involving public funds obtained through the CARES Act, PPP and other pandemic response funding programs. The audits are likely to continue, to evaluate how these funds were spent and accounted for. The U.S. Attorney General's office has assigned a coronavirus fraud coordinator in each federal district.

The CARES Act also establishes a Congressional Oversight Commission, which will likely take an active role in reviewing and investigating the use of CARES Act funds. Additionally, the CARES Act established the Pandemic Response Accountability Committee (PRAC), with a goal to "promote transparency and conduct and support oversight of [CARES Act] funds and the Coronavirus response to (1) prevent and detect fraud, waste, abuse, and mismanagement, and (2) mitigate major risks that cut across program agency boundaries." [CARES Act, Section 15010(b)] The CARES Act also includes funding for various government agencies and departments to oversee and audit programs it funded.

While the CARES Act establishes a new Inspector General and a congressional oversight committee, it does not take away any preexisting investigatory jurisdiction. This means that, in addition to the above-named agencies, any alleged fraud or misuse of government funds can also be investigated by the FBI, the U.S. Secret Service, and the Internal Revenue Service's Criminal Investigations Division, as well as other existing federal agencies. It is important to note that the guidance on proper use of funds under the CARES Act is continuously shifting and all providers should continue to evaluate their use of funds, potential payback of funds, and keep detailed information readily available on all applications for funds and use of funds should the government seek information from the provider at a future date.

B. State Agencies

For California hospitals, most compliance contacts with state agencies will involve routine audit activity by DHCS regarding their Medi-Cal claims and cost reports, rather than criminal or civil false claims investigations.

Historically, both DHCS and California's Medicaid Fraud Control Unit, the Division of Medi-Cal Fraud & Elder Abuse, have focused on fraud or abuse by provider types other than hospitals (e.g., physicians, durable medical equipment providers, adult day health care centers, laboratories, and pharmacies), and elder abuse by long-term care facilities. In addition, there has been little activity by relators and the California Department of Justice (CADOJ) against hospitals under the state False Claims Act.

California Compliance and Enforcement Agencies

With respect to both regulatory compliance under the Medi-Cal program and criminal investigations of health care fraud, California has fewer separate agencies and contractors than the federal government.

DHCS Audits and Investigations

DHCS's Audits and Investigations program (A&I) is responsible for preserving the Medi-Cal program's fiscal integrity through audits and investigations and is divided into the following three branches:

1. A&I's Financial Audit Branch (FAB) has regular contact with hospitals because it is responsible for conducting financial audits of hospitals' Medi-Cal claims and annual cost reports. Although the FAB will make adjustments to hospital claims based on violations of Medi-Cal coverage and other regulatory requirements, it is primarily a "bean counting" organization and typically will not engage in substantive investigation of fraud and abuse issues, including review of underlying patient medical records.
2. A&I's Medical Review Branch (MRB) conducts post-payment audits of physician and other provider claims, usually focusing on medical necessity, coding and documentation issues. Typically, the MRB will not investigate fraud and will perform its audits based exclusively on the patient medical records submitted by the provider. However, it will refer suspicions of fraud to the State Controller's Office and the MICs for further investigation.
3. A&I's Medi-Cal Fraud Investigations Branch (IB) is primarily responsible for investigating Medi-Cal beneficiary fraud, but also conducts preliminary investigations of complaints that Medi-Cal providers are engaged in fraud. However, if its investigation establishes "reasonable cause" to believe that fraud occurred, the IB is required to refer the case to the CADOJ's Bureau of Medi-Cal Fraud and Elder Abuse (DMFEA) for criminal investigation.

Most of A&I's contacts with hospitals will be by letter (including records requests) and telephone, although audit entrance and exit conferences by FAB are sometimes conducted in person at the hospital.

California Department of Justice, Division of Medi-Cal Fraud and Elder Abuse[8]

The CADOJ's DMFEA is the Medicaid Fraud Control Unit (required for any state participating in the Medicaid program) for California, and Is responsible for investigating and prosecuting entities and persons who commit Medi-Cal fraud or elder abuse.

The DMFEA employs teams of prosecutors (known as deputy attorneys general), special agents and auditors who are deployed in major California cities. These teams conduct coordinated investigations of criminal activity by Medi-Cal providers, including abuse of the elderly, with a focus on senior patients being mistreated in long-term care facilities.

California state agencies are authorized to issue administrative subpoenas for records as part of an investigation concerning matters relating to the subjects under the agency's jurisdiction *(see Government Code Section 111807 et seq.)*. Under state law such subpoenas, unlike their federal equivalents, while not required to meet a probable cause standard, are subject to the state constitutional provisions prohibiting unreasonable searches and seizures. As a result, historically, the DMFEA has not used subpoenas to obtain records needed for a health care fraud or other criminal investigation, but the use has expanded recently, particularly in the long-term care industry. *(For more information, see C. "Administrative Subpoena," page 16.15.)*

Instead, the DMFEA often uses criminal search warrants to obtain documents. In the case of a hospital investigation, the DMFEA will often treat the warrant as though it were a subpoena and provide a reasonable period of time for the hospital to produce the records subject to the warrant.

8 In 2020, the California Department of Justice made the "Bureau" of Medi-Cal Fraud and Elder Abuse into a :division." It is now the DMFEA.

In addition, the DMFEA has begun using state grand jury subpoenas to obtain records and compel witness testimony before the grand jury in cases where facilities and employees will not provide records or submit to interviews voluntarily. *(For more information, see D. "Grand Jury Subpoena," page 16.16.)*

California Department of Consumer Affairs

California's Department of Consumer Affairs (DCA) is the umbrella agency that oversees the disciplinary and other enforcement proceedings brought by healing arts boards against 19 different types of professional licensees, including doctors, physician assistants, nurses, and pharmacists.

Usually, a hospital's first contact with DCA will be receipt of an administrative subpoena requesting medical records for a particular patient or documents concerning a particular licensed professional on the hospital's staff. *(See C. "Administrative Subpoena," page 16.15.)*

In disciplinary proceedings against licensees, the DCA may compel sworn testimony of the licensee about the care provided or other conduct being investigated.

California State Controller's Office (SCO)

The SCO is responsible for accountability and disbursement of the state's financial resources. The SCO also safeguards many types of property until claimed by the rightful owners, independently audits government agencies that spend state funds, and administers the payroll system for state government employees and California State University employees.

A hospital's contact with the SCO may come from audits that are performed under agreement with DHCS. In such cases, the SCO performs the audit, but DHCS must handle the matter and defend the findings should the hospital appeal. Therefore, SCO and DHCS sometimes work jointly.

III. GOVERNMENT INVESTIGATION TOOLS

Hospitals should be familiar with the different tools, ranging from a simple request for medical records to agents executing a search warrant at their facilities, that are used by federal and state agencies to obtain information from health care providers. In many cases, the government's choice of method to request information will help the hospital determine whether it is simply the subject of a routine audit or, more seriously, the target of a civil false claims or criminal health care fraud investigation. The type of request can also provide an indication of the stage of the agency's investigation.

A. Letter Request

Most of the federal agencies and contractors (CMS, OIG, RACs, MICs, ZPICs) and their state counterparts (DHCS, A&I) that have direct oversight over hospital participation in the Medicare and Medi-Cal programs have the legal authority to request and inspect all records relating to the hospital's claims to the respective programs without a subpoena or other formal legal process.

In most cases, but not all, a letter request from an agency or contractor typically means that the hospital records are being requested as part of routine civil processing or auditing of hospital claims, rather than as part of a civil false claims or criminal health care fraud investigation. Recently, DHCS has sent letters asking hospitals to conduct "self-audits"

related to the federal 340B Program and report the results to DHCS. DHCS relied, in part, on authority under the federal 60-day report and return law.

In the past, OIG has sometimes used letter requests to obtain records from hospitals as part of national initiatives to determine whether certain categories of claims are being improperly submitted and paid.

B. Civil Investigative Demand

A DOJ civil investigative demand (CID) is similar to a subpoena and authorizes the DOJ to obtain documents, oral deposition testimony, and answers to interrogatories relating to a federal civil investigation under the FCA of potential false claims.

Local civil Assistant U.S. Attorneys can issue a CID requiring the production of relevant documents and requiring the person who has possession, custody, or control of the documents to answer interrogatories or give oral testimony under oath about the requested information.

If a hospital receives a CID (issued under 31 U.S.C. Section 3733), then the hospital's attorneys should be immediately notified. Such a CID likely indicates that a civil FCA case has been filed by a whistleblower against the hospital and the federal government is investigating the alleged false claims to determine whether it should take over and prosecute the civil lawsuit against the hospital.

C. Administrative Subpoena

The DOJ and local U.S. Attorney's Offices may issue administrative subpoenas (known as "investigative demands") to obtain records for criminal investigations relating to federal health care crimes [18 U.S.C. Section 3486].

Such an administrative subpoena may *not*:

1. Compel witness testimony, other than the authenticating testimony of a custodian of the records being produced;
2. Require production of the records at a location more than 500 miles from the hospital; or
3. Require immediate production of records at the time it is served.

If a subpoena issued pursuant to 18 U.S.C. Section 3486 is received, immediately contact the hospital's compliance officer and/or attorney, because such a subpoena may mean the hospital is the target of a criminal health care fraud investigation.

Compliance Tip: While both routine audit requests and investigative enforcement requests for information will often ask for medical records, the following categories of requested information often indicate that the hospital is the target of a civil false claims or a criminal health care fraud or kickback investigation:

- Medical and claim records for patients who all received the same procedure or item;
- Medical and claim records for patients who all received services ordered by the same physician;
- Contracts and financial records relating to the hospital's financial relationships with physicians and other referral sources, or with outside vendors, including marketers;
- Current or former employee lists or other employee records; or
- Information about the hospital's record retention or destruction policies.

D. Grand Jury Subpoena

If a federal or state grand jury is conducting a criminal investigation of health care fraud, it may issue subpoenas to persons (including hospitals) compelling them to provide relevant documents or oral testimony to the grand jury.

As a practical matter, once a grand jury is convened, any USAO or DMFEA prosecutor can issue subpoenas on its behalf as part of a criminal health care fraud investigation.

In cases of subpoenas which only request documents, no appearance of the custodian is usually required and the subpoena will instead permit the records to be sent to the prosecutor or one of the investigating agents by mail, accompanied by an appropriate certification by the custodian.

While receipt of a grand jury subpoena does not necessarily mean that the hospital is the target of the possible crimes being investigated, the hospital's compliance officer and/or attorneys should still be contacted immediately. By handling the subpoena production, the hospital's attorneys will usually be able to quickly determine whether the hospital is being investigated or is simply in possession of evidence relevant to the investigation of someone else.

E. Search Warrant

Execution of a search warrant by a federal or state law enforcement agency at a hospital is a very rare event because agents can usually obtain all the evidence they need for a criminal health care fraud investigation through subpoenas.

When agents execute a warrant at a hospital by securing the location and searching for records themselves, this inevitably means that the hospital is the target of a very serious criminal investigation and that the government believes that there is a significant risk that relevant hospital records may be hidden or destroyed.

Note, however, that state agencies will sometimes use warrants as the equivalent of subpoenas to obtain hospital records. However, in that case, the agents will simply deliver the warrant to the hospital and usually permit the hospital to search for and produce the records sought by the warrant within a reasonable period of time.

If agents appear at a hospital with a warrant, hospital employees must comply with the agents' demands, but are not required to submit to questioning. The hospital's compliance officer and/or attorneys should be immediately contacted so that an attorney, rather than a hospital employee, can come to the hospital and assert any objections to the manner in which the warrant is being executed.

IV. RESPONDING TO GOVERNMENT REQUEST FOR INFORMATION

A hospital's response to a government request for information should be timely, comprehensive, organized, and well-documented. As further described below, critical components of an effective response usually include:

1. Notification of the hospital's compliance officer, in-house counsel, and/or outside attorneys;
2. Internal preservation of all potentially responsive information;
3. Written notice to key employees about the government request;
4. Appointment of a single custodian responsible for supervising the search for responsive documents and organizing them in a central repository; and
5. Initiation of an internal investigation into the subject matter of the underlying audit or investigation.

A. Notification of Hospital In-House Counsel, Compliance Officer and Outside Attorneys

Any time a hospital receives a government request for information, whether orally or in writing, that request should be sent immediately to the hospital's compliance officer or other designated point of contact for appropriate handling.

Other than with respect to routine letter audit requests, the compliance officer should be the sole hospital employee responsible for communicating with government employees; notifying the hospital's attorneys about the CID, subpoena, or warrant; and supervising and coordinating the hospital's response to a government request for information.

The compliance officer should immediately inform the hospital's attorneys about any CID, subpoena, or warrant, or any other request for information that does not seem to be part of routine claim processing or audit activity.

Hospital employees should be instructed that all government CIDs, subpoenas, warrants, or other contacts MUST be referred to the compliance officer. Likewise, hospital employees should understand that all hospital communications with a government investigator or auditor about the CID, subpoena, or warrant are handled by this officer.

Before communicating directly with a government auditor or investigator in person, the compliance officer or other hospital employee should request to see identification and request a business card.

Some hospitals may wish to have in-house counsel handle these responsibilities in lieu of the compliance officer. Hospital administration should be notified as appropriate.

B. Internal Preservation of Potentially Responsive Information

After receiving a CID, subpoena, warrant, or other non-routine government request for information, the hospital should suspend its routine document retention/destruction policy and put a "litigation hold" on all relevant documents and other information that appears relevant to the subject matter of the request. Hospital employees should be notified immediately in writing when the hospital triggers a "litigation hold" in response to a government request for information and the scope of the records being preserved.

The hospital's communication of its information preservation policy is critically important with respect to the preservation, location, and ability to later disclose electronically stored information (ESI), including emails and other data, that may be relevant to the government's investigation. Failure to appropriately preserve relevant ESI can expose the hospital to increased penalties and damages.

C. Written Notice to Key Hospital Employees

While a hospital never wants to unduly alarm its employees or unnecessarily publicize a government investigation that may conclude that the hospital behaved entirely appropriately, it is rarely possible to comprehensively respond to a CID, subpoena, or warrant, or other non-routine government request for information without involving a significant number of employees. In particular, the request will often involve records that may be located in different hospital departments, which usually requires some involvement of different department employees to be effective and efficient. In addition, human nature being what it is, hospital rumors will inevitably start once a non-routine government request for information is made relating to an investigation of the hospital.

As a result, in most cases where it appears the hospital is being investigated, it is a good idea to provide a written notice to all or some of the employees acknowledging the existence of, and the hospital's intent to fully cooperate with, the government investigation and generally describing the nature of the government request for information.

In addition, the notice should inform hospital employees of the possibility that they may be contacted by government investigators seeking information relevant to the investigation. This notice should NEVER inform or suggest to hospital employees that they cannot or should not talk to investigators if they wish to do so because this could be viewed by the government as an attempt to obstruct justice. However, the notice should inform hospital employees that the choice to talk with investigators and the location of any interview is entirely up to them. In addition, the notice should request that employees inform the hospital compliance officer and/or attorneys of any government contacts and also offer to have a hospital representative attend any interview with them and take notes if that would make them more comfortable. The notice should advise hospital employees to request to see identification and request a business card before communicating with someone claiming to be an investigator.

Compliance Tip: Occasionally, federal and state auditors and investigators will demand records or other information to which they are not legally entitled or otherwise behave illegally, aggressively, or rudely with hospital employees. However, DHHS may exclude a hospital from participation in the Medicare and Medi-Cal programs if the hospital intentionally obstructs a program audit or investigation. In addition, the OIG may impose a $15,000 per day civil monetary penalty on a hospital for failure to grant timely access, upon reasonable request, to OIG for an audit, investigation, or evaluation. As a result, hospital employees should not usually communicate directly with government auditors and investigators about their inappropriate conduct. Instead, they should immediately contact the hospital's attorneys so that the attorneys can raise necessary objections or complaints.

D. Appointment of Custodian of Records

In order to ensure that the hospital's response to a CID, subpoena, warrant, or other non-routine government request for information is comprehensive, organized, and well documented, the hospital should appoint a custodian of records to coordinate the search for documents and organize them in a central document repository.

All hospital employees who may have relevant documents should receive written instructions describing the documents that they are responsible for locating and sending to the custodian. Along with located documents, hospital employees should send a written memorandum describing the locations and methods of their search. Original documents should be sent to the custodian with copies retained if needed for ongoing operations.

Once all responsive records are gathered, the compliance officer and custodian should coordinate the manner and timing of the production of such documents to the government with the hospital's attorneys. Ordinarily, a review of all documents will be conducted by the attorneys to ensure that no attorney-client privileged materials are being produced. In addition, all documents produced to the government should be marked in a manner (usually by numeric bates stamping) that provides a definitive record of their production. The hospital should ensure both It and Its attorneys retain a copy of all documents provided to the government.

V. INTERNAL INVESTIGATION

The final and very important step of a hospital's response to a CID, subpoena, warrant, or other non-routine government request for information, is to conduct an internal investigation of the subject matter of the underlying audit or investigation.

Such an investigation serves the critical two purposes of:

1. Assessing the nature and extent of the hospital's liability, and
2. Staying ahead of the government's audit or investigation by being proactive with respect to the development and analysis of relevant information.

Such an internal investigation should always be conducted and supervised by the hospital's attorneys so that the investigation remains confidential and privileged until the hospital

determines that the results should, or must, be disclosed to a government agency. Note that for the purposes of report and repay obligations under what is known as the 60-day rule for reverse false claims, CMS expects hospitals to conduct and complete investigations, "at most 6 months from receipt of the credible information [of an overpayment], except in extraordinary circumstances." [81 Fed. Reg. 7654, 7662 (Feb. 12, 2016)] *(See chapter 15 for more information on the 60-day rule.)*

A. Communicate with the Government

The hospital's attorney should strongly consider contacting the government investigator to discuss the government's non-routine request for information. After communicating with the individual directing the government inquiry, the hospital attorney may have a better understanding of what is at issue and who may be relevant witnesses. If there is a government investigator identifiable from the documents, discuss the reason and background for the investigation. If there is any chance of further requests or interviews, counsel should request to coordinate any such requests. Even if the government investigator is not readily apparent from the investigation demand, the hospital can often learn the identity of the investigator by discussing the government inquiry with the special agent or other government contact that is identified in the request. At this time one should disclose the scope of representation that may exist for employees of the hospital.

This is also an opportunity to establish a good relationship and demonstrate an intent to cooperate. Of course, the utility of these discussions is dependent in large part on the cooperation of the government investigator, which varies based on the personality of the investigator and the focus of the investigation. Even if not much is accomplished in the initial contact, it is an important step to establishing a good rapport.

Communication efforts with the federal government should take into account the federal DOJ's October 2021 announcement[9] regarding changes to its corporate criminal enforcement policies. More specifically:

1. In government investigations, companies will need to identify all individuals involved in the misconduct and provide all non-privileged information about their involvement;
2. In charging decisions, DOJ will review companies' entire criminal, civil, and regulatory record; and
3. In corporate resolutions, there is no presumption against the imposition of a corporate compliance monitor[10], which may be imposed whenever DOJ prosecutors deem it appropriate to do so.

DOJ emphasized that these changes were only preliminary steps it would take in its renewed commitment to combatting corporate crime.

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[9] This information was relayed by Deputy Attorney General Lisa Monaco at the ABA's 36th National Institute on White Collar Crime and was put in writing in the DOJ's Oct. 28, 2021, Memorandum (the "Monaco Memo") available here: https://www.justice.gov/dag/page/file/1445106/download.

[10] A compliance monitor is an independent person appointed by the government to assess the sufficiency and effectiveness of the company's compliance program and adherence to the terms of settlement.

B. Evaluate and Assemble Investigation Team

At the very least, an internal investigation must include in-house counsel (unless, of course, counsel were implicated in the investigation). However, there is no hard and fast rule regarding whether a hospital can handle an internal investigation without involving outside counsel. Relevant factors would include the internal resources available, the experience of the internal investigators, the scope of the investigation, and the potential liability created by the investigation. If in-house counsel is sufficiently experienced and determines that internal resources are sufficient given the potential exposure and scope of the government inquiry, then it may be possible to proceed without involving outside counsel. However, when there is a significant government inquiry there may be inherent value in receiving perspective and feedback from someone who may not be as affected by institutional politics and culture. It also is most effective to consult outside counsel earlier in the investigation, so coordinated decisions can be made regarding document production and communications with the government.

Regardless of whether outside counsel is involved, the rest of the investigation team must be assembled. Depending on the size of the legal department and the scope of the investigation, it may be necessary to evaluate using other staff. In general, this is undesirable as an investigation should be protected by the attorney-client privilege to the fullest extent. Also, evaluation of witnesses and evidence is a key part of the investigation and is best performed by an experienced counsel. If non-legal resources will be used, then the attorney must be selective and consider the team's position with the hospital. For example, staff from the compliance department may have experience conducting investigations, but it may not be appropriate for the compliance department to conduct an internal investigation when it may not be clear whether the investigation could result in a self-disclosure. These decisions must be made on a case-by-case basis.

A good investigator knows the limits of his or her expertise. If an investigation involves an area of inquiry that requires expertise, then retention of an expert should be considered. The expert may also be able to provide input as to the evidence that should be assembled for review. When selecting an expert, one should consider whether the expert may be disclosed or merely retained and non-disclosed. Any expert who may be used and later disclosed will generally not be protected by the attorney-client privilege, so any correspondence with the expert would likely be discoverable by the government. Therefore, the hospital must be sensitive to correspondence with any experts from the time of initial contact. The hospital should also remember to have HIPAA business associate agreements in place with any experts that may review or receive protected health information.[11]

Again, a hospital may consider using internal experts to review, but this can pose unforeseen issues. For example, a hospital may have an investigation into cardiac services, and believe that there is an affiliated physician with the requisite expertise who could participate in the investigation and ask her to look at charts to provide her opinion regarding the services ordered and billed. This may be appropriate, but, among other things, it would be necessary to consider compensation to the physician. If no compensation were provided (and even if compensation is provided) there could be Stark or anti-kickback implications. An affiliated expert could also impact the perceived impartiality of a witness from the government's perspective.

[11] This would also extend to non-expert contractors that may be necessary for an investigation, such as copy companies or data processing contractors. They may propose their own agreements which should be carefully reviewed for compliance with state and federal health information privacy laws.

C. Identify Relevant Custodians and Data Sources

As was discussed above, it is important to preserve data and information that may be relevant to the government inquiry. The preservation is important not only to avoid allegations of impeding an investigation, but also to provide data and information for the investigation team to review. When evaluating the data and information to preserve, the hospital is also identifying relevant data sources and custodians. This can then be used to further the internal investigation.

For example, consider an investigation into hospital billing for a particular outpatient procedure. When evaluating preservation, the hospital will want to be sure to protect billing records from destruction. The hospital then considers who is involved with the creation of a billing record. The physician is often directing the care, but hospital coding staff may ultimately review a patient record and assign the appropriate billing codes for the procedures. Questions may have arisen over time regarding billing for certain specific procedures that involved various managers above the coding staff. The questions may have been addressed through internal system notes or through email. All of these individuals should be identified and evaluated as potential custodians. The hospital must also then preserve and consider reviewing the billing data, the system notes, and the email correspondence. Of course, the patient charts would likely be relevant and would also need to be preserved. Once this data is collected and reviewed, it may become apparent that other documents and evidence should be collected.

D. Review Documents and Evidence[12]

The preservation effort coupled with production of records will result in a set of documents and data to review. Some information may need to be shared with an expert for review and other information will be segregated. Reviewing documents should inform the investigator of relevant witnesses and follow-up investigation. There are various tools to assist with organizing and prioritizing evidence that has been reviewed. In-house counsel may set up internal databases. Outside counsel often has specialized software and document review tools to make review and organization efficient and more readily processed.

E. Conduct and Document Interviews

The investigator should have adequate preparation prior to meeting with a witness. Prior investigation efforts will determine how the witness fits into the investigation. This involves reviewing appropriate documents and drafting an appropriate interview outline. Of course, an investigator must also be skilled to react to the information that is being provided in the interview and be able to go off script, because that is frequently the best source of information. Therefore, an investigator should ask open-ended questions and listen carefully to responses. Although an investigator may be able to predict answers and want to make an interview more efficient, a witness who is able to talk freely will often share more information.

Conducting interviews can be intimidating for employees. It is important to provide appropriate disclosures and explanations while considering the need for secrecy. When conducting interviews, counsel should appropriately identify his or her role and representation of the hospital. The American Bar Association has provided a sample “warning” as follows:

12 This outline proceeds in a linear fashion for organization purposes, but an investigation is rarely so predictable. It is often necessary to have some preliminary discussion with custodians prior to reviewing relevant documents and evidence. Moreover, the investigation process is fluid and may require follow-up interviews or reviews, so while reviewing documents and interviewing witnesses are separated for this guide, it is unrealistic to expect to conduct an investigation in such a rote fashion.

I am a lawyer for or from [the hospital]. I represent only [the hospital], and I do not represent you personally. I am conducting this interview to gather facts in order to provide legal advice for [the hospital]. This interview is part of an investigation to determine the facts and circumstances of X in order to advise [the hospital] how best to proceed.

Your communications with me are protected by the attorney-client privilege. But the attorney-client privilege belongs solely to [the hospital], not you. That means that [the hospital] alone may elect to waive the attorney-client privilege and reveal our discussion to third parties. [The hospital] alone may decide to waive the privilege and disclose this discussion to such third parties as federal or state agencies, at its sole discretion, and without notifying you.

In order for this discussion to be subject to the privilege, it must be kept in confidence. In other words, with the exception of your own attorney, you may not disclose the substance of this interview to any third party, including other employees or anyone outside of the company. You may discuss the facts of what happened but you may not discuss this discussion.

Do you have any questions? Are you willing to proceed?

The investigator should evaluate the formality of the warning. It is not necessary to open an interview with this warning, and, in fact, it could undermine efforts to communicate effectively if the warning were the first statement from the investigator to the witness. However, prior to discussing the substance of the investigation, counsel should address the issues identified above and clearly explain his or her representation.

The import of the warning is Implicated in guidance from the DOJ. On Sept. 9, 2015, then Deputy Attorney General Sally Yates released a memorandum to all U.S. Attorneys entitled, "Individual Accountability for Corporate Wrongdoing." The thrust of the memorandum is a direction to federal prosecutors and investigators to focus on the role of individuals in perpetuating perceived corporate fraud and abuse. The guidance is a directive to pursue individuals and to ensure investigations are not resolved without considering potential action against individuals. Of significant import to the hospital is a suggestion that "… in order to qualify for any cooperation credit, corporations must provide to the Department all relevant facts relating to the individuals responsible for the misconduct…" This is an indication that, at least when the DOJ is involved, it is likely that discussions with individuals may have to be disclosed. Therefore, individuals who are interviewed by the hospital must be given an adequate disclosure.[13]

The investigator may also want to speak with former employees or non-employee witnesses not only to receive information, but to familiarize these individuals with the potential that the government may contact them. These interviews require careful consideration of privilege.

13 The memorandum also highlights the common issue of how to report the results of an investigation. Hospital policies should provide guidance regarding the chain of reporting and what to do if the individual who is expected to receive the report may also be the focus of the investigation. For example, if an executive officer is implicated, it may be necessary to consider reporting to the board.

For example, some third parties may be contractors or agents and clothed in the attorney-client privilege in a straightforward manner. However, some may involve relationships that would be subject to a joint defense or mutual interest agreement in order to provide some protection. Therefore, the investigator should identify third parties and what relationship they have with the hospital prior to contacting them.

Any interview should be carefully documented with notes. Some practitioners find it helpful to have a second person in the interview primarily to take notes. Others conduct the interview and take notes at the same time. Some may also consider recording the interview. There is no single approach appropriate for all circumstances. However, interview notes should be summarized and synthesized into witness summaries as soon as possible after the interview. Mental impressions and memories fade with time, so the best time to document an interview is immediately after it is conducted or as soon thereafter as possible.

F. Synthesize the Evidence and Follow Up

An investigation evolves over time. As documents and evidence are reviewed and witnesses are contacted, additional areas for investigation will be identified. As appropriate, these further areas will need to be developed. After the investigation has been sufficiently developed, the investigator can document the results in a risk assessment memorandum or investigation report. The format and detail vary with the facts and circumstances of every case. For example, in some cases, no written report will be made. If a report will be made, one of the most important considerations is circulation of the report. An investigator should be careful to protect privileges and only circulate appropriately.

G. Waiver of Privilege and Self-Disclosure

In addition to being a self-assessment tool, a goal of an investigation may be to disclose the results to the government. A primary method of self-disclosure is the OIG's Health Care Fraud Self-Disclosure Protocol (the "Protocol") which provides a process to voluntarily identify, disclose, and resolve instances of potential fraud involving a federal health care program for which the disclosing party may be liable. The Protocol provides guidance regarding how to investigate health care fraud, quantify the damages of health care fraud, and how to report such conduct to the government. On Nov. 8, 2021, the Office of Inspector General (“OIG”) issued multiple updates to the Protocol, the first such revisions since 2013. One revision included an update to the minimum settlement amounts under the Protocol. The minimum settlement amount for kickback-related submissions was increased from $50,000 to $100,000. The OIG also increased the settlement amount for all other Protocol matters from $10,000 to $20,000. The Protocol was also updated to require that self-disclosures include an estimate of the amount of damages caused to each federal health care program and a sum of all damages caused to all federal health care programs relevant to the disclosed conduct. OIG further clarified that it would coordinate with the DOJ to resolve Protocol matters and cases involving potential criminal conduct. *(See chapter 15 for details about the OIG's Health Care Fraud Self-Disclosure Protocol.)*

Any decision to share information with the government must be carefully vetted and considered. Government investigators and attorneys sometimes pressure subjects and targets to share the investigation as part of a showing of cooperation. Counsel must be careful to resist the pressure to the extent appropriate. It may be that certain facts should be disclosed, but rarely will it be appropriate to disclose privileged correspondence or attorney

impressions developed through the course of the investigation. Regardless, the decision to waive privileged information or disclose facts should be made by fully informed counsel after thorough discussion with the hospital-client.

H. Using the Results of the Investigation

The investigation may have been used primarily for risk assessment, but the investigation process may uncover problematic practices. The compliance department may need to stop certain conduct or provide guidance and training to improve compliance going forward. Therefore, the goal of an investigation must not only be to generate a valuable risk assessment report, but also to provide a tool to improve operations going forward. The results of any investigation should be well documented. Any needed policy, training, or process changes based on the results of the investigation should be implemented to improve the compliance program on a go-forward basis.

17 Surprise Billing and Price Transparency

I. Introduction 17.1

A. Background 17.1

B. Recent Federal Rulemaking 17.2

C. Web Resources 17.4

D. Definitions under the No Surprises Act 17.4

II. Restrictions on Balance Billing for Emergency Services 17.5

A. Federal Law: The No Surprises Act 17.6

General Rule 17.6

Exception for Post-Stabilization Services: Notice and Consent 17.6

Scope of Patient's Consent to Balance Billing 17.9

Record Retention 17.9

Notification to Payer 17.9

B. State Law: Knox-Keene Act 17.9

III. Restrictions on Balance Billing for Non-Emergency Services Performed by Nonparticipating Providers at Participating Facilities 17.10

A. Federal Law: No Surprises Act 17.11

General Rule 17.11

Exceptions: Notice and Consent 17.11

Content of Notice 17.13

Consent Form 17.13

Additional Prohibition on Balance Billing 17.14

Record Retention 17.15

Notification to Payer 17.15

B. State Law: AB 72 ..... 17.15

IV. Miscellaneous Compliance Considerations 17.17

A. Uncertainty About Patient's Coverage 17.17

B. Cancelled Appointment Charges 17.18

C. Declining to Provide Care 17.18

D. Acceptance of Provider Relief Funds or HRSA Funds 17.18

V. Price Transparency Laws 17.18

A. Providing Chargemaster to the Public 17.18

Posting Notices 17.19

B. Federal Price Transparency Requirements: Disclosure of Payer-Specific Negotiated Rates and other "Standard Charges" 17.19

Machine-Readable File Requirements 17.20

Requirements for Displaying Shoppable Services in a Consumer-Friendly Manner 17.21

Price Estimator Tool as Alternative to Consumer-Friendly List 17.21

Civil Monetary Penalties 17.22

C. Reporting Charges to HCAI and Patients 17.22

VI. Required Notices to Patients 17.23

A. Federal Good Faith Estimate Notice 17.23

B. Federal Balance Billing Disclosures 17.23

Content of Disclosure Notice 17.23

Dissemination of Notices 17.24

Language Access 17.25

Exceptions: No Disclosure Notice Required 17.25

Practitioners Providing Services in a Facility 17.25

C. State Law — Outpatient Clinics 17.26

Definitions 17.26

D. State Law — Ancillary Services 17.27

Which Providers Must Provide Notice 17.27

Exception 17.27

Definitions 17.27

VII. Providing Estimates to Patients 17.28

A. Insured Patients 17.28

B. Uninsured and Self-Pay Patients 17.29

State Law 17.29

Federal Law 17.29

17 Surprise Billing and Price Transparency

I. INTRODUCTION

A. Background

California has had laws on the books for many years governing balance billing and surprise billing. However, the same has not been true in other states or at the federal level. As a result, members of Congress have felt political pressure to help their constituents avoid surprise medical bills and to take them out of the middle of disputes between payers and providers over appropriate reimbursement amounts. In response to this political pressure, the No Surprises Act (NSA) was passed by Congress and signed by the President as part of the Consolidated Appropriations Act of 2021.

The NSA is intended to protect patients in job-based health plans or individual health insurance coverage from surprise bills when they receive emergency services, non-emergency services from nonparticipating providers at participating facilities, and air ambulance services from nonparticipating providers. The NSA also gives patients the right to receive estimates in advance, and to notification about various rights they are granted under federal law.

What is a surprise bill? As background, it's important to understand that most health plans have a network of providers and health care facilities (participating providers or preferred providers) who agree by contract to accept a specific amount for their services. Providers and facilities that are not part of a plan's network often charge higher amounts than the contracted rates that plans have negotiated with participating providers and facilities. When an insured patient receives care from a nonparticipating provider, the payer may decline to pay for the service or may pay an amount less than the provider's billed charges, subjecting the patient to greater cost-sharing requirements than would have been charged had the services been furnished by a participating provider. Prior to the No Surprises Act, the nonparticipating provider could generally balance bill the individual for the difference between the provider's billed charges and the sum of the amount paid by the plan and the cost sharing paid by the patient, unless otherwise prohibited by state law (California law did prohibit this practice in many cases). A balance bill may come as a surprise for the patient. A surprise medical bill is an unexpected bill from a health care provider or facility that occurs when a patient receives services from a provider or facility that, often unknown to the patient, is a nonparticipating provider or facility and does not accept the plan's reimbursement as payment in full. Surprise billing occurs both for emergency and non-emergency care. [86 Fed. Reg. at 36874] The amount of the bill, or the "balance bill" is the difference between (1) the provider's billed charges, and (2) the amount paid by the health plan plus the amount collected from the patient in the form of cost sharing (such as a copayment, coinsurance, or amounts paid toward a deductible). Out-of-network providers often seek to collect the balance bill from the patient.

This chapter explains state and federal restrictions on balance billing and related state and federal laws that hospital compliance officers should understand. Portions of the law related to calculation of reimbursement amounts, air ambulances, and payer obligations are not covered in this chapter. Readers of this manual should be aware that various federal agencies are issuing new rules and guidance on an ongoing basis, and several lawsuits have been brought challenging the legality of various provisions of the NSA. For these reasons, it is important to consult your legal counsel for guidance and the latest updates.

Finally, this chapter also describes state requirements that hospitals make their chargemasters public and federal requirements that hospitals make public their gross charges, payer-specific negotiated charges, de-identified minimum and maximum negotiated charges, and discounted cash price (collectively, "standard charges") for all items and services in a machine-readable file. In addition, hospitals must either make public their standard charges for at least 300 shoppable services and ancillary services in a consumer-friendly manner, or maintain an internet-based price-estimator tool that provides estimates for at least 300 shoppable services.

Key Chapter Compliance Tips:

1. Develop a process for billing out-of-network services.
2. Make public all of the hospital's standard charges in a machine-readable file and, for at least 300 shoppable services, provide a consumer-friendly disclosure of standard charges or an online price-estimator tool.
3. Make public and provide to patients information regarding legal protections against balance billing.
4. Identify uninsured and self-pay patients and provide a good-faith estimate for each item or service along with those items and services reasonably expected to be provided In conjunction with the primary item or service upon patient request or scheduling of a service.

B. Recent Federal Rulemaking

As mentioned above, the NSA was enacted in 2021. Several federal agencies are charged with implementing and enforcing its provisions:

1. The Office of Personnel Management, which administers the Federal Employees Health Benefits (FEHB) program.
2. The Internal Revenue Service (IRS), Department of the Treasury.
3. The Employee Benefits Security Administration, Department of Labor (DOL), which regulates health benefit plans subject to the Employee Retirement Income Security Act (ERISA).
4. The Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

These agencies have worked together to achieve consistency in their regulations and published two interim final rules with comment requested as well as one proposed rule. An interim final rule with comment requested is a regulation package that takes effect before the

federal government has received and considered comments from the public. A proposed rule does not take effect until the federal government has considered public comments and published a final rule.

Each rule includes a "preamble" explaining the background and intent of the regulations as well as the exact language of the new regulations or amendments to existing regulations that will take effect on the specified date(s). The federal agencies will consider comments from the public and then issue a final rule, which may be the same as, or different from, the interim final rule or the proposed rule. It will take several months, at least, for the final rules to be published.

The NSA rules include:

1. Surprise Billing Part I — This 114-page interim final rule with comment requested was released on July 1, 2021, and published in the Federal Register on July 13, 2021. It includes requirements for both payers and providers. Topics include surprise billing prohibitions and exceptions, calculating payers' initial payment amounts for emergency services and patient cost-sharing amounts, prohibition on prior authorization for emergency services, providing notices to patients, and related matters. Providers and payers must comply with the rule starting Jan. 1, 2022 (although the technical effective date was Sept. 13, 2021). Comments were due Sept. 7, 2021. The rule is found at 86 Fed. Reg. 36872 (July 13, 2021).
2. Surprise Billing Part II — This 163-page interim final rule with comment requested was released on Sept. 30, 2021, and published in the Federal Register on Oct. 7, 2021. It establishes a federal independent dispute resolution process for use when a payer and provider cannot agree on an appropriate out-of-network payment amount for emergency services, nonemergency services furnished by nonparticipating providers at participating facilities, or air ambulance services furnished by nonparticipating providers. This rule also addresses requirements for providers to give good faith estimates to uninsured or self-pay patients and the associated patient-provider dispute resolution process, as well as a way to appeal certain payer decisions. The NSA requirement to provide a good faith estimate to insured patients has been delayed indefinitely and is not included in this interim final rule. Providers and payers must comply with the rule starting Jan. 1, 2022 (although the technical effective date was Oct. 7, 2021). Comments were due Dec. 6, 2021. The rule is found at 86 Fed. Reg. 55980 (Oct. 7, 2021).
3. Transparency and Enforcement — This 50-page proposed rule was released on Sept. 10, 2021, and published in the Federal Register on Sept. 16, 2021. It describes how HHS will investigate potential violations of the No Surprises Act by providers and payers, and take enforcement action, including imposing civil money penalties. The rule will also require payers to submit information about insurance agent and broker commissions to the federal government, and payers and air ambulances to submit data about air ambulance costs. At this time there is no effective date — the federal government will consider comments before issuing a final rule. Comments were Oct. 18, 2021. The rule is found at 86 Fed. Reg. 51730 (Sept. 16, 2021).

The Consolidated Appropriations Act of 2021 also included provisions regarding transparency in plan and insurance identification cards, continuity of care, accuracy of provider network directories, prohibition on gag clauses, good faith estimates for insured patients, and pharmacy benefit and drug cost reporting. No regulations have been issued yet on these topics. CHA will inform its members of developments affecting hospitals as they take place.

C. Web Resources

CMS maintains a webpage (www.cms.gov/nosurprises) with each NSA interim final rule, press releases, fact sheets, model notices, and other information. In addition, the California Hospital Association maintains a webpage (https://calhospital.org/no-surprises-act/) with NSA resources, including rule summaries and webinars.

D. Definitions under the No Surprises Act

"Authorized representative" means an individual authorized under state law to provide consent on behalf of a patient, provided that the individual is not a provider affiliated with a facility or an employee of a provider or facility (either treating the patient or represented in the good faith estimate, as applicable) unless the provider or employee is a family member of the patient. [45 C.F.R. Sections 149.410(b)(3) and 149.610(a)]

Chapters 3 and 4 of CHA's *Consent Manual* describe state laws regarding who may consent on behalf of an incapacitated adult patient or a minor patient, respectively. (In some states, health care providers may consent to medical treatment on behalf of patients in certain circumstances. For this reason, the federal regulation states that the authorized representative for purposes of agreeing to balance billing may not be a provider affiliated with the facility or an employee of the facility, unless the provider or employee is a family member of the patient. However, California does not allow health care providers to consent to care on behalf of patients in a hospital or other health care facility as defined in the NSA regulations.)

"Emergency medical condition" means a medical condition, including a mental health condition or substance use disorder, manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in:

1. Placing the health of the patient (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy;
2. Serious impairment to bodily functions; or
3. Serious dysfunction of any bodily organ or part.

[45 C.F.R. Sections 149.30 and 149.110(c)(1)]

"Emergency services" means, with respect to an emergency medical condition:

1. An appropriate medical screening examination (as required under EMTALA) that is within the capability of the hospital's emergency, including ancillary services routinely available to the emergency department to evaluate the emergency medical condition; and
2. Within the capabilities of the staff and facilities available at the hospital, further medical examination and treatment as required under section 1867 of the Social Security Act (42 U.S.C. 1395dd), to stabilize the patient (regardless of

the department of the hospital in which this further examination or treatment is furnished).

[45 C.F.R. Sections 149.30 and 149.110(c)(2)]

[EMTALA (The Emergency Medical Treatment and Labor Act), 42 U.S.C. Section 1395dd; 42 C.F.R. Sections 489.20 and 489.24]

"Health care facility" means a hospital, hospital outpatient department, critical access hospital, and ambulatory surgical center [45 C.F.R. Section 149.30].

"Payer" is not a term defined in the No Surprises Act, but for purposes of this chapter, this term is used for ease in reading to mean a group health plan, group or individual health insurance coverage offered by a health insurance issuer, or a carrier in the Federal Employees Health Benefits (FEHB) Program.

"Post-stabilization services" means services provided by a nonparticipating provider or nonparticipating emergency facility (regardless of the hospital department in which the items or services are furnished), after the patient is stabilized and as part of outpatient observation or an inpatient or outpatient stay with respect to the visit in which the emergency services are furnished.

"To stabilize" means, with respect to an emergency medical condition, to provide medical treatment as necessary to assure, within reasonable medical probability, that no material deterioration of the condition is likely to result from, or occur during, the transfer of the individual from a facility, or, with respect to a pregnant woman who is having contractions, to deliver the infant and placenta [42 U.S.C. Section 1395dd(e)(3); 45 C.F.R. Section 149.110].

"Visit," with respect to items and services furnished to a patient at a health care facility, includes, in addition to items and services furnished by a provider at the facility, equipment and devices, telemedicine services, imaging services, laboratory services, and preoperative and postoperative services, regardless of whether the provider furnishing these items or services is at the facility [45 C.F.R. Section 149.30]. For example, if a sample is collected during an individual's hospital visit and sent to an off-site laboratory, the laboratory services are considered to be part of the visit at the participating health care facility, if laboratory services are covered by the payer. Similarly, if an individual receives a consultation with a specialist via telemedicine during a visit to a participating hospital, the telemedicine services are considered part of the visit to a participating facility. [86 Fed. Reg. at 36883] Note that for purposes of the NSA regulations, "visit" is not limited to an outpatient visit — it can include inpatient, emergency department, and observation services as well.

II. RESTRICTIONS ON BALANCE BILLING FOR EMERGENCY SERVICES

Both state and federal laws limit the ability of facilities and other health care providers to balance bill patients who received emergency services. Balance billing refers to the practice of out-of-network providers billing patients for the difference between (1) the provider's billed charges, and (2) the amount collected from the health plan plus the amount collected from the patient in the form of cost sharing (such as a copayment, coinsurance, or amounts paid toward a deductible).

Most health plans have a network of providers and health care facilities (participating providers or preferred providers) who agree by contract to accept a specific amount for their

services. Providers and facilities that are not part of a plan's network often charge higher amounts than the contracted rates that plans have negotiated with participating providers and facilities. When a patient receives care from a nonparticipating provider, the payer may decline to pay for the service or may pay an amount less than the provider's billed charges, subjecting the patient to greater cost-sharing requirements than would have been charged had the services been furnished by a participating provider. Prior to the No Surprises Act, the nonparticipating provider could generally balance bill the individual for the difference between the provider's billed charges and the sum of the amount paid by the plan and the cost sharing paid by the patient, unless otherwise prohibited by state law (balance billing is prohibited in California in many cases). A balance bill may come as a surprise for the patient. A surprise medical bill is an unexpected bill from a health care provider or facility that occurs when a patient receives services from a provider or facility that, often unknown to the patient, is a nonparticipating provider or facility. Surprise billing occurs both for emergency and non-emergency care. [86 Fed. Reg. at 36874]

This part of the chapter describes state and federal restrictions on balance billing.

A. Federal Law: The No Surprises Act

The No Surprises Act restricts balance billing by a health care facility or provider that provides services to patients for an emergency medical condition, if the patient is a participant, beneficiary, or enrollee covered by a group health plan, group or individual health insurance coverage offered by a health insurance issuer, or carrier under the Federal Employees Health Benefits Program [see 45 C.F.R. Section 149.410]. For ease in reading, the term "patient" is used in place of "participant, beneficiary, or enrollee of a group health plan, group or individual health insurance coverage offered by a health insurance issuer, or carrier under the FEHB program." In instances where more clarity is needed, it is provided by using the lengthier description.

California hospitals and other health care providers must also comply with state law restrictions on balance billing, described in B. "State Law: Knox-Keene Act," page 17.9.

General Rule

Starting Jan. 1, 2022, nonparticipating health care facilities and nonparticipating providers are restricted from balance billing a patient (or holding a patient liable) who is covered by a plan listed above for amounts greater than the patient's cost-sharing amount for emergency services, as determined by the payer in accordance with applicable law. Specifically, facilities and providers are completely prohibited from billing more than the cost-sharing amount for services provided to a patient prior to stabilization. Under certain circumstances, as described below, a facility or provider may balance bill a patient for post-stabilization services.

Exception for Post-Stabilization Services: Notice and Consent

The balance billing prohibition does not apply to post-stabilization items and services if all of the following four conditions are met:

1. Patient's ability to travel. The attending emergency physician or treating provider must determine that the patient is able to travel using nonmedical transportation or nonemergency medical transportation to an available participating provider or facility located within a reasonable travel distance, taking into account the patient's medical condition. There is no guidance at this time as to what constitutes a "reasonable" travel distance. The preamble to the rule states that:

> [T]he Departments recognize that an individual's transportation options may vary based on the individual's location, social risk, and other risk factors. In cases of underserved and geographically isolated communities and those with social risk factors related to income and transportation options, individuals may face additional barriers to obtaining post-stabilization services without a disruption in care. For example, individuals may not have the ability to pay for a taxi, may not have access to a car, may not be able to safely take public transit due to their medical condition, or may not have public transit options available. In these cases, the net effect would be the same: The individual would face unreasonable travel burdens that could prevent them from being able to consent freely to a waiver of the otherwise applicable balance billing protections. The Departments expect the attending emergency physician or treating provider to consider such factors when assessing the individual's ability to travel to a participating provider or facility. [86 Fed. Reg. at 36880]

Although the preamble to the rule contains the language cited above regarding "unreasonable travel burdens," it is not included in the text of the regulations themselves. The regulations themselves only mention ability to travel "to an available participating provider or facility located within a reasonable travel distance, taking into account the individual's medical condition." There is no additional guidance available on whether or how to consider socioeconomic factors.

The attending emergency physician's or treating provider's determination about ability to travel using nonmedical or nonemergency medical transportation is binding on the facility.

2. Notice and consent. The provider or facility furnishing the post-stabilization services must satisfy the notice and consent criteria described under "Exceptions: Notice and Consent," page 17.11, with respect to the items and services, as well as the following additional requirements:

    a. In the case of a participating emergency facility and a nonparticipating provider, the written notice must include (i) a list of any participating providers at the facility who are able to furnish the items and services involved and (ii) notification that the patient may be referred, at the patient's option, to a participating provider.

    b. In the case of a nonparticipating emergency facility, the written notice must include the good faith estimated amount that the patient may be charged by the facility and other providers *(see VII. "Providing Estimates to Patients," page 17.28, for detailed information about the requirements of a good faith estimate)*.

HHS has stated its view that patients cannot consent to waive balance billing and cost-sharing protections unless they have been informed of their potential liability with respect to both the facility and provider charges related to receiving post-stabilization services at a nonparticipating emergency facility. Therefore, nonparticipating hospitals must include in the written notice the good faith estimated amount that the patient may be charged for items or services furnished by nonparticipating physicians and other nonparticipating providers (including any reasonably expected items and services). HHS has stated that, to the extent the nonparticipating facility omits from the good faith estimate information about items and services provided by a nonparticipating provider, the notice and consent criteria

will be not be considered met for items and services furnished by that provider. [86 Fed. Reg. at 36907]

3. Capacity to consent. The patient or authorized representative must be in a condition to (a) receive the information as determined by the attending emergency physician or treating provider using appropriate medical judgment, and (b) provide informed consent (as described in "Exceptions: Notice and Consent," page 17.11).

The preamble to the rule states that the treating provider must make this determination based on all the relevant facts and circumstances and should apply the same principles as they would when determining if a patient is able to provide informed consent for treatment — that is, whether the patient is capable of understanding the information and the implications of consenting. Consideration must be given to the patient's emotional state at the time of consent, the effect of any alcohol or legal or illegal drug use, and any pain. The preamble also states that:

> In addition, consideration must be given to cultural and contextual factors that may affect the informed decision-making and consent process for members of underserved communities, including lack of trust arising from historical inequities, misinformation about the informed consent process, or barriers to comprehension of the information given through the informed consent process and after the informed consent document is signed. These barriers may include accessibility, language, and literacy barriers. [86 Fed. Reg. at 36881]

The preamble also notes that consent must be made voluntarily and freely, without undue influence, fraud, or duress. HHS states that, "if post-stabilization services must be provided quickly after the emergency services are provided, it may be challenging for the individual or their authorized representative to have adequate time to make a clear-minded decision regarding consent. Consent obtained through a threat of restraint or immediacy of the need for treatment is not voluntary." [86 Fed. Reg. at 36881]

HHS is clear the post-stabilization notice and consent procedure should be applied only in limited circumstances, where the patient knowingly and purposefully seeks care from a nonparticipating provider or facility — such as wanting to be under the care of a specific provider or facility that they are familiar or comfortable with. This process should not be permitted to circumvent the consumer protections in the No Surprises Act. [86 Fed. Reg. at 36881]

If the patient does not have the requisite mental capacity to consent, an authorized representative may receive the information and provide consent. An authorized representative is a person permitted by state law to provide consent on the patient's behalf. Chapters 3 and 4 of CHA's *Consent Manual* describe state laws regarding who may consent on behalf of an incapacitated adult patient or a minor patient, respectively.

In some states, health care providers may consent to medical treatment on behalf of patients in certain circumstances. For this reason, the federal regulation states that the authorized representative for purposes of agreeing to balance billing may not be a provider affiliated with the facility or an employee of the facility, unless the provider or employee is a family member of the patient. However, California does not allow

health care providers to consent to care on behalf of patients in a hospital or other health care facility as defined in the NSA regulations.

4. Other requirements. The provider or facility must satisfy any additional requirements or prohibitions imposed by state law. In brief, California law prohibits emergency services providers from balance billing an enrollee of a health plan regulated by the Department of Managed Health Care (DMHC) under the Knox-Keene Act. More information about this prohibition is found in B. "State Law: Knox-Keene Act," page 17.9. The state law prohibition does not apply to health insurance products regulated by the California Department of Insurance. For these insureds, only the NSA federal law is applicable.

Scope of Patient's Consent to Balance Billing

A nonparticipating provider or nonparticipating facility is always subject to the balance billing prohibition for items and services furnished as a result of unforeseen, urgent medical needs that arise while post-stabilization services are being furnished after providing notice and obtaining the patient's consent. In other words, if a patient signs a Notice and Consent document for post-stabilization hand surgery at a nonparticipating facility, and suffers a heart attack during the surgery, the patient may be balance billed for the hand surgery, but not for the services provided to treat the heart attack. The heart attack services would be considered emergency services and subject to the NSA restrictions.

Record Retention

The facility must retain the written notice and consent for at least seven years after the date of service. A nonparticipating provider (such as a physician or medical group) may either retain the records itself, or coordinate with the facility to have the facility retain them for seven years.

Notification to Payer

For patients who are provided covered post-stabilization services, a nonparticipating provider or nonparticipating facility must notify the payer, when transmitting the bill, as to whether all four conditions listed above were met with respect to each item and service billed for. This notification must be on the bill or in a separate document. If the patient received a notice and signed a consent form, the provider or facility must provide the payer a copy of the signed written notice and consent document.

B. State Law: Knox-Keene Act

California law prohibits providers of emergency services, including but not limited to hospitals and hospital-based physicians such as radiologists, pathologists, anesthesiologists, and on-call specialists, from billing an enrollee of a health care service plan for amounts owed to the provider by the health care service plan or its capitated provider for the emergency services [28 CCR Section 1300.71.39]. This prohibition applies to health care service plans licensed under the Knox-Keene Act and regulated by the DMHC. It does not apply to insurance products regulated by the California Department of Insurance.

For purposes of this state law, **"emergency services"** means:

1. Medical screening, examination, and evaluation by a physician or other appropriate professional under the supervision of a physician and surgeon, to determine if

an emergency medical condition or active labor exists and, if it does, the care, treatment, and surgery necessary to relieve or eliminate the emergency medical condition, within the capability of the facility.

2. An additional screening, examination, and evaluation by a physician, or other personnel to determine if a psychiatric emergency medical condition exists, and the care and treatment necessary to relieve or eliminate the psychiatric emergency medical condition, within the capability of the facility. The care and treatment necessary to relieve or eliminate a psychiatric emergency medical condition may include admission or transfer to an acute psychiatric hospital or a psychiatric unit in a general acute care hospital.

"Active labor" means labor at a time at which either of the following would occur:

1. There is inadequate time to effect safe transfer to another hospital prior to delivery.
2. A transfer may pose a threat to the health and safety of the patient or the unborn child.

"Psychiatric emergency medical condition" means a mental health disorder that manifests itself by acute symptoms of sufficient severity that the patient is either of the following:

1. An immediate danger to himself or herself or to others.
2. Immediately unable to provide for, or utilize, food, shelter, or clothing, due to the mental disorder.

[Health and Safety Code Sections 1317.1 and 1371.4(i)]

The terms "emergency medical condition" and "stabilized" or "stabilization" have the same meanings as provided in the NSA *(see D. "Definitions under the No Surprises Act," page 17.4)*.

Emergency services providers may bill enrollees for co-payments, coinsurance and deductibles — these amounts are considered to be the financial responsibility of the enrollee, not amounts owed to the provider by the health care service plan.

III. RESTRICTIONS ON BALANCE BILLING FOR NON-EMERGENCY SERVICES PERFORMED BY NONPARTICIPATING PROVIDERS AT PARTICIPATING FACILITIES

Both state and federal law limit the ability of nonparticipating providers who render services in a participating facility to balance bill patients. This part of the chapter describes these restrictions.

A. Federal Law: No Surprises Act

General Rule

Starting Jan. 1, 2022, a nonparticipating provider who provides covered items or services at a participating facility is prohibited from billing a patient (or holding a patient liable) for amounts greater than the patient's cost-sharing amount, as determined by the payer in accordance with applicable law [45 C.F.R. Section 149.420]. As a reminder, this law applies

to a participant, beneficiary, or enrollee of a group health plan, group or individual health insurance coverage offered by a health insurance issuer, or carrier under the FEHB program.

If the patient is receiving emergency services (including post-stabilization services), the law described under II. "Restrictions on Balance Billing for Emergency Services," page 17.5, applies. If the patient is receiving non-emergency services, an exception exists, as described under "Exceptions: Notice and Consent," page 17.11.

California noncontracting individual health professionals must also comply with state law restrictions on balance billing, described in B. "State Law: AB 72," page 17.15.

A facility that has a single case agreement with a payer for a particular patient is considered a "participating facility" for that patient. Therefore, if non-emergency services are furnished by a nonparticipating provider at a health care facility that has a single case agreement with respect to a patient (as opposed to an agreement that applies to all the payer's patients), the non-emergency services are subject to the protections described in this part of the chapter. [86 Fed. Reg. at 36882]

Exceptions: Notice and Consent

The general rule prohibiting balance billing does not apply to covered items and services if the provider takes all of the following steps listed below. Nonparticipating providers are required to follow these steps only if they want to balance bill the patient. They can instead choose to accept the payer's payment plus the in-network cost-sharing amount as payment in full and forgo balance billing.

1. Provides the patient the Notice and Consent Document developed by HHS and filled in by the provider. The HHS document to be given to patients says at the very top, "Surprise Billing Protection Form." The instruction sheet for facilities and other providers says at the very top, "Standard Notice and Consent Documents Under the No Surprises Act." HHS has posted both documents together at www.cms.gov/files/document/standard-notice-consent-forms-nonparticipating-providers-emergency-facilities-regarding-consumer.pdf, but providers should not give the instructions to patients. Facilities and providers must use the HHS document unless the state develops a notice and consent document. At this time, California has not done so.

   The form requires providers to write in a cost estimate and to list providers who can furnish the items or services described in the notice and who are in-network with the patient's plan. It may be necessary to call a patient's plan to learn which providers are in-network.

   The NSA permits a participating health care facility to provide the Notice and Consent Document to the patient on behalf of nonparticipating physicians or other professionals. However, state law does not allow this. *See B. "State Law: AB 72," page 17.15.*

   The notice and consent must be provided on paper or in electronic form, as selected by the patient, and be given:

   a. In accordance with HHS guidance. This includes completing the blanks in the form appropriately before presenting it to the patient. HHS has stated that an

incomplete consent document is treated as a lack of consent and balance billing protections apply [86 Fed. Reg. at 36908]. In addition, a patient cannot provide informed consent to waive balance billing protections with respect to an unnamed provider. The patient may choose to consent to waive balance billing protections with respect to items or services furnished by none, some, or all of the nonparticipating providers listed in the notice. [86 Fed. Reg. at 36909]

b. Physically separate from other documents and not attached to or incorporated into any other document; and

c. To the patient in accordance with the following timeframe:

- If the appointment is scheduled at least 72 hours in advance, the notice must be provided not later than 72 hours before the date on which the patient is furnished the items or services; or
- If the appointment is scheduled less than 72 hours in advance, the notice must be provided on the date the appointment is scheduled. If a patient is provided the notice on the same date that the items or services are to be furnished, the notice must be provided no later than 3 hours before furnishing the items or services. (If state law also applies, however, the consent must be obtained at least 24 hours in advance, and may not be obtained at the time of admission or at any time when the patient is being prepared for surgery or any other procedure. *See B. "State Law: AB 72," page 17.15.*)

Given that the notice must include a good faith estimate — and the time it may take to obtain estimates from various providers — complying with the notice timeframes above may require making appointments longer in advance than otherwise necessary or rescheduling a patient.

2. Obtains the patient's or authorized representative's consent to be treated by the nonparticipating provider. The consent must meet the following requirements:

   a. Be provided voluntarily, meaning the patient is able to consent freely, without undue influence, fraud, or duress;

   b. Be obtained in accordance with, and in the form and manner specified in, HHS guidance; and

   c. Not be revoked, in writing, by the patient prior to the receipt of items and services to which the consent applies.

   An authorized representative — a person permitted by state law to provide consent on a patient's behalf — may consent if the patient lacks the mental capacity to do so.

3. Provides a copy of the signed notice and consent to the patient in-person or through mail or email, as selected by the patient.

Content of Notice

As mentioned above, HHS has developed a Notice and Consent Document. The notice must:

1. State that the health care provider is a nonparticipating provider.
2. Include the good faith estimated amount that the nonparticipating provider may charge the patient for the items and services involved. The estimate must include any item or service that is reasonably expected to be furnished by the nonparticipating provider in conjunction with these items or services. Multiple nonparticipating providers that are furnishing related items and services for a patient may provide a single notice to the patient, provided that:
    a. Each provider's name is specifically listed on the notice;
    b. Each provider includes a good faith estimate for the items and services they are furnishing, and the notice specifies which provider is providing which items and services in the estimate; and
    c. The patient has the option to consent to waive balance billing protections with respect to each provider separately. [86 Fed. Reg. at 36907]

    For self-pay patients, the good faith estimated amount is described in VII. "Providing Estimates to Patients," page 17.28. HHS will undertake a future rulemaking to provide guidance about good faith estimates for insured patients.
3. Inform the patient that providing the estimate or consent to be treated does not constitute a contract with respect to the estimated charges or a contract that binds the patient to be treated by that provider or facility.
4. State that prior authorization or other care management limitations may be required before receiving the items or services at the facility.
5. State that consent to receive the items and services from the nonparticipating provider is optional and that the patient may instead seek care from an available participating provider, and that if the patient seeks care from a participating provider, the patient's cost-sharing responsibility will not exceed the amount that applies to items and services furnished by a participating provider.

Consent Form

The consent form must be signed by the patient before the items and services are furnished, and it must:

1. Acknowledge that the patient has been:
    a. Provided the written notice described above, on paper or electronically as selected by the patient.
    b. Informed that the payment of the charges might not count toward meeting any limitation the payer places on cost sharing, including an explanation that the payment might not apply to an in-network deductible or out-of-pocket maximum applied under the plan or coverage.
2. State that by signing the consent form, the patient agrees to be treated by the nonparticipating provider and understands the patient may be balance billed

and subject to cost-sharing requirements that apply to services furnished by the nonparticipating provider.

3. Document the date and time on which the patient received the notice and the date and time the patient signed the consent form. HHS has stated that the time must be documented In order to ensure that consent is provided prior to when the item or service is received [86 Fed. Reg. at 36909]. There is no requirement that the notice be given a certain length of time before the consent is obtained (although there is a requirement that the notice be given a certain length of time before the items/services at issue are provided, as described in paragraph 1.c. on page 17.12).

4. Comply with language access requirements. A nonparticipating provider must provide the patient with the choice to receive the written notice and consent document in any of the 15 most common languages in either:

   a. The state in which the facility is located (in California, these languages are Spanish, Chinese, Vietnamese, Tagalog, Korean, Armenian, Persian (Farsi), Russian, Japanese, Arabic, Panjabi, Mon-Khmer/Cambodian, Hmong, Hindi, and Thai); or

   b. A geographic region that reasonably reflects the geographic region served by the facility.

   If the patient's preferred language is not one of these 15 languages and the patient cannot understand a language in which the notice and consent documents are provided, the notice and consent criteria are not met unless the nonparticipating provider has obtained the services of a qualified interpreter to help the patient understand the information in the notice and consent. HHS has stated that patients should be asked what language they prefer to communicate in regarding health care information, for written or verbal communication, as applicable. A patient's preference might not be the same for written and verbal communication, and a patient's preference might not correlate with his or her native language. [86 Fed. Reg. at 36910]

   In addition, other applicable state and federal interpreter services laws may apply, as well as laws requiring facilities and other providers to take appropriate steps to ensure effective communication with individuals with disabilities, including provision of appropriate auxiliary aids and services at no cost to the individual. Auxiliary aids and services may include sign language interpreters, large print materials, accessible information and communication technology, open and closed captioning, and other aids or services for persons who are blind or have low vision, or who are deaf or hard of hearing. *(See chapter 1 of CHA's* Consent Manual *for detailed information about these laws.)*

Additional Prohibition on Balance Billing

If all of the above conditions are met, the provider may balance bill. However, a nonparticipating provider is always subject to the balance billing prohibition and may never balance bill for the following services:

1. Ancillary services, meaning:

a. Items and services related to emergency medicine, anesthesiology, pathology, radiology, and neonatology, whether provided by a physician or non-physician practitioner;

b. Items and services provided by assistant surgeons, hospitalists, and intensivists;

c. Diagnostic services, including radiology and laboratory services; and

d. Items and services provided by a nonparticipating provider if there is no participating provider who can furnish the items or services at the facility.

2. Items or services furnished as a result of unforeseen, urgent medical needs that arise at the time an item or service is furnished, regardless of whether the nonparticipating provider satisfied the notice and consent criteria described above.

Record Retention

A participating health care facility that obtains the consent on behalf of a nonparticipating provider (which is not allowed when state law applies) must retain the notice and consent document for at least seven years after the date of service. If a nonparticipating provider obtains the consent, the provider may either coordinate with the facility to retain the notice and consent document for seven years, or the provider must retain it for seven years.

Notification to Payer

For each item or service furnished by a nonparticipating provider pursuant to the notice and consent provisions of this law, the provider must (1) timely notify the payer that the item or service was furnished during a visit at a participating health care facility, and (2) provide the payer a copy of the signed notice and consent document. In instances where, to the extent permitted by law, the nonparticipating provider bills the patient directly, the provider may satisfy the requirement to notify the payer by including the notice with the bill to the patient.

B. State Law: AB 72

California had already enacted laws restricting balance billing by nonparticipating providers in participating facilities prior to the enactment of the No Surprises Act. This part of the chapter describes these existing state laws, often referred to as "AB 72." They are codified at Health and Safety Code Section 1371.9 and Insurance Code Section 10112.8.

For purposes of this state law, a "contracting health facility" means a health facility that is contracted with the patient's payer and includes, but is not limited to, the following:

1. A hospital.

2. An ambulatory surgery or other outpatient setting, including a licensed primary care or surgical clinic, an accredited outpatient setting, and a setting, including, but not limited to, a mobile van, in which equipment is used to treat patients admitted to a facility but which setting is not a part of the facility. [Health and Safety Code Section 1248.1]

3. A laboratory.

4. A radiology or imaging center.

The state law restrictions on balance billing apply to patients who are covered by:

1. A health plan licensed under the Knox-Keene Act and regulated by the DMHC, except for a Medi-Cal managed care plan or other Medi-Cal contracted plan; and
2. A health insurance product regulated by the California Department of Insurance.

They apply to "individual health professionals," which means physicians or other professionals licensed in California to provide health care services. However, dentists are excluded from this definition.

If the patient's plan includes coverage for out-of-network benefits, a noncontracting individual health professional may bill or collect from the patient the out-of-network cost sharing only when the criteria listed below are met. If they are not met, the noncontracting individual health professional may only bill or collect the in-network cost-sharing amount. The criteria are:

1. The patient consents in writing at least 24 hours in advance of care to receive services from the identified noncontracting individual health professional.
2. The consent document is separate from any document used to obtain consent for any other part of the care or procedure.
3. The consent may not be obtained by the facility or any representative of the facility. (A facility can be a convening facility and coordinate good faith estimates among various providers, but cannot obtain consent in instances where state law applies.)
4. The consent may not be obtained at the time of admission or at any time when the patient is being prepared for surgery or any other procedure.
5. When consent is provided, the noncontracting individual health professional must give the patient a written estimate of the total out-of-pocket cost of care. The written estimate must be based on the professional's billed charges for the service to be provided. The noncontracting individual health professional may not attempt to collect more than the estimated amount without receiving separate written consent from the patient or the patient's authorized representative, unless circumstances arise during delivery of services that were unforeseeable at the time the estimate was given that would require the professional to change the estimate. (If circumstances arise during delivery of services that were unforeseeable at the time the estimate was given, the hospital should consider whether resulting unanticipated serves should be considered an emergency services and thus subject to the balance billing restrictions applicable to emergency services.)
6. The consent must advise the patient that he or she may elect to seek care from a contracted provider or may contact their health plan or insurer to arrange to receive the services from a contracted provider for lower out-of-pocket costs.
7. The consent and estimate must be provided to the enrollee in the language spoken by the patient, if the language is a Medi-Cal threshold language. Medi-Cal threshold languages are defined in Health and Safety Code Section 128552(c) as primary languages spoken by limited-English-proficient (LEP) population groups meeting a numeric threshold of 3,000, eligible LEP Medi-Cal beneficiaries residing in a county; 1,000 Medi-Cal eligible LEP beneficiaries residing in a single ZIP Code; or 1,500

LEP Medi-Cal beneficiaries residing in two contiguous ZIP Codes. The Medi-Cal threshold languages are found at www.dhcs.ca.gov/formsandpubs/Documents/MMCDAPLsandPolicyLetters/APL2021/LanguagesJuly2019.pdf. A provider will be in compliance with this requirement if it has available the federal Notice and Consent form in the 15 most common languages in California (Spanish, Chinese, Vietnamese, Tagalog, Korean, Armenian, Persian (Farsi), Russian, Japanese, Arabic, Panjabi, Mon-Khmer/Cambodian, Hmong, Hindi, and Thai).

8. The consent must advise the patient that any costs incurred by using the out-of-network benefit will be in addition to in-network cost-sharing amounts and may not count toward the annual out-of-pocket maximum on in-network benefits or a deductible, if any, for in-network benefits.

The payer must notify the patient and the professional of the cost-sharing amount when the payer pays the professional. Any communication from the noncontracting professional to the patient prior to the receipt of information about the in-network cost-sharing amount must include a notice in 12-point bold type stating that the communication is not a bill and informing the patient that the he or she may not pay until informed of the cost-sharing amount by the payer.

If a noncontracting professional receives more than the in-network cost-sharing amount from a patient, the professional must refund the overpayment to the patient within 30 calendar days of being informed of the cost-sharing amount. After 30 days, the professional will also be required to pay interest at the rate of 15 percent per annum beginning with the date payment was received from the patient. Interest must automatically be included in the refund without requiring the patient to specifically request it.

A noncontracting individual health professional, or any entity acting on his or her behalf, including any assignee of the debt, may not report adverse information to a consumer credit reporting agency or commence civil action against a patient for at least 150 days after the initial billing for amounts owed under this law. In addition, wage garnishments or liens on primary residences cannot be used as a means of collecting unpaid bills under this law.

IV. MISCELLANEOUS COMPLIANCE CONSIDERATIONS

A. Uncertainty About Patient's Coverage

HHS has stated that compliance with the NSA balance billing restrictions may require nonparticipating providers and nonparticipating emergency facilities to refrain from billing a patient directly, even in cases that are not subject to these requirements. For example, the protections applicable to non-emergency services provided by a nonparticipating provider in a participating health care facility apply only to services that are covered by the payer. A nonparticipating provider may not have the information necessary to determine whether the services are covered. As a result, the nonparticipating provider may need to bill the payer directly for the services in order to determine whether the protections apply. Otherwise, the provider risks violating the law by billing the patient.

HHS understands that nonparticipating providers and facilities frequently bill patients directly for out-of-network services, leaving the patient to submit the bill to the payer. If a provider or facility balance bills a patient in violation of the NSA, HHS may impose civil money penalties

in states where HHS is directly enforcing the law against providers and facilities. (At this time, HHS/CMS has not finalized an agreement with California determining which agency will enforce the NSA against providers and facilities.) However, the law requires HHS to waive penalties for a provider or facility who does not knowingly violate, and should not have reasonably known it violated, the law if the provider or facility, within 30 days of the violation, withdraws the bill and reimburses the payer or patient, as applicable, in an amount equal to the difference between the amount billed and the amount allowed to be billed under the law, plus interest, at an interest rate determined by the HHS. [86 Fed. Reg. at 36905

B. Cancelled Appointment Charges

HHS is aware that some providers and facilities charge fees for cancelled appointments. HHS is of the view that a patient cannot provide consent freely if a provider or facility will require him or her to pay a fee if the appointment is cancelled because the patient refuses or revokes consent to be balance billed [86 Fed. Reg. at 36905].

C. Declining to Provide Care

HHS has stated that a provider or facility may, subject to other state or federal laws, decline to treat a patient who does not consent to be balance billed in instances where the NSA allows the provider or facility to obtain consent for this [86 Fed. Reg. 36905]. However, providers and facilities should consider their contractual obligations, patient abandonment issues, potential medical malpractice lawsuits, public relations optics, and other factors when deciding whether to decline to provide further care to a particular patient.

D. Acceptance of Provider Relief Funds or HRSA Funds

Hospitals and other providers may be prohibited from balance billing patients with a presumptive or actual case of novel coronavirus 2019 (COVID-19) if they accepted distributions from the Department of Health and Human Services Provider Relief Fund. The terms and conditions associated with acceptance of these funds prohibit the recipient from collecting out-of-pocket expenses for care for a presumptive or actual case of COVID-19 in an amount greater than what the patient would have otherwise been required to pay if the care had been provided by an in-network provider. This rule also applies to providers that submit claims and accept reimbursement through the Health Resources & Services Administration COVID-19 Claims Reimbursement fund for testing uninsured individuals for COVID-19, for treating uninsured individuals with a COVID-19 primary diagnosis, or for COVID-19 vaccine administration to the uninsured.

V. PRICE TRANSPARENCY LAWS

The California Legislature and Congress have passed several laws related to hospital pricing transparency. This chapter describes legal requirements regarding providing the chargemaster to the public and to the Office of Statewide Health Planning and Development (OSHPD), now called the Department of Health Care Information and Access (HCAI); posting notices of the availability of the chargemaster; reporting specified charges to HCAI, and other related matters.

A. Providing Chargemaster to the Public

California law requires general acute care hospitals, acute psychiatric hospitals, and special hospitals that use a charge description master to make a written or electronic copy of it available, either by posting an electronic copy on its website, or by making a written or electronic version available at the hospital. For purposes of this requirement, **"charge description master"** or **"chargemaster"** means a uniform schedule of charges represented by the hospital as its gross billed charge for a given service or item, regardless of payer type.

Along with the chargemaster, the hospital must provide information about where to obtain information regarding hospital quality, including hospital outcome studies available from OSHPD and hospital survey information available from The Joint Commission. The law does not address hospitals that are accredited by other accreditation organizations, such as the American Osteopathic Association's Healthcare Facilities Accreditation Program (HFAP) or Det Norske Veritas Healthcare, Inc. (DNV Healthcare).

Hospitals that are both small and rural are exempt from these requirements. For purposes of this law, **"small and rural hospital"** means an acute care hospital that meets either of the following criteria:

1. Meets the criteria for designation within peer group six or eight, as defined in the report entitled "Hospital Peer Grouping for Efficiency Comparison," dated Dec. 20, 1982.
2. Meets the criteria for designation within peer group five or seven and has no more than 76 acute care beds and is located in an incorporated place or census designated place of 15,000 or less population according to the 1980 federal census.

[Health and Safety Code Sections 1339.51 and 124840]

Posting Notices

A hospital that uses a chargemaster must post a clear and conspicuous notice in its emergency department (if any), admissions office, and billing office that informs patients that the hospital's chargemaster is available and how it can be accessed [Health and Safety Code Section 1339.51(c)].

B. Federal Price Transparency Requirements: Disclosure of Payer-Specific Negotiated Rates and other "Standard Charges"

The ACA requires hospitals to establish, update and make public, on a yearly basis, a list of their standard charges for items and services. Previously, hospitals could satisfy this requirement by making public their policies for allowing the public to view a list of charges in response to an inquiry, or beginning on Jan. 1, 2019, by posting publicly online a list of chargemaster charges for all items and services in a machine-readable format. Effective Jan. 1, 2021, however, hospitals are required to disclose both their chargemaster charges and the rates that they have negotiated with third-party payers in two publicly available files: a machine-readable file with charges and negotiated rates for all items and services, and a consumer-friendly list that focuses on charges and negotiated rates for 300 "shoppable services." These requirements were proposed in the Calendar Year (CY) 2020 Hospital

Outpatient Prospective Payment System (OPPS) proposed rule [84 Fed. Reg. 39398 (Aug. 9, 2019)] (the "Price Transparency Proposed Rule") and finalized in the CY 2020 OPPS final rule issued Nov. 12, 2019 [84 Fed. Reg. 61142] (the "Price Transparency Final Rule"). CMS modified the Price Transparency regulations in the CY 2022 OPPS final rule [86 Fed. Reg. 63458 (Nov. 16, 2021)]. Although the Price Transparency Final Rule was the subject of a legal challenge, it was upheld by the D.C. Circuit [*Am. Hosp. Ass'n v. Azar*, 983 F.3d 528 (2020)] and the U.S. Supreme Court declined to hear the case.

The Price Transparency regulations apply to all hospital types, including small and rural hospitals, inpatient rehabilitation facilities, inpatient psychiatric hospitals, critical access hospitals, and sole community hospitals. CMS has provided a number of resources and FAQs on its website regarding compliance with the Price Transparency regulations at www.cms.gov/hospital-price-transparency/resources.

In the Price Transparency Proposed Rule, CMS characterized these requirements as "bold action ... to empower patients with price transparency." The Price Transparency Final Rule adopted an extremely broad definition of the "standard charges" that must be disclosed under PHSA Section 2718(e) in a manner that requires the disclosure not only of a hospital's chargemaster rates (which it now refers to as "gross charges") but also the following:

1. The **"discounted cash price,"** which is the 'charge' that applies to an individual who pays cash, or cash equivalents, for a hospital item or service.
2. The **"payer specific negotiated charge,"** which is the 'charge' that a hospital has negotiated with a third-party payer for an item or service. In the Final Rule, CMS clarified that payer-specific negotiated rates must be associated with both a payer and the specific health plan offered by that payer – in spite of hospitals' limited insight into the various kinds of health plans offered by each payer.
3. The **"de-identified" minimum negotiated charge,"** which is the lowest charge that a hospital has negotiated with a third-party payer for an item or service.
4. The **"de-identified" maximum negotiated charge,"** which is the highest charge that a hospital has negotiated with a third party payer for an item or service.

All of these kinds of "standard charges" must displayed in both formats, e.g., the machine-readable file and the consumer-friendly list of 300 shoppable services. More specific requirements are outlined below.

Machine-Readable File Requirements

1. Hospitals must provide a single digital file in machine-readable format. Acceptable machine-readable formats include, but are not limited to, .xml, .json, and .csv.
2. The file must be displayed prominently and clearly identify the hospital location with which the standard charges information is associated on a publicly available website using a CMS-specified naming convention.
3. Data must be updated at least annually, and the file must clearly indicate the date of the last update, either within the file itself, or in information clearly associated with the file.
4. The hospital must ensure the data is easily accessible, without barriers, including ensuring the data is accessible free of charge, does not require a user to establish

an account or password or submit Personal Identifying Information (PII), and is digitally searchable. Further, as of January 1, 2022, the data must be accessible to automated searches and direct file downloads through a link posted on a publicly available website.

CMS has posted resources, including an Aug. 11, 2021, presentation and a guide entitled "8 Steps to a Machine-Readable File of All Items & Services," designed to help hospitals understand and implement the requirements for the machine-readable file, at www.cms.gov/hospital-price-transparency/resources.

Requirements for Displaying Shoppable Services in a Consumer-Friendly Manner

A **"shoppable service"** is defined as a service that can be scheduled by a health care consumer in advance. The following requirements apply:

1. The hospital must display the required information about "standard charges" for a total of 300 shoppable services, including 70 specified by CMS in the Price Transparency Proposed and Final Rules (which include various evaluation and management services, laboratory and pathology services, radiology services, and medicine and surgery services), and an additional 230 selected by the hospital.

   NOTE: A hospital that offers fewer than 300 shoppable services may confine its consumer-friendly disclosure to those shoppable services it does offer.

   a. The hospital must provide a plain-language description of each shoppable service and any primary code used by the hospital for purposes of accounting or billing.

   b. The hospital must group the primary shoppable service with all ancillary services that the hospital customarily provides in conjunction with the primary shoppable service.

   c. The hospital must indicate the location at which the shoppable service is provided, and whether the standard charge for the shoppable service applies at that location to the provision of that shoppable service in the inpatient setting, the outpatient department setting, or both.

2. The information must be displayed prominently on a publicly available Internet location that clearly identifies the hospital location with which the information is associated.

3. The information must be easily accessible, without barriers, including ensuring the data is accessible free of charge, does not require a user to register, establish an account or password or submit PII, and is searchable by service description, billing code, and payer.

4. The information must be updated at least annually, and must clearly indicate the date of the last update.

CMS has posted resources, including an Aug. 11, 2021, presentation and a guide entitled "10 Steps to a Consumer-Friendly Display," designed to help hospitals understand and implement the requirements for the consumer-friendly display of shoppable services, at www.cms.gov/hospital-price-transparency/resources.

Price Estimator Tool as Alternative to Consumer-Friendly List

The Price Transparency regulations also permit a hospital to satisfy the consumer-friendly requirement through the use of an internet-based price estimator tool (e.g., one that allows health care consumers who use the tool to obtain an estimate of the amount they will be obligated to pay for the shoppable service.) The tool must be prominently displayed on the hospital's website, be accessible without charge, and not require the user to register or establish a user account or password prior to use. The use of such a tool, however, does *not* impact the separate requirement that the hospital make all of its "standard charges" separately available in a machine-readable file.

Civil Monetary Penalties

CMS may initiate enforcement actions and impose civil monetary penalties (CMPs). Beginning Jan. 1, 2022, CMS will determine the daily dollar amount for a CMP as follows:

1. For a hospital with 30 or fewer beds, the maximum daily CMP amount is $300.
2. For a hospital with 31 to 550 beds, the maximum daily CMP amount is the number of beds times $10.
3. For a hospital with more than 550 beds, the maximum daily CMP amount Is $5,500.

The CMP will generally follow a written warning and the failure to either submit or comply with a corrective action plan. CMS will post each notice of imposition of a CMP online, even while such CMP is being appealed, only removing the public notice if the CMP is overturned by a final and binding decision.

C. Reporting Charges to HCAI and Patients

Each July 1, every hospital must submit to the Department of Health Care Access and Information (HCAI) (formerly the Office of Statewide Health Planning and Development):

1. A copy of its chargemaster as of June 1 of the same year;
2. The calculated estimate, along with supporting documentation, of the percentage change in gross revenue (charges) due to price changes during the 12-month period beginning with the effective date of the previous chargemaster submitted; and
3. A list of its average charges for 25 common outpatient procedures as of June 1 of the same year.

The documents must be submitted in Microsoft Excel (.xls) or Comma Separated Value (.csv) as attachments to one email to chargemaster@oshpd.ca.gov or on one compact disc sent to:

HCAI
Accounting and Reporting Systems Section
818 K Street, Room 400
Sacramento, CA, 95814

Hardcopy documents are not acceptable. [Title 22, California Code of Regulations, Sections 96005-96020] HCAI has specific information available about how to file this information (and requests for exceptions) on its website at https://hcai.ca.gov/data-and-reports/cost-transparency/hospital-chargemasters/.

A hospital may be liable for a civil penalty of $100 a day for each day the filing of any report is delayed. No penalty will be imposed if an extension is granted in accordance with the guidelines and procedures established by HCAI. [Health and Safety Code Sections 1339.59 and 128770]

HCAI must:

1. Establish a list of the 25 most commonly performed inpatient procedures in California hospitals, as grouped by Medicare diagnostic-related group; and
2. Develop a list of each hospital's average charges for those procedures, if applicable, and update the list at least annually.

HCAI will publish this information on its website.

Hospitals must provide a copy of any list described above to any person who requests it.

[Health and Safety Code Sections 1339.55 and 1339.56]

VI. REQUIRED NOTICES TO PATIENTS

A. Federal Good Faith Estimate Notice

Effective Jan. 1, 2022, hospitals, other facilities, and other providers that are considered "convening" facilities or providers under the No Surprises Act regulations must inform all uninsured and self-pay individuals of the availability of a good faith estimate of expected charges as follows:

1. In a written notice prominently displayed on its website, in Its office, and on-site where scheduling or questions about the costs of care occur and
2. Orally when scheduling or when questions about costs arise.

These disclosures must be available in accessible formats and in the language(s) spoken by self-pay and uninsured individual(s) who are considering or scheduling items or services with the convening provider or facility. [45 C.F.R. Section 149.610(b)(1)(iii)] HHS has made available an optional, model notice titled, "Standard Notice: Right to Receive a Good Faith Estimate of Expected Charges," at www.cms.gov/regulations-and-guidancelegislationpaperworkreductionactof1995pra-listing/cms-10791.

B. Federal Balance Billing Disclosures

Starting Jan. 1, 2022, each hospital (and other facilities and providers) must give patients a handout about balance billing legal protections. The No Surprises Act calls this a "disclosure notice." [45 C.F.R. Section 149.430] This part of the chapter describes the required content, dissemination methods, and timing of the Disclosure Notice.

Content of Disclosure Notice

Notices must be in clear and understandable language, and include the information described below.

1. A statement explaining the requirements and prohibitions that apply to the health care provider or facility under the No Surprises Act and implementing regulations. HHS has provided an optional model notice, described below.

2. A statement explaining state law requirements governing the amounts a non-contracting provider or facility may bill a patient after receiving payment (if any) from the payer and any cost-sharing amounts from the patient. CHA has drafted optional model California-specific language, described below.
3. Contact information for the state and federal agencies that patients may contact if they believe the provider or facility violated a requirement described in the notice.

HHS has provided instructions and an optional model disclosure notice, with blanks for state-specific language, This document says at the very top, "Your Rights and Protections Against Surprise Medical Bills." The instruction sheet for facilities and other providers says at the very top, "Model Disclosure Notice Regarding Patient Protections Against Surprise Billing." HHS has posted both documents together at https://www.cms.gov/files/document/model-disclosure-notice-patient-protections-against-surprise-billing-providers-facilities-health.pdf, but providers should not give the instructions to patients.

CHA has drafted sample state-specific language that California providers may use, found at https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fcalhospital.org%2Fwp-content%2Fuploads%2F2021%2F12%2FNSA-Model-Disclosure-Notice-Regarding-Patient-Protections-Against-Surprise-Billing_CHA_State_Specific_Final.docx&wdOrigin=BROWSELINK. Facilities and other providers are not required to use the HHS or CHA model notice — they may create their own if they wish, as long as it contains all the required information.

The federal regulation states that additional information may be included in the notice, as long as it doesn't conflict with the required information. However, the Disclosure Notice must be limited to one page, which doesn't leave much (if any) room for additional information.

Dissemination of Notices

Facilities and other providers must make notices available in three ways:

1. Website posting. The notice, or a link to it, must appear on a searchable homepage of the provider's or facility's website. The disclosure must be easily accessible, without barriers, to the general public, and must be findable through public search engines free of charge, without having to establish a user account, password, or other credentials, accept any terms or conditions, and without having to submit any personal identifying information such as a name or email address. A provider or facility that does not have its own website is not required to comply with this requirement.
2. Public notice. A provider or facility (including an emergency department) must post a notice "prominently" on its premises. The federal regulation itself is not specific as to where in the facility the notice must be posted, besides the emergency department. However, HHS has stated that it would consider a notice to be posted prominently if it is posted in a central location, such as where patients schedule care, check-in for appointments, or pay bills, as this would allow individuals to be aware of the protections available before or at the time of service or payment [86 Fed Reg. at 36914]. Because the regulation defines "facility" to include a hospital outpatient department, hospitals are advised to post notices in outpatient departments as well. (A provider that does not have a publicly accessible location

— for example, a pathologist or radiologist — is not required to comply with this requirement.)

3. Patient notice. A notice must be given to patients who are participants, beneficiaries, or enrollees of (a) a group health plan, (b) a group or individual health insurance coverage offered by a health insurance issuer, or (c) the FEHB program. The notice must be:

    a. One-page (double-sided) using print no smaller than 12-point font.

    b. Provided in-person or through mail or email, as selected by the patient.

    c. Provided no later than the date and time on which the provider or facility requests payment from the individual. If the provider or facility does not request payment from the individual, the notice must be provided no later than the date on which the provider or facility submits the claim to the payer. The provider may give the patient the notice at the time of admission or outpatient registration, if desired, or when other notices (such as the Notice of Privacy Practices) are given.

Language Access

The No Surprises Act regulations do not specify language translation requirements for the Disclosure Notice. Therefore, facilities and other providers must translate these notices as required by applicable general state and federal interpreter services laws. In addition, facilities and other providers must take appropriate steps to ensure effective communication with individuals with disabilities, including provision of appropriate auxiliary aids and services at no cost to the individual. Auxiliary aids and services may include sign language interpreters, large print materials, accessible information and communication technology, open and closed captioning, and other aids or services for persons who are blind or have low vision, or who are deaf or hard of hearing. Detailed information about these laws is found in chapter 1 of CHA's *Consent Manual* (available free to CHA members at www.calhospital.org/publications/consent-manual).

Exceptions: No Disclosure Notice Required

There are certain exceptions from the notice requirement for some health care providers, such as physicians or medical groups, as described below. However, these exceptions do not apply to hospitals or other facilities.

A health care provider is not required to provide notices:

1. If it does not furnish items or services at a health care facility, or in connection with visits at health care facilities; or

2. To patients who are not furnished items or services at a health care facility, or in connection with a visit at a health care facility.

These exceptions were included to avoid confusing patients who otherwise might see a notice under circumstances in which the balance billing protections would never apply. For instance, providing a notice of balance billing protections in a primary care provider's office could lead patients to incorrectly assume balance billing protections exist where they do not.

Practitioners Providing Services in a Facility

To the extent a health care provider, such as a physician or medical group, furnishes an item or service at a health care facility, the provider can satisfy the requirements to provide public notice and patient notice if the provider and facility enter into a written agreement in which the facility agrees to provide these notices. The provider must still post a notice on its website, if it has one. It doesn't matter whether the facility and provider bill jointly or separately.

A facility and provider can amend an existing contract to include this new provision or may enter into a new written agreement specifically outlining the notice requirements regarding balance billing protections.

C. State Law — Outpatient Clinics

Effective Jan. 1, 2017, general acute care hospitals are required to notify each patient scheduled for a service in a hospital-based outpatient clinic when that service is also available in another location that is not hospital-based.

The notification must be in substantially the following form:

> The location where you are being scheduled to receive services is a hospital-based clinic, and, therefore, may have higher costs. The same service may be available at another location within our health system that is not hospital-based, which may cost less. Check with the *[insert name of office]* at *[insert telephone number]* for another location within our health system, or check with your health insurance company, for more information about other locations that may cost less.

This law does not apply to a general acute care hospital operated by a nonprofit corporation under common control with a nonprofit health care service plan that exclusively contracts with no more than two medical groups in the state to provide and arrange for medical services for the enrollees of the health care service plan, so long as the cost-sharing design does not vary based on whether the care is provided in a hospital-based clinic or a medical office building. This exception likely applies only to Kaiser hospitals.

[Health and Safety Code Section 1323.1]

Definitions

A **"hospital-based outpatient clinic"** means a department of a provider that is not located on the campus of that provider.

"Department of a provider" means a facility or organization that is either created by, or acquired by, a main provider for the purpose of furnishing health care services of the same type as those furnished by the main provider under the name, ownership, and financial and administrative control of the main provider. A department of a provider comprises both the specific physical facility that serves as the site of services of a type for which payment could be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at that facility. A department of a provider may not by itself be qualified to participate in Medicare as a provider under federal law, and the Medicare conditions of participation do not apply to a department as an independent entity. The term "department of a provider" does not include:

1. A rural health clinic, or
2. A federally qualified health center (FQHC), except as specified in 42 C.F.R. Section 413.65(n) (concerning FQHC look-alikes).

[42 C.F.R. Section 413.65(a)(2)]

D. State Law — Ancillary Services

Which Providers Must Provide Notice

If supplies or services are provided on an outpatient basis by an ancillary health service provider that is not on the same site as, or not on a site adjacent to, a general acute care hospital or an acute psychiatric hospital which has a significant beneficial interest in the ancillary health service provider, or if the ancillary health service provider has a significant beneficial interest in the hospital, the ancillary health service provider must disclose that interest in writing to the patients/customers of the ancillary health service provider (or their representatives) and advise them that they may choose to have another ancillary health service provider provide any supplies or services ordered by a member of the hospital's medical staff.

A health facility that has a significant beneficial interest in an ancillary health service provider or that knows that an ancillary health service provider has a significant beneficial interest in the health facility must disclose that interest in writing to the patients of the health facility (or their representatives) and advise them that they may choose to have another ancillary health service provider provide any desired supplies or services. This paragraph applies to skilled nursing facilities, intermediate care facilities, intermediate care facilities/developmentally disabled habilitative, special hospitals (this means dental and maternity hospitals, not "specialty" hospitals), and intermediate care facilities/developmentally disabled.

Hospitals and health facilities noted above may not charge, bill, or otherwise solicit payment from a patient on behalf of, or refer a patient to, another hospital or health facility in which it has a significant beneficial interest unless the it first discloses in writing to the patient (or his or her representative) that the patient may choose to have another hospital or health facility provide the supplies or services.

[Health and Safety Code Section 1323]

Exception

A hospital, health facility or ancillary health service provider is not required to make these disclosures if the patients are enrolled in organizations that provide or arrange for the provision of health care services in exchange for a prepaid capitation payment or premium.

Definitions

"Adjacent" means real property located within a 400-yard radius of the boundaries of the site on which the health facility is located.

"Ancillary health service provider" includes, but is not limited to, providers of pharmaceutical, laboratory, optometry, prosthetic, or orthopedic supplies or services, suppliers of durable medical equipment, home-health service providers, and providers of mental health or substance abuse services.

"Significant beneficial interest" means any financial interest that is equal to or greater than the lesser of the following:

1. Five percent of the whole.
2. Five thousand dollars ($5,000).

However, significant beneficial interest does not include any of the following interests:

1. A lease agreement between a health facility, ancillary health service provider, another health facility, or a parent corporation of the health facility, or any combination thereof.
2. Any financial interest held by a health facility or ancillary health service provider in the stock of a publicly held health facility or ancillary health service provider, or any parent corporation of a health facility or ancillary health service provider, if that financial interest does not exceed five percent of any class of equity securities of the health facility, ancillary health service provider, or parent corporation.
3. An ownership interest in a health facility or ancillary health service provider if more than three-fourths of the patients of the health facility or ancillary health service provider are members of a prepaid group practice health care service plan. **"Health care service plan"** means either of the following:
    a. Any person who undertakes to arrange for the provision of health care services to subscribers or enrollees, or to pay for or to reimburse any part of the cost for those services, in return for a prepaid or periodic charge paid by or on behalf of the subscribers or enrollees.
    b. Any person, whether located within or outside of this state, who solicits or contracts with a subscriber or enrollee in this state to pay for or reimburse any part of the cost of, or who undertakes to arrange or arranges for, the provision of health care services that are to be provided wholly or in part in a foreign country in return for a prepaid or periodic charge paid by or on behalf of the subscriber or enrollee. [Health and Safety Code Section 1345(f)]

VII. PROVIDING ESTIMATES TO PATIENTS

A. Insured Patients

Under the federal No Surprises Act, when an individual schedules a service (or Item) or requests an estimate of the cost of an item or service, the hospital or other health care facility or provider is required to provide a good faith estimate to the individual's health plan or insurer, as applicable, or to the individual if s/he is uninsured or is electing to proceed on a self-pay basis. As discussed in B. "Uninsured and Self-Pay Patients," page 17.29, this requirement is effective with respect to uninsured and self-pay patients beginning Jan. 1, 2022. However, HHS has stated that it will defer enforcement of the requirement that providers and facilities provide good faith estimate information for insured individuals that are not proceeding on a self-pay basis until rulemaking to fully implement this requirement is adopted and applicable. [HHS, FAQs About Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 49 (Aug. 20, 2021), question 5, at www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/FAQs%20About%20ACA%20%26%20CAA%20Implementation%20Part%2049_MM%20508_08-20-21.pdf] At the time

of publication of this manual, no rules have been proposed about providing good faith estimates for individuals seeking to have a claim submitted to a health plan or insurer for their care.

B. Uninsured and Self-Pay Patients

State Law

California hospitals have been required to provide estimates to uninsured patients upon request since 2006. Effective Jan. 1, 2022, state law will require hospitals to provide an estimate even if the uninsured patient does not request one.

Specifically, state law requires a hospital to provide an uninsured person with a written estimate of the amount the hospital will require the person to pay for the health care services, procedures, and supplies that are reasonably expected to be provided by the hospital, based upon an average length of stay and services provided for the person's diagnosis. An estimate need not be given for emergency services. The hospital may provide this estimate during normal business office hours.

In addition to the estimate, the hospital must provide:

1. Information about its financial assistance and charity care policies and contact information for a hospital employee or office from which the person may obtain further information about these policies.
2. An application form for financial assistance or charity care.

[Health and Safety Code Section 1339.585]

The requirement to provide an estimate applies to all persons without health coverage, whether or not they qualify for free or discounted care under the hospital's charity care or discount payment policies. A hospital should not assume that a person will qualify for charity care or a discount when it prepares an initial written estimate. If the person later completes an application and proves eligibility for the hospital's charity care or discount payment policy, the hospital can revise the estimate accordingly.

[Health and Safety Code Section 1339.585]

Federal Law

Starting Jan. 1, 2022, a health care facility and health care provider must provide a good faith estimate of expected charges for uninsured or self-pay patients (or their authorized representatives) upon request and when scheduling a service [45 C.F.R. Section 149.610]. The Interim Final Rule regarding good faith estimates is published at 86 Fed. Reg. 55980 (Oct. 7, 2021). The requirements for providing good faith estimates are described below.

Convening and Co-Providers and Facilities

Significantly, the No Surprises Act requires that the good faith estimate include the expected charges for Items and services reasonably expected to be provided by other health care providers and facilities, if any [42 U.S.C. Section 300gg-136; 45 C.F.R. Section 149.610]. The provider that receives the initial request for the estimate from a self-pay patient and is responsible for scheduling the primary item or service is called the "convening" provider or facility. All other facilities or providers whose items or services must be included in the estimate are called "co-providers" or "co-facilities." HHS, however, stated In the Interim Final Rule that from January 1 through Dec. 31, 2022, it will exercise its enforcement discretion,

and will not punish, convening providers or facilities if the good faith estimate does not include expected charges from co-providers or co-facilities. Of course, nothing prevents the patient from separately requesting a good faith estimate directly from the co-provider or co-facility, in which case the co-provider and co-facility would be required to provide the good faith estimate. Otherwise during this period, HHS encourages convening providers and convening facilities to include a range of expected charges for items or services reasonably expected to be provided and billed by co-providers and co-facilities. [86 Fed. Reg. at 56023]

When a surgery or other procedure is scheduled by a physician, it is unclear whether the physician or the facility is the convenor. HHS has been asked to answer this question.

The obligations of convening providers/facilities and co-providers/facilities are described below.

Identifying Uninsured and Self-Pay Patients

Each convening provider or facility is responsible for determining whether a patient is uninsured or self-pay by (1) inquiring about coverage and (2) inquiring if an insured patient is seeking to have a claim submitted for the primary item or service. A patient is uninsured if s/he does not have coverage under a group health plan, group or individual health insurance coverage offered by an issuer, federal health care program, or the Federal Employee Health Benefits Program. A patient is also considered self-pay if s/he has such coverage but does not seek to have a claim submitted to his or her plan or coverage for the items or services at issue. [45 C.F.R. Section 149.610(a)(xiii), (b)(i)-(ii)]

Timing and Coordination

The obligation to provide a good faith estimate is triggered when an uninsured or self-pay patient schedules an item or service or requests a good faith estimate. The estimate must be provided within the following timeframes:

1. If the primary item or service is scheduled at least three business days in advance: Not later than one business day after the date of scheduling.
2. If the primary item or service is scheduled at least 10 business days In advance: Not later than three business days after the date of scheduling.
3. When a good faith estimate Is requested by a self-pay patient: no later than 3 business days after the request. Any discussion or inquiry with a convening provider or facility about the costs of items or services under consideration Is considered a request for a good faith estimate. [45 C.F.R. Section 149.610(b)(1)(iv), (vi)]
4. When a service is scheduled with less than three business days' notice, no good faith estimate Is required.

The convening facility or provider must provide the good faith estimate either on paper or electronically (in a manner the individual can save and print), pursuant to the uninsured or self-pay patient's requested method of delivery. The estimate may also be provided orally if requested, but the convening provider or facility must still issue the estimate to the patient in writing, also. [45 C.F.R. Section 149.610(e)]

In order to provide the good faith estimate, the convening provider may need to obtain information from co-providers or co-facilities. The regulations contain required timeframes for this coordination. When the convening provider or facility receives a request or schedules an

Item or service for an uninsured or self-pay patient, must, within one business day, contact expected co-providers and co-facilities to request that they submit good faith estimate information to the convening provider, and include the date the Information must be received by the convening provider or facility. The co-provider and co-facility must respond with good faith estimate information within one business day of receiving the information and request from the convening facility or provider. The response must include:

1. The patient name and date of birth;
2. An itemized list of items or services expected to be provided by the co-provider or co-facility in conjunction with the primary item or service;
3. Applicable diagnosis codes, expected services codes, and expected charges for each listed item or service,
4. The co-provider or co-facility's name, National Provider Identifier (NPI), and Tax Identification Number (TIN) and the state(s) and office or facility location(s) where it expects to furnish the items and services, and
5. A disclaimer that the good faith estimate is not a contract and does not require the patient to obtain the items or services from any of the co-providers or co-facilities identified in the estimate.

[45 C.F.R. Section 149.610(b)(1)(v), (2)]

When a good faith estimate is provided upon request of a self-pay patient, and the patient then schedules the service, the convening provider or facility must provide a new good faith estimate within the timeframes specified above.

Content of Good Faith Estimate

Using the responses from co-facilities and co-providers and its own information, the convening facility or provider must prepare the good faith estimate using clear and understandable language calculated to be understood by the average uninsured or self-pay patient. The good faith estimate must include the following data:

1. The patient name and date of birth;
2. A description of the primary item or service (and, if scheduled, the date of the primary item or service);
3. An itemized list of items or services, grouped by provider or facility, reasonably expected to be furnished for or in conjunction with the primary item or service.
4. Applicable diagnosis codes, expected services codes, and expected charges for each listed item or service;
5. The name, NPI, and TIN of each provider or facility in the estimate and the state(s) and officer or facility location(s) where items and services are expected to be furnished by each provider or facility;
6. A list of other items or services that will require separate scheduling and that are expected to occur before or following the expected period of care for the primary item or service. The good faith estimate must include a disclaimer directly above this list that includes the following Information:

a. Separate good faith estimates for these items or services will be issued upon scheduling or request by the uninsured or self-pay individual;

b. Notification that for items or services included in the list, information such as diagnosis codes, service codes, expected charges and provider or facility identifiers do not need to be included as that information will be provided in separate good faith estimates upon request or scheduling of such items or services; and

c. Instructions for how a self-pay patient can obtain good faith estimates for the items or services.

7. A disclaimer stating that there may be additional items or services that the convening provider or facility recommends as part of the course of care that must be scheduled or requested separately and are not reflected In the good faith estimate;

8. A disclaimer stating that the information provided Is only an estimate for items or services reasonably expected to be furnished at the time the estimate is issued and that actual Items, services, or charges may differ from the good faith estimate;

9. A disclaimer stating that the patient has the right to initiate the patient-provider dispute resolution process if the actual billed charges are substantially in excess of the expected charges included in the good faith estimate. This disclaimer must include instructions for where a self-pay patient can find information about how to initiate the patient-provider dispute resolution process and state that initiation of the process will not adversely affect the quality of health care services furnished by the provider or facility to the patient.

10. A disclaimer that the good faith estimate Is not a contract and does not obligate the patient to obtain the items or services from any of the listed providers or facilities.

HHS has made available an optional, model good faith estimate form at www.cms.gov/regulations-and-guidancelegislationpaperworkreductionactof1995pra-listing/cms-10791.

[45 C.F.R. Section 149.610(c)]

Recurring Items and Services

A single good faith estimate may be provided for recurring primary items or services across up to a 12-month period if the good faith estimate includes the scope of the recurring primary Items or services (e.g., timeframes, frequency, and total number of recurring items or services). If additional recurrences of furnishing such items or services are expected beyond 12 months, the convening provider or facility must provide a new good faith estimate and communicate changes to help patients understand what has changed between the initial and new good faith estimate.

Changes to the Good Faith Estimate and Correcting Errors

The convening provider or facility must provide a new good faith estimate no later than one business day before the scheduled date of service if any convening or co- provider or facility anticipates or is notified of any changes to the scope of a good faith estimate (e.g., anticipated changes to the expected charges, Items, services, frequency, recurrences,

duration, providers, or facilities). Co-providers and co-facilities that anticipate a change to the scope of the good faith estimate information previously submitted must notify the convening provider/facility and provide updated information. If changes in expected providers or facilities occur less than one business day before the item or service Is scheduled to be furnished, the replacement provider or facility must accept the replaced provider or facility's good faith estimate as its own.

Errors or Omissions in the Estimate

A provider or facility is not considered out of compliance with the good faith estimate requirements if it makes an error or omission in an estimate despite acting in good faith and reasonable due diligence, if the provider or facility corrects the information as soon as practicable. If the estimate is not corrected before the care is furnished, the provider or facility may be subject to the patient-provider dispute resolution process if the actual billed charges exceed the estimate by $400.

To the extent that compliance with the good faith estimate requirements necessitates obtaining information from any other entity or individual, a provider or facility will not fail to comply with the requirements if it relies in good faith on such information

Recordkeeping and Retention

Each good faith estimate is considered part of the patient's medical record and must be maintained in the same manner as the patient's medical record. Convening providers and facilities must provide a copy of any previously Issued good faith estimate furnished within the last six years upon the patient/s request.

Index

SYMBOLS

72-day rule, 1.3
72-hour rule—*See Three-day payment rule*

A

ACA (Patient Protection and Affordable Care Act of 2010), 1.7, 8.31, 9.43, 9.53, 10.38, 15.17
Accountable Care Organizations (ACOs), 9.32, 9.33, 14.3
    Mandatory compliance plan, 1.7
Administrative subpoena, 16.15
Advertising—*See Marketing*
Affordable Care Act of 2010—*See ACA (Patient Protection and Affordable Care Act of 2010)*
Anti-kickback laws
    Safe harbors
        Donations to FQHCs—*See Federally-qualified health center (FQHCs)*
        Electronic health records items and services—*See also Information technology, electronic health records items and services*
        Electronic prescribing items and services—*See also Information technology, electronic prescribing items and services*
        Group purchasing arrangements, 14.4
        Price reductions offered by contractors—*See also Discounts, contractors*
Anti-markup—*See Laboratory, anti-markup, See Laboratory*
Arbitrage, 9.64
Auditing, 1.5, MP.19 to MP.20

B

Background check, 1.10
Bad debt, 8.9
    Payments, 5.28
Bates stamping, 16.4, 16.19
Board of directors
    Compensation of directors, 9.20
Bonds—*See Tax-exemption, financing*
Bureau of Medi-Cal Fraud and Elder Abuse (BMFEA), 16.13

C

Cafeteria, 9.23
California Department of Justice—*See Department of Justice, California*
California Department of Public Health (CDPH)
    All Facility Letters, 10.6
    District Offices, 10.6
    Licensing and Certification (L&C) program, 10.1
California Nonprofit Integrity Act, 9.48
Campaigns—*See Political activities*
CDPH—*See California Department of Public Health (CDPH)*
Centers for Medicare & Medicaid Services (CMS), 16.2
    Accrediting Organizations, 10.17
    Change of Ownership, 10.28
    Provider-based rules, 10.31
    Survey procedures, 10.16
Centralized Applications Unit (CAB), 10.12
Changes of ownership, 10.11, 10.28
Chargemaster, 17.19
Charity care—*See Fair pricing laws*
Civil investigative demands (CIDs), 16.5, 16.15
Civil Monetary Penalties Law, 3.20, 3.21
Civil Monetary Penalty Law (CMP Law), 11.3
Claims submission—*See Billing*
CMS—*See Centers for Medicare & Medicaid Services (CMS)*
Code of conduct, 1.22, MP.2, MP.3 to MP.12
Community benefits plan, 9.50, 9.52
Community needs assessment, 9.50, 9.52
Compensation arrangements, 9.7
Complaints, MP.18
Compliance
    Committee, MP.14 to MP.15
    Hotline—*See Hotline*

Model hospital compliance plan—*See Model hospital compliance plan*
Officer, MP.13
Policies, MP.21 to MP.23
Training—*See Training*
Compliance:Policies, 1.22
Comprehensive Error Rate Testing, 16.2
Conditions of Participation, 10.2
Confidentiality—*See Privacy laws*
Conflicts of interest, , MP.1, MP.9 to MP.13
Consolidating hospitals, 10.13
Conversion of beds, 10.11
Corrective action—*See Employee discipline*
Credit reporting, 8.19
Criminal conviction
Question on employment application, 1.10

D

DEA (Drug Enforcement Administration), 16.11
Debt collection—*See Collection agencies*
Deemed status, 10.17
Defense Criminal Investigative Service (DCIS), 16.10
Deficit Reduction Act (DRA) of 2005, 1.1
Department of Consumer Affairs, 16.14
Department of Justice, California, 16.13
DHCS Audits and Investigations, 16.12
Disclosure—*See Self-disclosure*
Documentation
Recording and reporting information, MP.7
Drug Enforcement Administration (DEA)—*See DEA (Drug Enforcement Administration)*
Drugs, illegal use of, MP.5

E

Emergency service reduction or elimination, 10.14
Employee discipline, MP.19 to MP.21
Employee handbook, 1.19
Entertainment, MP.7
Equipment rental—*See Rental, equipment*
Excluded providers, 1.2
Exclusion from federally-funded health care program, 1.10
Exempt purposes, 9.3
Expense reimbursement, 9.63

F

Fair market value, 9.7
Fair pricing laws
OSHPD reporting, 8.28
Rural hospitals, 8.8
False Claims Act (FCA), 1.17, 1.18
Federal Bureau of Investigations (FBI), 16.5
Federal Sentencing Guidelines for Organizations (FSGO), 1.1
Fiduciary duties, 2.2
Food and Drug Administration (FDA), 16.11
Form 990, 8.46, 9.42
Fundraising, 9.34, 9.48

G

Gifts, MP.7
Gift shop, 9.23
Governing board, 1.8, MP.13 to MP.14
Grand jury subpoena, 16.16
Group purchasing, 14.4

H

Hardware—*See Information technology*
Health club, 9.24
High medical costs, 8.7
Hospital beds:Changes in, 10.9
Hospital beds:Conversion of, 10.11
Hospital beds:Reclassification of, 10.10
Hospital within a hospital, 10.39
Hotline, 1.10, MP.2, MP.17

I

Interested party—*See Whistleblower*
Internal Revenue Service—*See Tax-exemption*
Interpretive Guidelines, 14.5
Inurement—*See Private benefit (inurement)*
Investigation, 1.6, 1.12

J

Joint ventures
Whole hospital, 9.30

L

Laundry services, 9.24
Legal hold, 14.9
Legislative activities—*See Political activities*

Licensing—*See also California Department of Public Health (CDPH)*
Accrediting organizations, 10.17
Changes of ownership, 10.11
Consolidating hospitals, 10.13
Deemed status, 10.17
Denial of license, 10.5
Emergency service elimination, 10.14
Emergency service reduction, 10.14
Hospital beds:Changes in, 10.9
Hospital beds, Conversion of, 10.11
Penalties, 10.11
Program flexibility, 10.3
Special permits
Reinstatement, 10.10
Suspension of, 10.10
Voluntary cancellation of, 10.10
Special services, 10.4
Supplemental services, 10.4, 10.14
Suspension of, 10.8
Voluntary cancellation of, 10.8
Lobbying—*See Political activities*
Long-term care facility, 1.19

M

MAC (Medicare Administrative Contractor), 10.2
Management contracts, 9.61
Marketing, , MP.8 to MP.9
Medicaid Fraud Control Unit, 16.12
Medicaid Integrity Contractor (MIC), 16.9
Medi-Cal
Certification, 10.36
Enrollment, 10.36
TARs—*See Treatment Authorization Requests (TARs)*
Medicare
Change of ownership, 10.28
Crossover—*See Crossover claims*
Medicare Administrative Contractor (MAC)—*See MAC (Medicare Administrative Contactor)*
Recovery Auditor (RA)—*See Recovery Auditor (RA)*
MIC (Medicaid Integrity Contractor)—*See Medicaid Integrity Contractor (MIC)*
Model hospital compliance plan, 1.22, MP.1 to MP.23
Code of conduct, 1.22, MP.2, MP.3
Compliance policies, 1.22
Motel, 9.23

N

National Practitioner Data Bank, 11.13
National Provider Identifier, 10.2
Needs assessment, 9.53
Nonprofit hospital
Sale or transfer of, 9.47
Tax-exempt issues—*See Tax-exemption*
Nonretaliation policy, MP.18
Nursing facility, 1.19

O

Office for Civil Rights (OCR), 16.10
Office of Inspector General (OIG)
Self-disclosure protocol, 15.1
Work plan, 1.9, 1.13
Office of Personnel Management, 16.11
Office of Statewide Health Planning and Development (OSHPD), 9.51
Office space rental—*See Rental, office space*
OIG (Office of Inspector General)—*See Office of Inspector General (OIG)*
Ordering/Referring Provider Enrollment, 10.24
Organ acquisition costs—*See also Cost Reporting*
Overcharging patients, 8.27
Overpayment—*See also Credit balances, See also Reverse false claim, See also Credit balances, Reverse false claim*

P

Parking lot, 9.23
Partnerships, 9.26
Whole hospital, 9.30
Patient Protection and Affordable Care Act of 2010—*See ACA (Patient Protection and Affordable Care Act of 2010)*
Patient Safety Licensing Survey (PSLS), 10.16
Payment suspensions, 10.24
Performance evaluation, MP.15 to MP.16
Pharmaceuticals, sale of, 9.24
Physician
Recruitment, 9.7
Self-referral laws—*See Self-referral laws*
Postal Inspection Service, 16.11
Price fixing, 14.2
Primary residences, 8.22
Private benefit (inurement), 9.3, 9.5, 9.28

Program flexibility, 10.3
Promotions, MP.8 to MP.9—*See also Discounts*
Proprietary information, MP.6 to MP.7
Provider-based rules, 10.31

Q

Quality Assurance Fee (QAF), 10.36
Quality Improvement Organization, 16.2

R

Rebate—*See Discounts*
Reclassification of beds, 10.10
Records retention, 9.48, 9.65
Relator—*See Whistleblower*
Reporting
    Violations of laws, MP.12, MP.21
Requisition—*See Laboratory*
Retaliation—*See Nonretaliation policy, See Whistleblower, See Nonretaliation policy, Whistleblower*
Rural providers—*See also Rural Health Clinics (RHC)*

S

Safe harbor, 9.61
Salary surveys, 14.4
Same-day readmission—*See Readmission, same-day*
Schedule D, 9.45
Schedule H, 9.43
Schedule K, 9.45
Search warrant, 16.16
Signage, 12.1 to 12.52
Skilled nursing facility, 1.19
Software—*See Information technology*
Special permits
    Suspension of, 10.10
    Voluntary cancellation of, 10.10
Special services, 10.4
"Speier" law—*See also Self-referral laws*
"Stark" law—*See also Self-referral laws*
Subpoena
    Administrative, 16.15
    Grand jury, 16.16
Supplemental services, 10.4
Suspension of license, 10.9

T

Tax-exemption
    Board of directors
        Compensation of directors, 9.20
    Charity care—*See Fair pricing laws*
    Community benefits plan, 9.50
    Community needs assessment, 9.50
    Exempt purposes, 9.3
    Form 990, 9.42
    Hospital Audit Guidelines, 9.29
    Inurement, 9.6
    Legislative activities, 9.34
    Lobbying, 9.34
    Partnerships, 9.26
    Private benefit, 9.5
    Schedule D, 9.45
    Schedule H, 9.43
    Schedule K, 9.45
Title 22, 10.2
Training, 1.5, 1.9, MP.2, MP.16 to MP.17

U

United Program Integrity Contractors, 16.7
UPIC—*See United Program Integrity Contractors*
U.S. Attorney's Office, 16.5
U.S. Postal Inspection Service (USPIS), 16.11

V

Violations
    Reporting to government, MP.21
Voluntary cancellation of license, 10.10

W

Wage garnishments, 8.22
Wage surveys, 14.4
Warrant, 16.16
Whistleblower, 1.18—*See also Nonretaliation policy*

Z

Zone Program Integrity Contractor, 16.3, 16.5, 16.9
ZPIC—*See Zone Program Integrity Contractor*