California Hospital Compliance Manual

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

CALIFORNIA HOSPITAL ASSOCIATION

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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

FORMS & APPENDICES

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.]

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 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

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