Survey

California Hospital
Survey Manual

2021

A Guide to the Licensing & Certification Survey Process

CALIFORNIA HOSPITAL ASSOCIATION

California Hospital Survey Manual

A Guide to the Licensing and Certification Survey Process

January 2021
4th Edition

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Quick Reference Guide

PREFACE

WHERE TO FIND LAWS REFERENCED IN THE MANUAL

LIST OF ACRONYMS

CHAPTERS

Chapter 1	Introduction and Background
Chapter 2	State Surveys
Chapter 3	Federal Surveys
Chapter 4	Tips for Achieving a Successful Survey
Chapter 5	After the Survey: Preparing the Plan of Correction

INDEX

APPENDIXES

Appendix HS-1	California Department of Public Health Organization Chart
Appendix HS-2	Adverse Events Reporting Requirement
Form 20-1	Adverse Event Report Form — Sample
Appendix HS-4	Unusual Occurrences Reporting Requirement
Appendix HS-5	State-2567: Statement of Deficiencies and Plan of Correction
Appendix HS-6	Maximum Time Frames Related to the Federal On-Site Investigation of Complaints/Incidents
Appendix HS-7	Form CMS-2567: Statement of Deficiencies and Plan of Correction
Appendix HS-8	Timeline for 90-Day Termination Track
Appendix HS-9	Timeline for 23-Day Termination Track
Appendix HS-10	Sample Cover Letter for Hospital's CMS-2567 Response (for a CMS survey)
Appendix HS-11	Definitions of Hospitals Under California Law
Appendix HS-13	FAQs on Writing Hospital Policies and Procedures
Appendix HS-14	Instructions For Calculating an Administrative Penalty
Appendix HS-15	Federal vs. State Immediate Jeopardy Definition and Implementation Comparison

Preface

It is fitting that the release of this fourth edition of the *California Hospital Survey Manual* coincides with the California Department of Public Health's reorganization, modernization, and performance improvement program — as well as heightened nationwide efforts to improve patient safety and the quality of care in hospitals and other settings.

Now more than ever, hospitals, government agencies, payers, and other interested parties are devoting significant resources to protect hospital patients from further illness or injury and decrease or eliminate complications.

A key component of improved quality centers around compliance with governmental requirements. Hospitals must expect and prepare for close scrutiny of patient care, as well as transparency regarding errors, financial penalties when errors are made, and incentives for providing quality care.

This manual focuses on licensing and certification surveys — the process that state and federal government agencies use to ensure hospitals comply with the law, with the ultimate goal of promoting high-quality patient care.

The *California Hospital Survey Manual* is intended to help hospital administrators prepare for and understand the survey process, from start to finish. It is written specifically for California's hospital licensing and certification professionals, compliance officers, legal counsel, risk managers, and other members of the hospital's licensing and compliance teams. It is the only hospital survey manual that is specific to California and explains both state and federal requirements.

CHA is pleased to publish this manual as a service to our members and others and hope you find it useful. If you have any comments or suggestions on how to improve the *California Hospital Survey Manual*, please feel free to contact me by phone or email.

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Where to Find Laws Referenced in the Manual

All of the laws discussed in the *California Hospital Survey 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 are 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 are 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* is found at at www.federalregister.gov.

The Centers for Medicare & Medicaid Services (CMS) publishes its *Interpretive Guidelines* on the Internet. The *Interpretive Guidelines* include information for surveyors on how CMS interprets its regulations (the Conditions of Participation), and instructions for surveyors on how to assess hospitals' compliance with them. The *Interpretive Guidelines* are 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 1250. State statutes are 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 is 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 are 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.)

List of Acronyms

AFL	All Facilities Letter (issued by CDPH)
ALJ	Administrative Law Judge
AO	Accreditation Organization
AOA	American Osteopathic Association
APH	Acute Psychiatric Hospital
CAB	Centralized Applications Branch (part of CDPH)
CAH	Critical Access Hospital
CDPH	California Department of Public Health
CEO	Chief Executive Officer
C.F.R.	Code of Federal Regulations
CHA	California Hospital Association
CHCQ	Center for Health Care Quality (part of CDPH)
CHHS	California Health and Human Services Agency
CIHQ	Center for Improvement in Healthcare Quality
CLIA	Clinical Laboratory Improvement Amendments of 1988
CMS	Centers for Medicare & Medicaid Services
CoP	Condition of Participation
DAB	Departmental Appeals Board
ED	Emergency Department
EMTALA	Emergency Medical Treatment and Labor Act
EHR	Electronic Health Record
ER	Emergency Room
ERI	Entity-reported Event
FAQs	Frequently Asked Questions
FRI	Facility-reported Event
GACH	General Acute Care Hospital
HFAP	Healthcare Facilities Accreditation Program
HFEN	Health Facilities Evaluator Nurse
ICU	Intensive Care Unit
IJ	Immediate Jeopardy
IOM	Internet-Only Manual (also Institute of Medicine)
LCA	Licensing, Certification and Accreditation
L&C	Licensing and Certification

LSC	Life Safety Code
MRSA	Methicillin-Resistant Staphylococcus Aureus
NF	Nursing Facility
NFPA	National Fire Prevention Association
OB	Obstetrics
OR	Operating Room
OSHA	Occupational Safety and Health Administration
PoC	Plan of Correction
PSO	Patient Safety Organization
QAPI	Quality Assessment and Performance Improvement
QSO	Quality, Safety and Oversight
RO	Regional Office (of CMS)
SA	State Agency (CDPH in California)
SSA	State Survey Agency (CDPH in California)
SNF	Skilled Nursing Facility
SoD	Statement of Deficiencies (2567)
SOM	State Operations Manual
TJC	The Joint Commission
VBP	Value-Based Purchasing

1 Introduction and Background

I. Introduction 1.1

II. Background 1.1

A. State Licensing 1.1

Types of Hospitals 1.1

Hospital Services 1.2

B. Federal Certification 1.2

C. Accreditation 1.4

D. Other 1.4

1 Introduction and Background

I. INTRODUCTION

The surveyors have arrived, unannounced, at your hospital. What do you do first? What will the surveyors do?

This manual 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. You will find tips on:

1. How to prepare for surveys,
2. How to interact with the surveyors,
3. How to write plans of correction, and
4. How to appeal adverse actions.

Both state and federal surveys are described throughout the manual. Although the surveyors may be the same people, there are differences in processes and potential outcomes. This manual will help hospitals understand the differences.

II. BACKGROUND

A. State Licensing

Hospitals in California must obtain and maintain a license from the California Department of Public Health (CDPH). CDPH's Licensing and Certification (L&C) Program is responsible for issuing the license and assessing a hospital's compliance with state licensing laws *(see III. "Which Laws are State Surveyors Assessing Compliance With?," page 2.6, for information about these laws)*. If CDPH determines that a hospital is not in compliance with state licensing laws, it may require the hospital to complete a plan of correction, issue a cease and desist order, close a unit or service, require a reduction in patients, prohibit new admissions, and/or assess a fine against the hospital. CDPH may also suspend or revoke the hospital's license, a supplemental service approval, or a special permit.

Types of Hospitals

California law establishes three types of hospitals:

1. General acute care hospitals,
2. Acute psychiatric hospitals, and
3. Special hospitals.

The legal definitions for these hospitals are found in Appendix HS-11, "Definitions of Hospitals Under California Law," at the end of this manual.

The licensure category of "special" hospital is frequently confused with the term "specialty" hospital. A special hospital is defined in state law as a facility that provides inpatient or

outpatient care in dentistry or maternity. There is no definition in state law for a specialty hospital, which is typically a hospital that specializes in cardiac care or orthopaedic care. In California, specialty hospitals are licensed as general acute care hospitals.

There is also no definition in California law for a critical access hospital, frontier hospital, or sole community hospital. These are federal terms. These hospitals are licensed in California as general acute care hospitals, and generally must comply with all requirements under state law for general acute care hospitals.

Hospital Services

Hospitals must offer the following basic services: medical, nursing, surgical, anesthesia, laboratory, radiology, pharmacy, and dietary (some hospitals are exempt from offering surgical and anesthesia services). CDPH has a long list of supplemental services that require special approval, such as cardiovascular surgery, cardiac catheterization, chronic dialysis, emergency, coronary care, intensive care unit, nuclear medicine, occupational therapy, outpatient, pediatrics, perinatal, psychiatric, social service, etc. The hospital's license lists the supplemental services the hospital is authorized to provide, including locations and number/category of beds. If a hospital wishes to change any of these services (such as the number, location or type of beds), the hospital must obtain CDPH approval in advance. Hospitals work with CDPH's Centralized Applications Branch (CAB) in this regard. Hospitals should also work with CAB with regard to construction projects, addition or replacement of imaging equipment, and similar endeavors., For more information about CAB, including necessary forms and contact information, go to https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/ApplyForLicensure.aspx.

California hospitals are not required to have an emergency department, although most do.

B. Federal Certification

Hospitals are required to comply with the federal requirements set forth in the Medicare regulations called the "Conditions of Participation" (CoPs), as well as EMTALA and other requirements, in order to participate in the Medicare or Medicaid[1] programs (that is, to receive payment for services rendered to Medicare or Medicaid patients). *(See III. "Which Laws are Federal Surveyors Assessing Compliance With?," page 3.3, for more information regarding the CoPs.)* The federal government agency that certifies compliance with these requirements is the Centers for Medicare & Medicaid Services (CMS). CMS permits hospitals to become certified in two ways:

1. **Deemed status.** A hospital that is accredited by a CMS-approved accreditation organization is deemed to meet the CoPs. (The hospital must also complete the standard CMS enrollment forms and initial certification processes.) To receive approval from CMS to confer deemed status on hospitals, an accreditation organization must demonstrate to CMS that the requirements hospitals must meet to become accredited are equivalent to the CoPs. At this time, CMS has approved the following accreditation organizations to confer deemed status on hospitals:

1 Medicare pays for health care services for most people over age 65, Social Security disability recipients, and individuals needing renal dialysis or transplantation. Medicaid pays for health care services for specified low-income individuals. The Medicaid program in California is called "Medi-Cal." It is funded partially by the federal government, which is why Medi-Cal participating providers must comply with federal certification requirements.

a. The Joint Commission (TJC)

b. The Accreditation Association for Hospitals and Health Systems (AAHHS) Healthcare Facilities Accreditation Program (HFAP)

c. DNV GL Healthcare

d. The Center for Improvement in Healthcare Quality (CIHQ)

It is important to note that accreditation organizations offer many types of programs. If a hospital wishes deemed status for Medicare certification purposes, the hospital must become accredited under the accreditation organization's deemed status program. The accreditation organization will provide a copy of its survey report, indicate the date of accreditation, and recommend "deemed status" for the hospital. When CMS approves participation in the Medicare/Medicaid programs, the hospital is "deemed" to have met the applicable CoPs, and CMS will issue the hospital a Medicare provider agreement. The hospital is then considered "certified" on the basis of its deemed status. The hospital will need to be recertified periodically by the accreditation organization to confirm that the hospital continues to meet applicable requirements. A hospital that is accredited for Medicare participation by an accreditation organization does not fall under the jurisdiction of the State Survey Agency (which is CDPH in California) for recertification surveys. Instead, the accreditation organization is responsible for oversight of the hospital's ongoing compliance with the CoPs, unless CMS directs CDPH to perform a validation survey *(see C. "Validation Survey," page 3.3)*. In addition, CDPH may perform a state or federal complaint survey with respect to a hospital that is accredited by a deeming organization *(see B. "Complaint Survey," page 2.4 and B. "Complaint/Allegation Survey," page 3.2)*.

2. **Survey by State Survey Agency.** In most states, including California, CMS has contracted with the state government agency responsible for licensing hospitals to assist in determining compliance with the federal Medicare and Medicaid requirements (the CoPs). In California, the responsible state agency (called the "State Survey Agency") is CDPH. A hospital that is not accredited by a CMS-approved accreditation organization, but wishes to participate in the Medicare or Medicaid program, must submit an application to CMS. CMS will then direct CDPH to perform a certification survey. CDPH will provide a recommendation to CMS, which makes the final determination as to whether the hospital may participate in the Medicare and Medicaid programs. (The federal government uses the terms "State Agency" (SA) or "State Survey Agency" (SSA) interchangeably to refer to CDPH and its counterparts in other states.)

When CMS approves participation in Medicare, it issues the hospital a Medicare provider agreement, and the hospital is then considered "certified."

CMS also has contracted with CDPH to perform:

1. Validation surveys of hospitals with deemed status. Thus, a hospital that is accredited by TJC, HFAP, DNV GL Healthcare or CIHQ may be surveyed by CDPH to determine whether the accreditation organization properly accredited the hospital and whether the hospital is indeed in compliance with the CoPs.

2. Certification/Recertification surveys of hospitals without deemed status.
3. Complaint/Allegation surveys of any hospital.

(See II. "Types of Federal Surveys," page 3.2, for a discussion of the different types of federal surveys.)

CDPH uses the same surveyors for both state and federal surveys *(see B. "CDPH Staffing/Surveyors," page 2.1)*.

When preparing for a survey, hospitals should be sure to check compliance with the CoPs/*Interpretive Guidelines (see III. "Which Laws are Federal Surveyors Assessing Compliance With?," page 3.3)* as well as the applicable accreditation organization standards. If a hospital is found to be out of compliance with the CoPs, it will be required to complete a plan of correction. If it fails to complete an acceptable plan of correction, it may be terminated from the Medicare and Medicaid programs. *(See V. "Federal Survey Outcome," page 3.26, for detailed information about deficiencies, plans of correction, and penalties for noncompliance.)* In addition, if a hospital is found to be out of compliance with EMTALA requirements, it may be subject to financial penalties *(see C. "EMTALA," page 3.10)*.

C. Accreditation

A hospital may choose to be accredited by one or more accreditation organizations (AOs). Accreditation is voluntary — think of it as an independent third party's "gold seal of approval." Accreditation requires application to the AO as well as an inspection (a survey) to determine whether the hospital meets the organization's standards and requirements. These surveys are performed by employees of the AO, not by CDPH surveyors. The hospital pays the AO for the costs of the survey and related services.

AOs are private entities, not government agencies (although some may have a contract with a government agency or may be approved by a government agency). Some AOs, such as the organizations with deeming authority (TJC, HFAP, DNV GL Healthcare and CIHQ), may survey the entire hospital. Other AOs may focus on just a part of hospital operations (for example, the laboratory, home health agency, hospice, ambulatory surgical center, etc.). Some of these organizations have deeming authority and others do not. If an accreditation organization has deeming authority, it will provide information about survey findings and other data directly to CMS.

Some managed care plans require a hospital to be accredited in order to be included in the plan's network of participating providers.

Each AO provides extensive manuals and other resources about its accreditation process and requirements. This manual thus focuses on the state licensure and federal certification survey processes rather than accreditation surveys.

D. Other

Besides the CDPH hospital license, a hospital may need licenses or permits from the California Board of Pharmacy, CDPH Laboratory Field Services, CDPH Radiologic Health Branch, the U.S. Drug Enforcement Administration, and other government agencies. These licenses and permits are not discussed in this manual.

2 State Surveys

I. CDPH/L&C Organizational Structure and Staffing 2.1

A. CDPH Organizational Structure 2.1

B. CDPH Staffing/Surveyors 2.1

Los Angeles County 2.3

II. Types of State Surveys 2.3

A. Relicensing Surveys 2.3

Survey Protocol 2.3

Resources 2.4

B. Complaint Survey 2.4

C. Hospital Self-Report to CDPH: Privacy Breach, Adverse Event, Unusual Occurrence 2.5

Privacy Breach or Unusual Occurrence 2.5

Reportable Adverse Event 2.5

III. Which Laws are State Surveyors Assessing Compliance With? 2.6

A. Program Flexibility 2.6

B. Other Laws 2.7

IV. State Survey Process 2.8

A. Overview of Surveyors' Procedures 2.8

V. State Survey Outcome 2.9

A. No Deficiencies 2.9

B. Minor Deficiencies; No Penalties 2.9

C. Deficiencies Not Constituting Immediate Jeopardy; Possible Penalties 2.10

D. Deficiencies Constituting Immediate Jeopardy 2.10

E. Deficiencies Posing an Immediate and Substantial Hazard to the Health or Safety of Patients 2.10

VI. State-2567: Statement of Deficiencies and Plan of Correction 2.11

A. Plan of Correction 2.11

Hospital and CDPH Fail to Agree Upon Plan of Correction 2.11

Failure to Implement the Plan of Correction 2.12

Legal Effect of Plan of Correction 2.12

B. Public Availability of State-2567 ..... 2.12

VII. State Administrative Penalties 2.12

A. CDPH Process 2.13

Examples of State Immediate Jeopardy Citations 2.13

CHA Catalog of Administrative Penalties 2.15

B. Administrative Penalties: Calculating the Amount 2.15

Background and Application 2.15

Definitions 2.16

Calculating the Penalty: Deficiencies Unrelated to the Hospital Fair Pricing Policies Law 2.16

Scope and Severity Matrix 2.17

Calculating the Penalty: Deficiencies Related to the Hospital Fair Pricing Policies Law 2.20

Other Factors Influencing the Penalty Amount 2.22

C. Civil Penalties: Violation of State "Anti-Dumping" Laws 2.23

D. Administrative Penalties: Violations of Nurse-to-Patient Staffing Ratios 2.23

E. Administrative Penalties: Privacy Breaches 2.24

F. Public Notice of Administrative Penalties 2.25

G. Appealing a State Administrative Penalty 2.25

2 State Surveys

This chapter focuses on state surveys — surveys conducted by California Department of Public Health (CDPH) surveyors according to state rules and assessing the hospital's compliance with state laws. This chapter describes CDPH's organizational structure and staffing, types of state surveys, pertinent state laws, an overview of the surveyors' procedures, the Statement of Deficiencies and Plan of Correction, and administrative penalties. *(See chapter 3 regarding CDPH surveyors conducting federal surveys.)*

I. CDPH/L&C ORGANIZATIONAL STRUCTURE AND STAFFING

A. CDPH Organizational Structure

An organization chart for CDPH is found at CHA Appendix HS-1 at the back of this manual and at https://www.cdph.ca.gov/Programs/DO/CDPH%20Document%20Library/CDPHOrgChart%20September%202020.pdf. This chart shows that CDPH is divided into many different "centers," "offices," and other divisions. Missing from the chart is the fact that the director of CDPH reports to the secretary of the California Health and Human Services Agency (CHHS) who reports to the Governor.

The CDPH Licensing & Certification (L&C) Program is a part of the Center for Health Care Quality. A much more detailed organization chart for CDPH is found at www.calhospital.org/publication/california-hospital-survey-manual. This detailed chart shows the personnel in the Sacramento headquarters and distrtict offices, who in Sacramento supervises the district managers around the state, who manages various field offices, and who supervises the various CDPH consultants on medical issues, dietary, pharmacy, and life safety. Staff names and phone numbers are provided.

Although the main "headquarters" of CHHS and CDPH, and the executive management team, are located in Sacramento, hospitals are most likely to interact with CDPH staff located in the 14 district offices throughout the state. A list of the district offices, including their management personnel, addresses, phone/fax numbers, and email addresses is found at https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/DistrictOffices.aspx. Each district office has a District Manager, two District Administrators, surveyors and support staff. CHA recommends that hospital licensing and certification personnel proactively get to know the CDPH staff in their local district office in advance of any particular issue or situation. The district office is the place to start if a hospital has questions about licensing matters.

CDPH's vision and mission statement may be found at https://www.cdph.ca.gov/Pages/About.aspx. L&C is funded primarily by fees paid by health facilities ($760 per hospital bed for 2020–2021) and by payments from the federal government (CMS) for providing federal certification services. Additional general information about CDPH may be found at https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/HealthCareFacilities.aspx.

B. CDPH Staffing/Surveyors

The district office personnel who are most likely to interact with hospital staff are called "surveyors." Surveyors conduct in-depth inspections of hospitals and other health facilities

to determine compliance with state licensing requirements and federal certification requirements. (Federal surveys are performed by state surveyors as a result of a contract between the state and federal governments.) Surveyors also conduct complaint investigations, investigations of facility-reported events, and follow-up inspections. *(See II. "Types of State Surveys," page 2.3, and II. "Types of Federal Surveys," page 3.2, for more information about the various types of inspections that may be conducted.)* An on-site inspection is called a "survey."

CDPH employs more than 600 surveyors, 50 consultants, and 374 managers and support staff throughout the state. CDPH often uses teams, rather than individuals, to survey hospitals. Teams consist primarily of surveyors with the title of "Health Facilities Evaluator Nurse" (HFEN) and "Consultant." These surveyors are responsible for surveying skilled nursing facilities, home health agencies, chronic dialysis clinics, ambulatory surgical centers, clinics, intermediate care facilities, hospices, birthing centers, etc. — they do not spend all of their time on acute care hospitals. CDPH's Health Facility License Fees Annual Report, found at https://www.cdph.ca.gov/Programs/CHCQ/LCP/CDPH%20Document%20Library/CHCQ%202020-21%20Annual%20Fee%20Report_Final.pdf provides interesting information on types of facilities surveyed, hours spent per facility type, etc.

CDPH uses the same surveyors for both state and federal surveys. Although the surveyors may be the same people, there are differences in processes and potential outcomes, as described throughout this manual. To make matters more confusing, surveyors may figuratively "switch hats" while in the hospital. For example, CDPH may receive a self-report of an adverse event and begin a state survey. If the surveyors detect noncompliance with a federal requirement, they may call CMS while still at the hospital and request authorization to conduct a federal survey on behalf of CMS.

Hospitals should seek clarification from the surveyors if it is not clear whether they are representing the state or CMS. Hospital should also clarify what type of survey will take place *(See II. "Types of State Surveys," page 2.3, and II. "Types of Federal Surveys," page 3.2)*.

HFENs are registered nurses with at least one year of professional nursing experience. This nursing experience must include at least six months of administrative responsibility (for example, charge nurse, shift supervisor, nurse manager, director of staff development, or teaching experience in nursing education). Alternatively, a Bachelor of Science in Nursing may be substituted for the required administrative experience. Once hired, HFENs receive new surveyor orientation including didactic instruction and field training, one-week federal basic surveyor training, and specialty surveyor training.

HFENs are often assisted by other health professional surveyors, such as pharmacists, dieticians, physicians, registered health information administrators, etc. These personnel have titles such as "Pharmacy Consultant," "Medical Consultant," "Medical Records Consultant," etc.

The size and composition of the survey team depend upon the type of survey to be conducted, the size of the facility, the complexity of services offered, whether the facility has a historical pattern of serious deficiencies or complaints, and whether new surveyors are accompanying the team as part of their training. A survey may last for just a few hours or may last for several days, depending upon the reason for the survey.

Los Angeles County

CDPH contracts with the Los Angeles County Department of Health Services to have county employees perform state and federal surveys for hospitals located in Los Angeles County. Hospitals located in Los Angeles County pay an extra $157 per bed annual license fee. Hospitals owned by Los Angeles County, however, are surveyed by CDPH employees located in the Orange County district office. [Health and Safety Code Section 1257]

II. TYPES OF STATE SURVEYS

A. Relicensing Surveys

After a hospital is initially licensed, CDPH is required by law to periodically survey hospitals to ensure compliance with state licensing laws. These are called "relicensing" surveys.

These periodic inspections are called "relicensing surveys." CDPH plans to perform a relicensing survey for each hospital at least every three years, and more often as necessary to ensure quality of care.

Survey Protocol

Surveys will be unannounced and will follow the general steps outlined in IV. "Federal Survey Process," page 3.13 (entrance conference, information gathering/investigation, exit conference, etc.). The survey team will include a registered nurse who is the team coordinator, pharmaceutical consultant, nutrition consultant, medical consultant and 1–3 additional registered nurses, depending on the hospital size and the experience of the team coordinator. The team may include others based on the size of the hospital, its compliance history, number and complexity of approved supplemental services, distance of locations that will be visited, and subject matter expertise of the team members. The medical and nutritional consultants may be onsite or remote.

The surveyors will select patients to follow through hospital settings: preanesthesia, surgery, recovery, radiology/imaging, etc. The patient selections are intended to represent a cross-section of the patient population and services provided by the hospital. A total sample size will consist of 6–10% of the current inpatient census with a minimum of 30 patients. The surveyors will select patients who are in the facility during the time of the survey where possible, so they can conduct a patient-focused survey and validate the information obtained through observations, record reviews, and interviews with patient/staff/family.

Surveyors will interview patients to determine if they understand their medical condition, reason for hospital admission, and their plan of care. For example, a surgical patient may be asked about the process for surgery preparation, his or her knowledge of and consent for the procedure, pre-operative patient teaching, post-operative patient goals and discharge plan. Patients may also be asked about their knowledge of patient rights, advance directives, and the hospital's grievance/complaint procedure.

Surveyors will review nursing units and procedures (including compliance with nurse-to-patient ratio requirements), pharmacy, emergency department, surgery, dietary, infection control and antimicrobial stewardship, complex outpatient care units, and other areas. While preparing for the survey, the surveyors will have developed a list of concerns based on the hospital's past three years of deficiencies. The surveyors will check up on these areas also. The surveyors will review program flexes, and make sure their list of your hospital's approved flexes matches your list.

Resources

CDPH has created a web page with information about the Relicensing Surveys at https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/GeneralAcuteCareRelicensingSurvey.aspx. This web page includes information about the survey process, a list of Title 22 regulations and what surveyors are looking for in assessing compliance with each, survey time lines; medication pass worksheets for surveyors to use; lists of documents that hospitals will be asked to produce at the beginning of a relicensing survey; and an evaluation form that hospitals are asked to complete after the survey.

In addition, CDPH has created a web page on healthcare associated infections and antimicrobial stewardship that may be found at https://www.cdph.ca.gov/Programs/CHCQ/HAI/Pages/HAIProgramHome.aspx. CDPH has indicated that it is particularly interested in evaluating hospitals' compliance with appropriate infection control measures and the law mandating that hospitals implement antimicrobial stewardship programs.

B. Complaint Survey

CDPH is required by state law to make an on-site inspection or investigation whenever it receives a complaint indicating an ongoing threat of imminent danger of death or serious bodily harm to a patient. For purposes of this law, a **"complaint"** means any oral or written notice from any person to CDPH (other than an adverse event report made by the hospital) of an alleged violation of any applicable state or federal law, or an allegation of facts that might constitute such a violation.

The on-site inspection or investigation must take place within 48 hours or two business days (whichever is greater) after receipt of the complaint. The investigation must be completed within 45 days. If CDPH does not meet this time frame, it must provide written notice to the facility and the complainant (if any) of the basis for the extenuating circumstances preventing it from meeting the time frame, and the anticipated completion date.

If CDPH receives a complaint but determines from the information available that there is no threat of imminent danger of death or serious bodily harm to that patient or other patients, no on-site inspection is required, but an investigation (by document review and/or phone interviews) must be undertaken and completed within 45 days. If CDPH does not meet this time frame, it must provide written notice to the facility and the complainant (if any) of the basis for the extenuating circumstances preventing it from meeting the time frame, and the anticipated completion date.

CDPH does not always adhere to these time frames due to workload issues. CDPH sometimes saves lowest-level complaints to investigate the next time it visits the facility.

CDPH must notify the hospital and complainant in writing of its determination as a result of its investigation. [Health and Safety Code Section 1279.2]

C. Hospital Self-Report to CDPH: Privacy Breach, Adverse Event, Unusual Occurrence

Hospitals are required to report to CDPH regarding specified adverse events, privacy breaches, and unusual occurrences. The details of these reporting requirements are described in CHA Appendix HS-2, "Adverse Event Reporting Requirement," CHA's California *Health Information Privacy Manual*, and CHA Appendix HS-4, "Unusual Occurrences Reporting Requirement." The appendices are found in the back of this manual.

A hospital that reports an adverse event, privacy breach or unusual occurrence to CDPH should immediately convene key people to begin the root cause analysis of the problem, identify immediate corrective action to be taken, and prepare for a CDPH survey or other CDPH action (document request, phone interviews, etc.). It is not a good idea to wait until CDPH contacts the hospital to begin the corrective action process. All steps taken should be documented.

Privacy Breach or Unusual Occurrence

CDPH is not required by law to respond in any particular manner to hospital reports of privacy breaches or unusual occurrences. A CDPH surveyor may call the hospital, may ask for additional information or documentation, or may visit the hospital to perform a formal or informal survey. Or, CDPH may put the self-report in the hospital's file to investigate during its next survey. CDPH will use its judgment depending upon the nature of the reported event. *(See Health and Safety Code Section 1280.15 regarding privacy breaches and Title 22, California Code of Regulations, Section 70737 (general acute care hospitals) or 71535 (acute psychiatric hospitals) regarding unusual occurences.)*

Reportable Adverse Event

CDPH is required by law to make an on-site inspection or investigation whenever it receives an adverse event report indicating an ongoing threat of imminent danger of death or serious bodily harm. This on-site inspection or investigation must take place within 48 hours or two business days (whichever is greater) after receipt of the report. The law requires that the investigation be completed within 45 days; however, hospitals often do not receive the results of the investigation within this time frame. If CDPH does not meet this time frame, it must provide written notice to the facility and the complainant (if any) of the basis for the extenuating circumstances preventing it from meeting the time frame, and the anticipated completion date. Until CDPH determines by on-site inspection that the adverse event has been resolved, CDPH must conduct an unannounced inspection at least once per year of any hospital that has reported an adverse event.

If CDPH receives an adverse event report but determines from the information available that there is no threat of imminent danger of death or serious bodily harm to that patient or other patients, no on-site inspection is required, but an investigation (by document review and/or phone interview) must be undertaken and completed within 45 days. If CDPH does not meet this time frame, it must provide written notice to the facility and the complainant (if any) of the basis for the extenuating circumstances preventing it from meeting the time frame, and the anticipated completion date.

CDPH will check to see that the hospital informed the patient or patient's legal representative of the adverse event by the time the hospital reported to CDPH. Hospitals should take care to make this notification in a timely manner and to document it.

CDPH must notify the hospital in writing of its determination as a result of its investigation. [Health and Safety Code Sections 1279.1–1279.3]

III. WHICH LAWS ARE STATE SURVEYORS ASSESSING COMPLIANCE WITH?

Surveyors who are conducting a state survey will assess the hospital's compliance with state statutes and regulations. The majority of the hospital licensing statutes are found in the California Health and Safety Code, starting at Section 1250. The majority of the hospital licensing regulations are found in Title 22 of the California Code of Regulations, starting at Section 70001. *(See "Where to Find Laws Referenced in the Manual" at the beginning of the manual, for a discussion about the difference between a statute and a regulation and where the exact text of these laws may be found on the Internet.)*

In addition, many Title 22 regulations require that the hospital develop and implement specified policies and procedures (for example, regarding nursing services, the surgical service, the anesthesia service, laboratory, radiology, etc.). CDPH may cite a deficiency if the hospital does not comply with its own policies and procedures, even if the policies contain requirements that would not otherwise legally be required. In other words, 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 therefore be careful to tailor their policies to the requirements of the law to the extent possible. *(See Appendix HS-13, "FAQs on Writing Hospital Policies and Procedures.")*

> CDPH may cite a deficiency if the hospital does not comply with its own policies and procedures, even if the policies contain requirements that would not otherwise legally be required.

CDPH also publishes "All Facilities Letters" (AFLs) to provide guidance to hospitals regarding new or amended laws, new or revised programs and processes, and other information. AFLs may be found at https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/LNCAFL.aspx by year of publication. Hospitals should check this web page frequently for newly issued letters. Alternatively, hospital staff may register for the California Health Alert Network (CAHAN) email list by emailing cahaninfo@cdph.ca.gov. AFLs are distributed through the CAHAN email system.

A. Program Flexibility

While hospitals generally must maintain continuous compliance with Title 22 regulations, CDPH has the authority to grant flexibility from these regulatory requirements if the hospital demonstrates its ability to meet statutory requirements (that is, Health and Safety Code provisions). This is called "program flexibility." CDPH cannot provide flexibility with respect to statutory requirements in the absence of a Governor's Executive Order (for example, in a disaster).

A hospital that is interested in obtaining a program flex should discuss its situation with its local CDPH district office. Following these discussions, the hospital should complete and submit the CDPH 5000 form to its district office, explaining why a variance of one or more of the licensing requirements is appropriate under the circumstances. (Form CDPH 5000 is found at https://www.cdph.ca.gov/CDPH%20Document%20Library/ControlledForms/cdph5000.pdf.) The form must contain:

1. Each Title 22 regulation for which the facility requests flexibility.
2. An explanation of the alternative concepts, methods, procedures, techniques, equipment, personnel qualifications, or pilot projects the facility proposes to use.
3. Supporting evidence demonstrating how the facility's alternative concepts, methods, procedures, techniques, equipment, personnel qualifications, or pilot projects meet the intent of the regulation.
4. An authorized facility representative signature on all forms and/or requests.

If the district office determines the program flex request is incomplete, it will request additional information or supporting documentation. Upon receipt of a completed request, the district office will review it and may conduct an on-site inspection. The district office may identify terms and conditions under which the exception or flexibility is granted. In addition, the district office will determine an appropriate expiration date. Although older flexes may not include an expiration date, CDPH's eventual goal is for every approved program flex to specify an expiration date. Hospitals may request renewals when the expiration date is imminent.

Hospitals are required to post the program flex approval in the hospital, next to the hospital license. Alternatively, hospitals may keep their flex approvals in a binder, and post a sign next to the license advising viewers where the flex approvals are located and available for review.

If a hospital fails to comply with the terms and conditions of a program flex, or CDPH determines it does not adequately protect patient safety, CDPH may revoke it. CDPH will review all approved program flexes during the relicensing survey.

[Health and Safety Code Section 1276; Title 22, California Code of Regulations, Sections 70129, 70307 and 70363; All Facilities Letter 18-19, dated May 2, 2018]

CDPH has a different form for hospitals to use when requesting a program flex due to a pandemic or other disaster. This form is the CDPH 5000 A, found at https://www.cdph.ca.gov/CDPH%20Document%20Library/ControlledForms/cdph5000a.pdf. The hospital must submit the completed 5000A form to CDPH's Medical and Health Coordination Center (MHCC) at chcqdutyofficer@cdph.ca.gov. *(See also All Facilities Letter 18-09, dated Jan. 12, 2018.)*

B. Other Laws

There are many laws that hospitals must follow that CDPH is not required to, and does not, enforce. For example, CDPH is not responsible for assessing a hospital's compliance with occupational safety and health requirements (a Cal/OSHA responsibility) or wage and hour laws (a Department of Labor/Department of Industrial Relations responsibility). Therefore, CDPH surveyors will not focus on these areas. However, they may notify the Medicare Administrative Contractor, the CMS Regional Office, or another responsible government

agency if they detect a problem outside their area of responsibility, especially if fraud or abuse is suspected. They may also notify law enforcement if patient abuse or narcotics diversion is suspected.

IV. STATE SURVEY PROCESS

CDPH surveyors will assess the hospital's compliance with state licensing laws for all services, areas and locations listed on the hospital's license. This may include inpatient and outpatient services, both on- and off-campus. The surveyors will accomplish this through observations, interviews and document/record review.

Although surveys generally occur during daytime working hours (Monday through Friday), surveyors may conduct a survey at any time, including evening and weekends. All surveys are unannounced. A hospital may not refuse to allow access to the building and premises to a CDPH surveyor [Health and Safety Code Section 1278; Title 22, California Code of Regulations, Sections 70101 (general acute care hospitals) and 71101 (acute psychiatric hospitals)]. (The laws discussed in this manual regarding the state survey process may be found at Health and Safety Code Sections 1278 to 1282.)

Before the survey team arrives at the hospital, they will have familiarized themselves with the hospital's ownership, physical plant, previous survey results, waivers and variances that exist, types of services offered, media reports, the hospital's website, complaints and other information.

A. Overview of Surveyors' Procedures

The survey process, in general, consists of an entrance conference, observations by the surveyor(s) (including document review and interviews), and an exit conference. After the exit conference, the hospital will develop preliminary corrective action steps based on findings communicated by the surveyors at the exit conference, while the surveyors are writing up their survey findings on the State-2567 ("Statement of Deficiencies and Plan of Correction") form. After the hospital receives its 2567 form, the hospital will prepare and submit its formal plan of correction. Finally, the surveyors may return to the hospital to verify that the plan of correction was implemented. Information about these steps in the survey process is provided in this chapter as well as in chapters 3 and 5.

In many parts of this manual, the most extensive type of survey is described — a full state licensure or federal certification or validation survey, which can be a week-long (or longer) experience with multiple surveyors in the facility at the same time, with potentially serious consequences. The hospital will need to devote significant high-level staff time responding to this type of survey. However, many surveys will be abbreviated versions of those described in this manual. For example, if a hospital self-reports to CDPH a privacy breach wherein a respiratory therapist faxed a pulmonary function test to the local bank instead of the ordering physician's office because the physician provided an incorrect fax number, CDPH will not send multiple surveyors to the hospital for several days to investigate the entire facility. There will not be a formal entrance conference and formal exit conference, and the hospital will not want to convene an entire survey response team and record the "exit conference." Such a response would be excessive. Instead, CDPH may simply request the hospital's policy and procedure regarding the faxing of medical information and speak to the hospital's privacy

officer over the phone. Alternatively, a surveyor may investigate the privacy breach the next time he or she makes an on-site visit.

Hospitals should bear in mind that the information presented in this manual is written with the most extensive types of surveys in mind. They should adjust their response and procedure appropriately when responding to less extensive surveys.

The entrance conference, surveyors' procedures and exit conference for a state survey are substantially the same as for a federal survey. The surveyors are not required to adhere to the State Operations Manual, which was written by the federal government for federal surveys, unless they are surveying for compliance with state law at the same time as a federal inspection [Health and Safety Code Section 1279(g)]. *(See B. "Entrance Conference," page 3.13, C. "Surveyors' Procedures," page 3.16, and E. "Exit Conference," page 3.24, regarding these steps in the federal survey process.)* As a practical matter, however, the surveyors usually do follow the State Operations Manual; they will also follow the requirements described in II. "Types of State Surveys," page 2.3, and III. "Which Laws are State Surveyors Assessing Compliance With?," page 2.6.

V. STATE SURVEY OUTCOME

There are several possible state survey outcomes:

1. No deficiencies.
2. Minor deficiencies; no penalties.
3. Deficiencies not constituting an immediate jeopardy (IJ) to the health or safety of a patient; possible penalties.
4. Deficiencies constituting IJs.
5. Deficiencies posing an immediate and substantial hazard to the health or safety of patients.

Each is described below. **NOTE:** Although the law uses two somewhat different terms ("immediate jeopardy" and "immediate and substantial hazard to the health or safety of patients"), as a matter of practicality, both of these terms may apply to the same situations. Neither term has been interpreted further by CDPH or the courts.

A. No Deficiencies

Obviously, having no deficiencies is the best possible outcome. The hospital is then done with the survey process — congratulations!

B. Minor Deficiencies; No Penalties

If a CDPH survey finds noncompliance with state licensing requirements, but does not find any deficiencies that it is considering levying an administrative penalty for, the surveyors will return to their district office and prepare a "Statement of Deficiencies" (State-2567). The hospital should receive it within 10 days.

C. Deficiencies Not Constituting Immediate Jeopardy; Possible Penalties

If a CDPH survey finds noncompliance with state licensing requirements, but does not find any deficiencies that constitute an immediate jeopardy (IJ) to the health or safety of a patient, the surveyors will return to their district office and prepare a "Statement of Deficiencies" (State-2567). The hospital should receive it within 30 days.

D. Deficiencies Constituting Immediate Jeopardy

If a CDPH surveyor determines that a hospital's noncompliance with one or more state licensure requirements constitutes (or constituted) an immediate jeopardy to the health or safety of a patient, CDPH follows a slightly different procedure.

Under state law, **"immediate jeopardy"** means a situation in which the licensee's (the hospital's) noncompliance with one or more requirements of licensure has caused, or is likely to cause, serious injury or death to a patient [Health and Safety Code Section 1280.1]. (Federal law is somewhat different; *see E. "Immediate Jeopardy (Federal)," page 3.27, for more information about federal IJs)*.

Upon discovering an IJ, the on-site surveyor is required to consult a supervisor. If the supervisor agrees that the deficiency constitutes an IJ, the surveyor will immediately notify hospital administration that an IJ exists and immediately obtain a plan of correction. During the exit conference, the surveyor and/or supervisor will reaffirm that an IJ exists and that an administrative penalty may be issued at a later date. The surveyors will return to their district office and prepare two "Statement of Deficiencies" (State-2567) forms. One form will reflect the IJ; CDPH has not committed to a specific time frame in which the hospital will receive this document. The rest of the deficiencies will be noted on a separate 2567, which the hospital will receive within 30 days.

CDPH states that a deficiency may be considered an "immediate jeopardy" if the deficiency caused, or was likely to cause, serious injury or death to a patient at the time it occurred. This is true even if CDPH does not learn about the deficiency or incident until months later, and even if the hospital corrected the situation long before CDPH investigated. A hospital may have a deficiency, correct it, have no related problems, and then months later find out that CDPH considers it an "immediate jeopardy" and has issued a penalty *(see CDPH FAQs at* https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/AP_FAQ.aspx. This is not the case for federal IJs *(see E. "Immediate Jeopardy (Federal)," page 3.27)*. CHA has created a chart showing the differences between state and federal IJs; it may be found at the end of this manual as Appendix HS-15, "Federal vs. State Immediate Jeopardy Definition and Implementation Comparison." The California Hospital Association believes that CDPH's interpretation of the law in this respect is incorrect; however, hospitals should be aware of CDPH's legal interpretation.

E. Deficiencies Posing an Immediate and Substantial Hazard to the Health or Safety of Patients

If a deficiency poses an immediate and substantial hazard to the health or safety of patients, CDPH may order either of the following until the hazardous condition is corrected:

1. Reduction in the number of patients.
2. Closure of the unit or units within the hospital that pose the risk.

The hospital may appeal such an order to the superior court of the county in which the hospital is located.

[Health and Safety Code Section 1280]

VI. STATE-2567: STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

CDPH uses a form called the "State-2567" to record deficiencies (noncompliance) identified during a survey. The State-2567 is almost identical to the Form CMS-2567 *(seeVI. "The Form CMS-2567: Statement of Deficiencies and Plan of Correction," page 3.30).* A copy of the State-2567 is found at the back of this manual as CHA Appendix HS-5. Examples of completed State-2567s may be found at https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/Hospital-Administrative-Penalties-by-Year.aspx.

After the survey, the surveyors will complete the surveyor's portion of the State-2567. The State-2567 is the record of the survey where the survey team documents and justifies its determination of noncompliance. The State-2567 will list, in the two left-hand columns, all of the deficiencies found by the surveyors during the survey. Deficiencies may be addressed by a number (such as "E 242") in the very left-hand column, or this column may be left blank. (The "E" code refers to a CDPH indexing system and is not relevant or useful for hospitals.) The next column will contain the Title 22 provision or the Health and Safety Code provision that was not met and a detailed description of the findings. CDPH will frequently use the Title 22 or Health and Safety Code section number only. A number like "70215" — that is, five digits starting with a "7"— refers to Title 22. A number like "1280.1" — that is, four digits before the decimal point, starting with a "12" — refers to the Health and Safety Code. Each surveyor will draft his or her section of the 2567, so the style and detail may vary within the document. *(See III. "Which Laws are State Surveyors Assessing Compliance With?," page 2.6, for more information regarding Title 22 and the Health and Safety Code.)*

The third, fourth and fifth columns of the State-2567 are blank when the hospital receives it.

A. Plan of Correction

As mentioned above, the fourth column of the State-2567 is titled "Provider's Plan of Correction" (PoC) and is blank when the hospital receives it. The hospital will complete this portion of the State-2567 and submit it to CDPH (separate sheets of paper may be used). The law states that "the health facility shall agree with [CDPH] upon a plan of correction that shall give the health facility a reasonable time to correct" deficiencies identified on the State-2567 [Health and Safety Code Section 1280]. As a practical matter, CDPH will either approve or disapprove the hospital's PoC. If it is disapproved, the hospital must revise and resubmit it until CDPH approves it.

(See IV. "Drafting the Hospital's Final 2567 Response and PoC," page 5.7, for more information on preparing the hospital's response.)

Hospital and CDPH Fail to Agree Upon Plan of Correction

If the hospital fails to submit an acceptable plan of correction within a reasonable time, and if the deficiency poses an immediate and substantial hazard to the health or safety of patients, CDPH may take action to order implementation of a plan of correction devised by CDPH. The order must be in writing and must contain a statement of the reasons for the order.

If the hospital does not agree that the deficiency poses an immediate and substantial hazard to the health or safety of patients or if the hospital believes that the plan of correction will not correct the hazard, or if the hospital proposes a more efficient or effective means of remedying the deficiency, the hospital may, within 10 days of receiving the plan of correction from CDPH, appeal the order to the director of CDPH. The director must review information provided by the hospital, CDPH, and other affected parties and within a reasonable time render a decision in writing that must include a statement of reasons for the order. While the director is reviewing the appeal, the order to implement the plan of correction must be stayed. This appeal is not an adjudicative hearing and is not required to comply with the adjudicative hearing process set forth in Health and Safety Code Section 100171.

[Health and Safety Code Section 1280]

Failure to Implement the Plan of Correction

If the hospital fails to implement, within a reasonable time period, a plan of correction that was accepted by CDPH, CDPH may order implementation of it. A hospital should assume its PoC has been accepted by CDPH (and should thus work to implement it), unless and until it is rejected by CDPH. CDPH does not always inform the hospital that its PoC is acceptable – the hospital should check with CDPH if it hasn't heard back in a reasonable time period.

If CDPH conducts a survey and determines that a hospital failed to correct the deficiencies as indicated in the plan of correction, CDPH will issue another 2567 or, in unusual circumstances, CDPH may take action to revoke or suspend the deficient service or the hospital's license. [Health and Safety Code Section 1280] In addition, CDPH may suspend or revoke a supplemental service approval or a special permit [Title 22, California Code of Regulations, Sections 70309 and 70369].

Legal Effect of Plan of Correction

The act of providing a plan of correction, the content of the plan of correction, and the execution of a plan of correction, may not be used in any legal action or administrative proceeding as an admission (within the meaning of Evidence Code Sections 1220 to 1227) against the hospital, its licensee or its personnel. [Health and Safety Code Section 1280] In other words, the fact that the hospital submits a plan of correction does not mean the hospital is admitting it was noncompliant. A hospital may deny that it was noncompliant in court, despite having submitted a plan of correction.

B. Public Availability of State-2567

The Statement of Deficiencies portion of the State-2567is posted online at https://www.cdph.ca.gov/programs/chcq/lcp/calhealthfind/pages/home.aspx when CDPH has received verification that the hospital has received it from CDPH. The Plan of Correction portion is available for public inspection upon receipt by CDPH.. The public (including attorneys, newspapers, labor unions, etc.) may obtain 2567s by sending a Public Records Act request to CDPH. *(See also F. "Public Notice of Administrative Penalties," page 2.25.)*

VII. STATE ADMINISTRATIVE PENALTIES

CDPH may issue administrative penalties against hospitals for violations of licensing requirements that have been cited by surveyors on a State-2567. [Title 22, California Code of Regulations, Sections 70951 and 71702]

A. CDPH Process

The recommendation to issue an administrative penalty for a violation of a licensing requirement that constitutes an IJ is made at the district office level by the investigating surveyor and his or her supervisor. The recommended penalties are sent to the CDPH Office of Legal Services and to the Licensing and Certification Program deputy director in Sacramento for approval and issuance. The deputy director makes the final decision regarding whether a penalty is assessed and if so, the amount of the penalty. Hospitals should be aware that both the state and the federal governments use the term "immediate jeopardy" and define it similarly. However, the process and interpretations differ. *(See also E. "Immediate Jeopardy (Federal)," page 3.27, and Appendix HS-15, "Federal vs. State Immediate Jeopardy Definition and Implementation Comparison.")*

CDPH has full discretion to consider all factors when determining the amount of an administrative penalty. CDPH is required to consider the special circumstances of small and rural hospitals (as defined in Health and Safety Code Section 124840) in order to protect access to quality care in those hospitals.

Hospitals may appeal penalty assessments imposed by CDPH *(see G. "Appealing a State Administrative Penalty," page 2.25)*.

Examples of State Immediate Jeopardy Citations

CDPH has not published any regulations or specific descriptions of what types of noncompliance will trigger particular penalties.

Administrative penalties may arise from reportable adverse events, but an administrative penalty also may be issued for a deficiency that is not a reportable adverse event. For example, serving contaminated food to a patient may constitute an immediate jeopardy and be subject to an administrative penalty, but it is not in the list of reportable adverse events found in Health and Safety Code Section 1279.1. (However, this situation may be reportable under the "unusual occurrence" reporting requirement of Title 22, California Code of Regulations, Sections 70737 (general acute care hospitals) and 71535 (acute psychiatric hospitals).) In addition, a reportable adverse event often does not result in an administrative penalty.

Some of the immediate jeopardy violations for which CDPH has issued administrative penalties in the past include, but are not limited to, a hospital's:

1. Failure to develop and implement policies and procedures for the safe and effective administration of medications known to cause cardiac arrhythmias (in particular those with a black box warning);
2. Failure to develop and implement policies and procedures to ensure safe food-handling practices;
3. Failure to provide pharmaceutical services that would meet the needs of all patients by failing to develop and implement policies and procedures related to the use of preprinted medication order forms that would ensure safe and effective use of medications;
4. Failure to develop and implement written policies and procedures to ensure the safe and effective use of medications with black box warnings, such that staff was unaware of the warnings and patients using the medications were not monitored appropriately;

5. Failure to ensure that medications dispensed for patient care were administered as ordered and in accordance with facility-approved protocols, such that the hospital failed to clarify an incomplete medication order and failed to follow facility-approved policies and procedure for safe administration of a medication;
6. Failure to have written policies and procedures for the establishment of a safe and effective system for the distribution, dispensing, and use for patient care of biologicals;
7. Failure to ensure that staff could accurately and quickly calculate a dose for emergency medications for pediatric use;
8. Failure to provide patient safety by ensuring that written policies and procedures for the distribution of all drugs were developed and implemented to ensure the safe use of medications;
9. Failure to ensure specialty consultation by a physician, ongoing medical evaluation, medically-stabilizing treatment and physician intervention to ensure prompt transfer to a higher level of care for a patient who presented to the Emergency Department;
10. Failure to ensure prompt nursing assessments and medical care for a patient who presented to the emergency department, where the hospital failed to ensure the availability of competent and appropriate nurse staffing resources so that patients could receive prompt treatment;
11. Failure to ensure that registered nurses were appropriately trained, such that the inconsistency in the nurses' knowledge regarding the administration of intravenous medication boluses led to a lack of uniformity in the responses regarding the administration of potentially dangerous intravenous medication boluses in the intensive care unit setting;
12. Failure to develop and implement policies and procedures in the operating room to eliminate retained foreign objects after surgery; and
13. Failure to provide adequate on-call physician coverage to meet the needs of patients receiving emergency care in the emergency department and failure to maintain an effective call system to provide care to patients in the intensive care unit.

CDPH statistics show that many of the administrative penalties assessed in the past few years were related to medication or pharmacy errors, or to foreign objects retained after surgery, though the list of what circumstances can give rise to an administrative penalty expands from year to year. CDPH has posted information about the administrative penalties it has assessed, along with each hospital's State-2567, by year and by hospital, at https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/Hospital-Administrative-Penalties-by-Year.aspx.

CHA Catalog of Administrative Penalties

The California Hospital Association (CHA) has developed an administrative penalty catalog to track citations and fines resulting from IJs. For each event, the catalog provides key details about the event, including the CDPH district office that investigated the event, the number of days between the beginning of the investigation and the date the penalty was issued, the amount of the penalty, and a description of the event and plan of correction, if that information is available. The catalog uses publicly available information from CDPH press releases, the Health Facilities Consumer Information System website and State-2567 forms gathered from the CDPH website. Although information on these penalties is publicly available, it is difficult to find and compile, and difficult to use the data to identify trends and improve activities. The catalog makes this easier. Users should realize there are flaws and inaccuracies in CDPH's publicly available source material that is reflected in the catalog.

When reviewing the immediate jeopardy information in the catalog, hospitals are encouraged to review each State-2567 form in its entirety to fully understand the circumstances of the administrative penalty/immediate jeopardy and the plan of correction implemented to eliminate the immediate jeopardy. Please note that each plan of correction relates only to that specific deficiency; however, this can be helpful in understanding options when developing systems to prevent this type of error in the future.

The catalog is available (to CHA members only) at www.calhospital.org/ij-catalog/reports.

B. Administrative Penalties: Calculating the Amount

Background and Application

CDPH may issue administrative penalties against hospitals for violations of licensing requirements that have been cited by surveyors on a State-2567. [Title 22, California Code of Regulations, Sections 70951 and 71702]

The regulations described in this part of the manual describe how CDPH will determine the amount of the penalty. However, these regulations do not apply to settlement of enforcement actions or in the following situations:

1. Penalties imposed for discrimination or retaliation against a whistleblower pursuant to Health and Safety Code Section 1278.5.
2. Penalties imposed for privacy breaches *(see E. "Administrative Penalties: Privacy Breaches," page 2.24).*
3. Penalties imposed for failure to report, or late reporting of, an adverse event *(see Appendix HS-2, "Adverse Event Reporting Requirement.")* These penalties are different from the penalties for the adverse event itself, which are subject to these regulations.
4. Penalties imposed for violation of state "anti-dumping" laws *(see C. "Civil Penalties: Violation of State "Anti-Dumping" Laws," page 2.23)*.

CHA has created an abbreviated instruction sheet for calculating an administrative penalty; *see Appendix HS-14, "Instructions for Calculating an Administrative Penalty."* This portion of the manual explains the steps in detail.

Definitions

"Actual financial harm" means concrete financial loss for medical costs incurred by a patient, where the loss was not covered or reimbursed by health insurance.

"Deficiency" means a licensee's failure to comply with any law relating to the operation or maintenance of a hospital as a requirement of licensure under the Health and Safety Code or Division 5 of Title 22 of the California Code of Regulations.

"Hospital licensing requirements," "hospital licensing standards" and **"licensure requirements"** refer to the requirements in Health and Safety Code, Division 2, Chapter 2 and Division 107, Part 2, Chapter 2.5, Article 1 applicable to hospitals, and the regulations adopted thereunder. The former reference is to the hospital licensing provisions of the Health and Safety Code (Sections 1250-1339.59), while the latter reference is to the Hospital Fair Pricing Policies law (Health and Safety Code Sections 127400-127462).

"Repeat deficiencies" means violations of hospital licensing requirements or federal certification standards in the same or substantially similar regulatory grouping of requirements, which are found during an inspection, subsequently corrected, and found again at a subsequent inspection.

"Substantial compliance" means a level of compliance with state hospital licensing standards and with federal laws that set forth the Conditions of Participation for hospitals in the Medicare program, such that any identified deficiencies pose no greater risk to patient health and safety than the potential for causing minimal harm.

"Willfulness," "willfully" or **"willful"** means that the person doing an act or omitting to do an act intends the act or omission, and knows the relevant circumstances connected with the act or omission.

"Willful violation" means that the licensee (hospital), through its employees or contractors, willfully commits an act or makes an omission with knowledge of the facts, which bring the act or omission within the deficiency that is the basis for an administrative penalty.

[Title 22, California Code of Regulations, Section 70952]

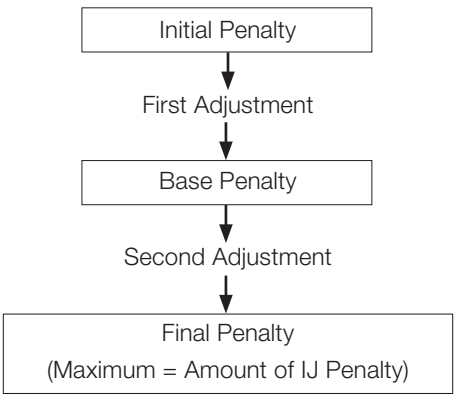
Calculating the Penalty: Deficiencies Unrelated to the Hospital Fair Pricing Policies Law

This part of the manual describes how CDPH will calculate a penalty for a deficiency unrelated to the Hospital Fair Pricing Policies law (also called the "charity care" law). This includes most deficiencies listed on the State-2567. *(See "Calculating the Penalty: Deficiencies Related to the Hospital Fair Pricing Policies Law," page 2.20, for information about calculating the penalty for a deficiency related to the Hospital Fair Pricing Policies law.)*

Scope and Severity Matrix

CDPH has developed a matrix to help its surveyors determine the amount of an administrative penalty for a particular deficiency. The starting amount of a penalty is based on the scope and severity of the deficiency. See the third page of Appendix HS-14, "Instructions for Calculating an Administrative Penalty," for the initial penalty amount in dollars.

CDPH starts by determining an initial penalty based on the matrix, 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 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.



Determining an Initial Penalty

CDPH determines the initial penalty for each deficiency by considering the severity and scope of the deficiency, using the matrix above [Title 22, California Code of Regulations, Section 70954].

Severity

The severity levels are designed to consider the actual and potential harm to patients that the deficiency caused or could have caused. CDPH will consider the patient's physical and mental condition, and the probability and severity of the risk that the violation presents to patients. The severity levels range from Severity Level 1 (no actual harm; potential for no more than minimal harm) to Severity Level 6 (immediate jeopardy to patient health or safety that caused the death of a patient).

Scope

CDPH will also determine the scope of the noncompliance with hospital licensure requirements using the matrix above. CDPH will label the scope as isolated, pattern or widespread, as follows:

Isolated:

1. One or a very limited number of patients affected, or
2. One or a very limited number of staff involved, or
3. The situation occurred only occasionally, or
4. The situation occurred in a very limited number of locations.

Pattern:

1. More than a very limited number of patients affected, or
2. More than a very limited number of staff involved, or
3. The situation occurred in several locations, or
4. The same patients had been affected by repeat occurrences.

Widespread:

1. The situation was pervasive throughout the hospital, or
2. The situation represented a systemic failure that affected or had the potential to affect a large portion or all of the hospital's patients.

To calculate the initial penalty, CDPH will find the percent figure in the cell that corresponds to the severity and the scope of the deficiency, and then apply that percentage to the dollar amount that applies, based on the severity and, if the deficiency is considered an IJ, the hospital's own history of receiving IJ penalties, as follows:

Severity Levels 6, 5 and 4 constitute immediate jeopardies. The initial penalties for these levels are the appropriate percentage of $75,000 if this is the hospital's first IJ penalty, $100,000 if this is the hospital's second IJ penalty, and $125,000 if this is a third or 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 CDPH finds that the hospital has been in substantial compliance for three years prior to the date of the violation.

Severity Levels 3 and 2 do not constitute immediate jeopardies. The initial penalty is the appropriate percentage of $25,000.

Severity Level 1 and minor violations do not result in a financial penalty. A minor violation means any violation of law relating to the operation or maintenance of a hospital that CDPH determines has only a minimal relationship to the health or safety of hospital patients. However, a violation of the Hospital Fair Pricing Policies law may result in a penalty even if it could be considered "minor" under this definition *(see "Calculating the Penalty: Deficiencies Related to the Hospital Fair Pricing Policies Law," page 2.20)*. [Title 22, California Code of Regulations, Sections 70951(a)(1) and 70952(a)(4)]

EXAMPLE 1. A hospital has a deficiency that CDPH considers to be a Severity Level 5 and of widespread scope. The hospital has never had an IJ penalty before. The initial penalty will be 80% of $75,000, which equals $60,000.

EXAMPLE 2. A hospital has a deficiency that CDPH considers to be a Severity Level 2 and of isolated scope. The initial penalty will be 20% of $25,000, which equals $5,000.

Adjusting the Initial Penalty

The initial penalty may be increased or decreased to calculate the "base penalty" (sometimes called the "adjusted initial penalty"), according to the following guidelines. [Title 22, California Code of Regulations, Section 70955]

1. **The patient's physical and mental condition**

   The initial penalty will be increased by 10 percent if the violation caused actual harm to the patient at Severity Level 3 or 5, resulting in a physical or mental impairment that substantially limits one or more of the major life activities of a patient, or the loss of bodily function, if the impairment or loss lasts more than seven days or is still present at the time of discharge, or the loss of a body part; or

   The initial penalty will be increased by 5 percent if the violation caused actual harm to the patient at Severity Level 3 or 5 resulting in a physical or mental impairment that substantially limits one or more of the major life activities of a patient, or the loss of bodily function, if the impairment or loss lasts more than three days.

2. **Financial harm to the patient**

   The initial penalty will be increased by 1 percent if the violation caused actual financial harm to the patient, based on information acquired by CDPH during the investigation.

3. **Factors beyond the hospital's control**

   The initial penalty will be decreased by 5 percent if there were factors beyond the hospital's control that restricted the hospital's ability to comply with licensure requirements, and if the hospital developed and maintained disaster and emergency programs as required by state and federal law that were appropriately implemented during a disaster.

4. **Willful violation**

   The initial penalty will be increased by 10 percent if the deficiency was the result of a willful violation.

Adjusting the Base Penalty

The "base penalty" (sometimes called the "adjusted initial penalty") will be adjusted to determine the final penalty. This adjustment is based upon whether the hospital immediately corrects the violation and the hospital's history of compliance with state hospital licensure laws and the federal Conditions of Participation [Title 22, California Code of Regulations, Section 70957].

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 all 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 take appropriate steps necessary to prevent the violation from recurring. The hospital must promptly, and in detail, document the corrective action. The appropriateness of the plan of correction must be approved by CDPH.

   b. The noncompliance that was corrected did not constitute immediate jeopardy or result in the death of a patient.

c. The hospital complied with mandatory reporting requirements before the noncompliance was identified by CDPH.

d. A penalty was not imposed for a repeat deficiency that received a penalty reduction under these regulations with the 12-month period prior to the date of the violation.

2. **History of compliance with state and federal laws**

A hospital's compliance history refers to its record of compliance with licensure requirements under the Health and Safety Code, and the regulations adopted thereunder, and with the Conditions of Participation for hospitals in the Medicare program, for a period of three years prior to the date the administrative penalty is issued.

The base penalty will be reduced by 5 percent if hospital inspections within the last three years noted no state or federal deficiencies that resulted in patient harm or immediate jeopardy (Severity Levels 3 through 6).

The base penalty will be increased by 5 percent if the hospital has three or more repeat deficiencies that pose a risk of more than minimal harm to patient health or safety (Severity Levels 2 through 6) within the three year period immediately prior to the date of the violation.

Determining the Final Penalty

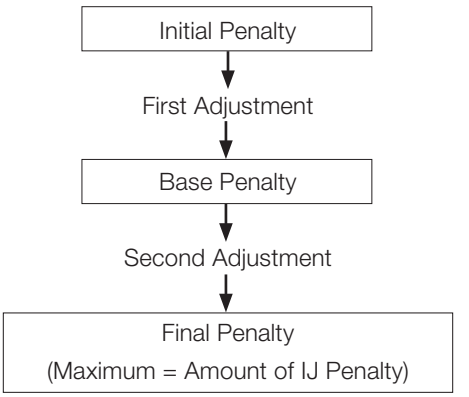
The calculations above will result in the final penalty. However, the final penalty may not exceed the maximum penalty specified in Health and Safety Code Section 1280.3, which is $25,000 for a violation that does not constitute an IJ, $75,000 for the hospital's first IJ penalty, $100,000 for the hospital's second IJ penalty, and $125,000 for the third or 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.

Calculating the Penalty: Deficiencies Related to the Hospital Fair Pricing Policies Law

This part of the manual describes how CDPH will calculate a penalty for a deficiency related to the Hospital Fair Pricing Policies law — also known as the "charity care" law. *(See "Calculating the Penalty: Deficiencies Unrelated to the Hospital Fair Pricing Policies Law," page 2.16, for information about calculating the penalty for a deficiency unrelated to the Hospital Fair Pricing Policies law.)* For these deficiencies, CDPH will consider the extent of noncompliance, the amount of financial harm to the patient, and the willfulness of the violation. Acute psychiatric hospitals are not subject to the Hospital Fair Pricing Policies law, and thus will not be penalized by CDPH under these regulations.

Just as with penalties for deficiencies unrelated to the Hospital Fair Pricing Policies law, 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 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 Hospital Fair Pricing Policies 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 is 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" (sometimes called the "adjusted initial 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" (sometimes called the "adjusted initial penalty") will be adjusted to determine the final penalty. This adjustment is based upon whether the hospital immediately corrects the violation and the hospital's history of compliance with the Hospital Fair Pricing Policies 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 with 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 Hospital Fair Pricing Policies law within the three-year period immediately prior to the date of the violation.

Determining the Final Penalty

The calculations 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 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 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, 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 the Office of Statewide Health Planning and Development or other governmental agency.

[Title 22, California Code of Regulations, Sections 70960 and 71703]

C. Civil Penalties: Violation of State "Anti-Dumping" Laws

CDPH may also assess a penalty against a hospital for a violation of state "anti-dumping" laws for up to $25,000 per violation. In determining the amount of the fine, CDPH must take into account all of the following:

1. Whether the violation was knowing or unintentional.
2. Whether the violation resulted or was reasonably likely to result in a medical hazard to the patient.
3. The frequency or gravity of the violation.
4. Other civil fines that have been imposed by the federal government for violations of EMTALA. The state may not impose a penalty that, when added to a penalty imposed under federal law, exceeds $30,000.

However, this penalty provision does not apply to an alleged violation by a hospital owned and operated by a health care service plan. Instead, the Department of Managed Health Care has the oversight authority for these violations of the state anti-dumping laws.

Physicians are subject to a civil penalty for violation of state anti-dumping laws by the Medical Board of California of up to $5,000 per violation. [Health and Safety Code Sections 1317-1317.9]

(See CHA's EMTALA: A Guide to Patient Anti-Dumping Laws, *available at* www.calhospital.org/emtala-manual*, for more information about federal and California anti-dumping laws.)*

D. Administrative Penalties: Violations of Nurse-to-Patient Staffing Ratios

If CDPH determines that a hospital violated the nurse-to-patient ratio regulation, it must issue an administrative penalty of $15,000 for the first violation and $30,000 for the second or subsequent violation. However, a general acute care hospital is not subject to a penalty if the hospital demonstrates to CDPH's satisfaction all of the following:

1. That any fluctuation in required staffing levels was unpredictable and uncontrollable.
2. Prompt efforts were made to maintain required staffing levels.
3. In making those efforts, the hospital immediately used and subsequently exhausted the hospital's on-call list of nurses and the charge nurse.

Hospitals must document their efforts to maintain required staffing levels. [Health and Safety Code Section 1280.3]

CDPH has adopted the following definitions:

1. **"Unpredictable"** means unable to be known in advance.
2. **"Uncontrollable"** means outside the facilitly's control.
3. **"Unpredictable and uncontrollable"** means the facility had no way to know or control the staffing shortage that occurred.

[All Facilities Letter 20-04, Jan. 16, 2020]

Multiple violations found during the same survey count as a single violation for purposes of determining whether the violation was a first, second, or subsequent violation. A violation occurring more than three years after the date of the last violation is treated as a first violation.

CDPH may issue an administrative penalty for a staffing violation under this provision of law as well as an administrative penalty for any resulting harm pursuant to Health and Safety Code Section 1280.3(a), which describes penalties for immediate jeopardy violations.

E. Administrative Penalties: Privacy Breaches

CDPH has the authority to issue administrative penalties for privacy breaches — that is, the inappropriate access, review or viewing of patient medical information without a direct need for medical diagnosis, treatment or other lawful use as permitted by the Confidentiality of Medical Information Act or any other statute or regulation governing the lawful access, use or disclosure of medical information [Health and Safety Code Section 1280.15].

CDPH may assess the following penalties for a hospital's failure to prevent unlawful or unauthorized access, use or disclosure of medical information:

1. Up to $25,000 per patient, and
2. Up to $17,500 per subsequent violation of that patient's medical information.

In addition, the hospital may also be fined up to $100 per day for failure to timely self-report a privacy breach to CDPH. However, the total combined penalties (for failure to prevent unlawful or unauthorized access, use or disclosure and for the failure to make the required self-reports) may not exceed $250,000 "per reported event." The term "reported event" means all breaches included in any single report that is made to CDPH, regardless of the number of breach events contained in the report.

In assessing the penalties, the law requires CDPH to consider:

1. The history of the facility's compliance with state and federal privacy and security laws;

2. The extent to which the facility detected violations and took preventative action to immediately correct and prevent past violations from recurring; and

3. Factors outside the facility's control that restricted the facility's ability to comply.

CDPH is required to consider the special circumstances of small and rural hospitals (as defined in Health and Safety Code Section 124840), and primary care clinics (as defined in Health and Safety Code Section 1204), in order to protect access to quality care in those hospitals and clinics.

Hospitals may appeal penalty assessments imposed by CDPH for privacy breaches following the same process as that for appealing IJ penalties *(see G. "Appealing a State Administrative Penalty," page 2.25)*. In lieu of disputing a penalty, a hospital may pay only 75 percent of the penalty provided they pay within 30 days of receipt of the penalty assessment.

A complete discussion of health information privacy law is beyond the scope of this manual. CHA has published the *California Health Information Privacy Manual* to help hospitals comply with the multitude of state and federal privacy laws. For more information, visit www.calhospital.org/privacy.

F. Public Notice of Administrative Penalties

CDPH periodically issues a press release regarding the administrative penalties it has levied. CDPH typically notifies each affected hospital's CEO a day or so before the press release is issued. The press release and each hospital's State-2567 will be put on the CDPH website at https://www.cdph.ca.gov/Programs/OPA/Pages/Office-of-Public-Affairs.aspx. The hospital should develop a communication plan to prepare hospital employees for media inquiries and to respond to those inquiries. *(See I. "Communicating Survey Results," page 5.1.)*

G. Appealing a State Administrative Penalty

If a hospital wishes to appeal a state administrative penalty, the hospital must notify CDPH by letter within 10 calendar days after being notified of the penalty – that is, within 10 calendar days after the hospital mailroom signs the certified mail receipt. The hospital may dispute:

1. A determination by CDPH regarding an alleged deficiency or alleged failure to correct a deficiency;

2. The reasonableness of the proposed deadline for correction; and

3. The reasonableness of the amount of the penalty.

There is no formal content requirement, but typically, the hospital will send a fairly comprehensive letter indicating why the immediate jeopardy deficiency should be withdrawn and/or why no administrative penalty (or a lesser amount) should be assessed. Since this letter serves as the basis to evaluate the legal standard and basis of an appeal, hospitals may wish to work with legal counsel in drafting this letter.

Hospitals have experienced a long lag time between sending the letter requesting the appeal and hearing from CDPH. During this lag time, the hospital does not need to pay the penalty; penalties are paid only after the appeal, if the appeal is unsuccessful.

After it has received the hospital's notice of appeal, the CDPH Office of Legal Services (OLS) Administrative Litigation Unit will draft an accusation as required by the Administrative Procedure Act and send it to the facility with an explanation of the next steps. The facility may

file a notice of defense and submit it to OLS. OLS will then arrange a hearing. Alternatively, CDPH will contact the hospital to determine whether the hospital wishes to continue the appeal process. This may be considered an opportunity to negotiate. Some hospitals have had their deficiency withdrawn, some have successfully challenged the imposition of a penalty (and thus did not have to pay any penalty) and some hospitals have settled with CDPH and paid a lower penalty than had originally been assessed by CDPH.

If a hearing is held, it will be conducted pursuant to the Government Code provisions that govern formal administrative hearings [Government Code Section 11500 *et seq.*]. Penalties need not be paid until all appeals have been exhausted and CDPH's position has been upheld. [Health and Safety Code Section 1280.1(b)]

3 Federal Surveys

I. CMS Organizational Structure and Staffing 3.1

II. Types of Federal Surveys 3.2

A. Certification/Recertification Survey 3.2

B. Complaint/Allegation Survey 3.2

C. Validation Survey 3.3

III. Which Laws are Federal Surveyors Assessing Compliance With? 3.3

A. Medicare Conditions of Participation 3.3

Acute Care Hospitals 3.4

Psychiatric Hospitals 3.5

Critical Access Hospitals (CAHs) 3.5

Other Facilities/Services 3.5

Condition vs. Standards 3.6

Interpretive Guidelines and Survey Procedures 3.7

B. State Operations Manual 3.7

Chapters 3.8

Exhibits 3.8

Appendixes 3.8

CMS Memos to Surveyors 3.10

C. EMTALA 3.10

D. Life Safety Code 3.11

Waivers 3.11

Resources 3.12

IV. Federal Survey Process 3.13

A. Overview 3.13

B. Entrance Conference 3.13

What to Provide the Survey Team 3.14

C. Surveyors' Procedures 3.16

Sample Size and Selection 3.16

Comprehensive Review 3.17

Information Gathering by Surveyors: Observation/Interviews/Record Review 3.17

Patient Privacy Rights 3.22

Daily Meetings 3.23

D. Decision Making by Survey Team 3.23
Condition-Level vs. Standard-Level Deficiency 3.23
Deficiency Determined to Have Occurred Prior to Survey 3.24
E. Exit Conference 3.24
Complaint Survey Exit Conference 3.25
Discontinuation of Exit Conference 3.25

V. Federal Survey Outcome 3.26
A. No Deficiencies 3.26
B. Standard-Level Deficiency 3.26
C. Condition-Level Deficiency 3.26
D. Financial Penalties 3.27
Value-Based Purchasing 3.27
E. Immediate Jeopardy (Federal) 3.27
Hospital Corrects IJ While Surveyors are On-Site 3.29
Hospital Corrects IJ While Surveyors are On-Site, But Deficiencies Remain: 90-Day Termination Track 3.29
Hospital Does Not Correct IJ While Surveyors are On-Site: 23-Day Termination Track 3.29

VI. The Form CMS-2567: Statement of Deficiencies and Plan of Correction ... 3.30
A. Statement of Deficiencies 3.30
B. Cover Letter From CMS Accompanying CMS-2567 ..... 3.31
C. Plan of Correction 3.32
D. Public Availability of CMS-2567 ..... 3.32

VII. CDPH/CMS Actions after PoC Submitted 3.33
A. Credible Allegation of Compliance 3.33
B. State Monitoring 3.33
C. Resurvey 3.34

VIII. The Termination Process 3.34
A. Notice of Termination 3.35
B. Hospital's Response 3.36
C. Public Notice 3.36

IX. Appealing a Final Determination to Terminate Medicare/Medicaid Certification 3.37
A. Effect of an Early Appeal 3.38
B. Filing a Lawsuit 3.38

3 Federal Surveys

This chapter focuses on federal surveys — surveys conducted according to federal rules and assessing the hospital's compliance with federal laws. This chapter describes the Centers for Medicare & Medicaid Services (CMS) organizational structure and staffing, types of federal surveys, pertinent federal laws, detailed information about the surveyors' procedures, the Statement of Deficiencies and Plan of Correction, and termination from the Medicare program. *(See chapter 2 regarding CDPH surveyors conducting state surveys.)*

I. CMS ORGANIZATIONAL STRUCTURE AND STAFFING

The CMS headquarters (often referred to as the "Central Office") are located in Baltimore, Maryland. CMS has ten regional offices (ROs) throughout the country. California is located in Region 9, and the RO is located in San Francisco.

The Deputy Regional Administrator for Region 9 is currently Catherine (Cate) Kortzeborn. The Associate Regional Administrator of the Division of Survey and Certification — the unit in charge of certifying Medicare providers — is Steve Chickering. Julius Bunch is the Certification and Enforcement Branch Manager for the Western Division of Survey and Certification; he is located in the CMS Seattle office. Judith Somerby is the point person for psychiatric hospitals. Contact information for all CMS employees may be found at https://directory.psc.gov/employee.htm.

CMS has a website that contains a wealth of information at www.cms.gov. Click on "About CMS" at the very top of the web page to learn more about CMS leadership, regional office structure, and more. Information about the Western Division of the Survey and Certification may be found at https://www.cms.gov/medicare/provider-enrollment-and-certification/surveycertificationgeninfo/downloads/regional_and_central_office_contacts.pdf.

As mentioned in B. "Federal Certification," page 1.2, CMS has contracted with CDPH to assist in assessing California hospitals' compliance with the federal Medicare and Medicaid requirements (the Conditions of Participation (CoPs)). CDPH surveyors, therefore, perform hospital surveys on behalf of CMS. *(See B. "CDPH Staffing/Surveyors," page 2.1, for more information about CDPH surveyors and the survey team.)* CMS also directly employs some surveyors itself. The CMS-employed surveyors perform surveys on a random sample basis. In addition, they may accompany CDPH surveyors where there are special circumstances, such as a very serious issue at a hospital, a dispute between a hospital and CDPH, or a potential difference of opinion between CDPH and CMS.

CMS provides on-training for surveyors around the country, available at https://qsep.cms.gov/welcome.aspx. Hospital staff may also access this free training.

II. TYPES OF FEDERAL SURVEYS

As described above, CMS contracts with CDPH to assess compliance with Medicare requirements. There are three types of surveys:

1. Certification/recertification survey
2. Complaint/allegation survey
3. Validation survey

These are described below. Surveys generally follow the same overall process, though there are some differences depending on the type of survey and its objective.

Surveyors may refer to any of the three types of surveys listed above as a "validation survey." This may be confusing to hospitals.

The size and composition of the survey team depends upon the type of survey to be conducted, the size of the facility, the complexity of services offered, whether the facility has a historical pattern of serious deficiencies or complaints, and whether new surveyors are accompanying the team as part of their training. A survey may last for just a few hours or may last for several days, depending upon the reason for the survey. CMS states that a suggested survey team for a full certification or recertification survey of a mid-size hospital would include two to four surveyors who will be at the facility for three or more days.

A. Certification/Recertification Survey

A certification survey is a comprehensive survey to determine whether the hospital meets all of the CoPs *(see III. "Which Laws are Federal Surveyors Assessing Compliance With?," page 3.3)*. Recertification occurs on a cyclical basis (approximately every 3 years) to confirm that the hospital continues to meet the Medicare requirements.

As described in B. "Federal Certification," page 1.2, many hospitals are accredited by The Joint Commission or other national accreditation organizations and therefore are "deemed" to be compliant with Medicare requirements. So long as a hospital remains deemed in compliance with Medicare requirements by an authorized accreditation organization, it is subject to a validation survey rather than a certification or recertification survey.

B. Complaint/Allegation Survey

A complaint/allegation survey is conducted when CMS has received a complaint and determined that it raises a "substantial allegation of noncompliance" that, if substantiated, would affect the health and safety of patients and may constitute a condition-level deficiency *(see "Condition-Level vs. Standard-Level Deficiency," page 3.23)*. If a complaint alleges condition-level noncompliance, CMS may refer it for investigation to either the State Survey Agency (CDPH in California) or, if the hospital has deemed status, to the accrediting organization. If a complaint does not allege condition-level noncompliance, CMS may do the same, or may advise the complainant to file the complaint with the accrediting organization or ask for the complainant's permission to release the information to the accrediting organization, if the hospital has deemed status. A hospital is not automatically informed if a complaint is referred to the accreditation organization.

Usually, CMS initially limits complaint/allegation surveys to only those CoPs related to the complaint. However, CMS and the State Survey Agency have leeway to expand the scope of the survey to other CoPs if the surveyors identify additional problems.

A complaint may be submitted by any patient, employee, visitor, other health care provider or any other individual in person, by telephone, through written correspondence, or in a newspaper or magazine article. The surveyors will follow the procedures set forth in chapter 5 of the State Operations Manual and described in this manual. *(See B. "State Operations Manual," page 3.7, for more information about the manual.)* The prioritization, investigation time frames, and referral possibilities related to various types of complaint surveys are shown in CHA Appendix HS-6, "Maximum Time Frames Related to the Federal On-Site Investigation of Complaints/Incidents."

If during a complaint/allegation survey, the State Survey Agency substantiates a deficiency (either related or unrelated to the complaint) and CMS determines the hospital is out of compliance with any CoP, CMS may authorize a "full review" (also called a "full survey") — that is, a survey for compliance with all of the CoPs. The CMS regional office will determine whether a full survey is appropriate after considering the manner and degree of noncompliance, the hospital's compliance history, recent changes in the provider's ownership or management, whether the resources to conduct a full survey are available in the time frame needed, and the length of time since the hospitals' last accreditation survey. Alternatively, if CMS determines that the hospital is out of compliance with a CoP, CMS may skip the "full review" and place the hospital on a termination track *(see VIII. "The Termination Process," page 3.34)*.

C. Validation Survey

Validation surveys are conducted on a random sample basis to validate the accreditation process and the accreditation organization's performance. In other words, a hospital that is accredited by The Joint Commission or other accreditation organization with deeming authority, and therefore is deemed to be compliant with the CoPs, may be subject to a validation survey to confirm that the accreditation organization did its job properly, and that the hospital in fact meets the CoPs. Validation surveys may be comprehensive or focused on a specific condition or standard. If an accredited hospital is found during a validation survey to have significant deficiencies, it will no longer be deemed to meet the CoPs and CMS will authorize a "full review" or "full survey" (that is, a survey for compliance with all of the CoPs).

A validation survey may also occur if CMS believes it has received a substantial allegation of noncompliance. This may arise in the context of a state survey or from a complaint.

III. WHICH LAWS ARE FEDERAL SURVEYORS ASSESSING COMPLIANCE WITH?

A. Medicare Conditions of Participation

Surveyors who are conducting a federal survey will assess the hospital's compliance with the federal regulations called the Medicare "Conditions of Participation" (CoPs). The CoPs are found in Title 42 of the Code of Federal Regulations, part 482 (for CAHs, they are found in part 485). *(See "Where to Find Laws Referenced in the Manual" at the beginning of the manual, to learn where the exact text of the CoPs may be found on the Internet.)*

The requirements in the CoPs apply to all patients in a Medicare- or Medicaid-participating hospital, not just to Medicare or Medicaid patients.

Acute Care Hospitals

There are 24 CoPs for acute care hospitals (not critical access hospitals). They are:

Administration

482.11. Condition: Compliance with federal, state and local laws

482.12. Condition: Governing body

482.13. Condition: Patient's rights

482.15. Condition: Emergency preparedness

Basic Hospital Functions

482.21. Condition: Quality assessment and performance improvement program

482.22. Condition: Medical staff

482.23. Condition: Nursing services

482.24. Condition: Medical record services

482.25. Condition: Pharmaceutical services

482.26. Condition: Radiologic services

482.27. Condition: Laboratory services

482.28. Condition: Food and dietetic services

482.30. Condition: Utilization review

482.41. Condition: Physical environment

482.42. Condition: Infection prevention and control and antibiotic stewardship programs

482.43. Condition: Discharge planning

482.45. Condition: Organ, tissue, and eye procurement

Optional Hospital Services

482.51. Condition: Surgical services

482.52. Condition: Anesthesia services

482.53. Condition: Nuclear medicine services

482.54. Condition: Outpatient services

482.55. Condition: Emergency services

482.56. Condition: Rehabilitation services

482.57. Condition: Respiratory care services

482.58. Condition: Special requirements for hospital providers of long-term care services ("swing-beds")

Psychiatric Hospitals

There are two additional CoPs for acute psychiatric hospitals:

482.61. Condition: Special medical record requirements for psychiatric hospitals

482.62. Condition: Special staff requirements for psychiatric hospitals

Critical Access Hospitals (CAHs)

There are different conditions for critical access hospitals. They are:

485.608. Condition: Compliance with federal, state and local laws and regulations

485.610. Condition: Status and location

485.612. Condition: Compliance with hospital requirements at time of application

485.616. Condition: Agreements

485.618. Condition: Emergency services

485.620. Condition: Number of beds and length of stay

485.623. Condition: Physical plant and environment

485.625. Condition: Emergency preparedness

485.627. Condition: Organizational structure

485.631. Condition: Staffing and staff responsibilities

485.635. Condition: Provision of services

485.638. Condition: Clinical records

485.639. Condition: Surgical services

485.640. Condition: Infection prevention and control and antibiotic stewardship programs

485.641. Condition: Quality assessment and performance improvement program

485.642. Condition: Discharge planning

485.643. Condition: Organ, tissue, and eye procurement

485.645. Special requirements for CAH providers of long-term care services ("swing-beds")

485.647. Condition: Psychiatric and rehabilitation distinct part units

Other Facilities/Services

There are additional or different CoPs for long-term care services ("swing-beds"), transplant centers, skilled nursing facilities, comprehensive outpatient rehabilitation facilities, and other providers and services. Hospitals should check the State Operations Manual appendix that applies to their facility to learn which CoPs apply *(see B. "State Operations Manual," page 3.7, for more information)*.

Condition vs. Standards

The CoPs are, in many cases, somewhat imprecise. For example, Section 482.26, Radiologic Services, states in its entirety:

> **Section 482.26 Condition: Radiologic services.** The hospital must maintain, or have available, diagnostic radiologic services. If therapeutic services are also provided, they, as well as the diagnostic services, must meet professionally approved standards for safety and personnel qualifications.
>
> (a) **Standard: Radiologic services.** The hospital must maintain, or have available, radiologic services according to needs of the patients.
>
> (b) **Standard: Safety for patients and personnel.** The radiologic services, particularly ionizing radiology procedures, must be free from hazards for patients and personnel.
>
> (1) Proper safety precautions must be maintained against radiation hazards. This includes adequate shielding for patients, personnel, and facilities, as well as appropriate storage, use, and disposal of radioactive materials.
>
> (2) Periodic inspection of equipment must be made and hazards identified must be promptly corrected.
>
> (3) Radiation workers must be checked periodically, by the use of exposure meters or badge tests, for amount of radiation exposure.
>
> (4) Radiologic services must be provided only on the order of practitioners with clinical privileges or, consistent with State law, of other practitioners authorized by the medical staff and the governing body to order the services.
>
> (c) **Standard: Personnel.**
>
> (1) A qualified full-time, part-time, or consulting radiologist must supervise the ionizing radiology services and must interpret only those radiologic tests that are determined by the medical staff to require a radiologist's specialized knowledge. For purposes of this section, a radiologist is a doctor of medicine or osteopathy who is qualified by education and experience in radiology.
>
> (2) Only personnel designated as qualified by the medical staff may use the radiologic equipment and administer procedures.
>
> (d) **Standard: Records.** Records of radiologic services must be maintained.
>
> (1) The radiologist or other practitioner who performs radiology services must sign reports of his or her interpretations.
>
> (2) The hospital must maintain the following for at least 5 years:
> (i) Copies of reports and printouts.
> (ii) Films, scans, and other image records, as appropriate.

Each CoP contains one or more component "standards." Notice that the Radiologic Services CoP printed above contains four standards (in bold type above and repeated below):

1. 482.26(a) Standard: Radiologic Services
2. 482.26(b) Standard: Safety for patients and personnel
3. 482.26(c) Standard: Personnel
4. 482.26(d) Standard: Records

If a hospital is found to be out of compliance with a CoP (called a "condition-level deficiency"), CMS will put the hospital on a termination track. However, if the hospital is not out of compliance with the entire CoP, but only out of compliance with one or more standards (called a "standard-level deficiency"), the hospital will be required to complete a plan of correction and undergo State Survey Agency monitoring, but will not be put on a termination path. *(See "Condition-Level vs. Standard-Level Deficiency," page 3.23, B. "State Monitoring," page 3.33, and VIII. "The Termination Process," page 3.34, regarding termination tracks.)*

If a hospital is found to be out of compliance with two CoPs, the surveyors will carefully assess compliance with the Governing Body CoP, also, and may very well find the hospital out of compliance with that CoP as well.

Interpretive Guidelines and Survey Procedures

CMS has published additional guidance, called "*Interpretive Guidelines*," to clarify surveyors' (and hospitals') understanding of the CoPs and to keep surveyors throughout the country consistent. The *Interpretive Guidelines* also include "Survey Procedures," directions for surveyors to follow when assessing compliance with the CoPs. The *Interpretive Guidelines* (and the survey procedures) are found in the appendixes to the State Operations Manual, discussed below.

B. State Operations Manual

CMS has prepared a manual for State Survey Agency surveyors so that they understand the survey process as well as how to interpret the CoPs. This manual is called the "State Operations Manual" (SOM). It is published only on the Internet, thus CMS calls it an "Internet-Only Manual" (IOM). It is found at www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo as Publication 100-07. It is searchable and printable. Many portions are hundreds of pages long; be sure to check before you print.

CMS occasionally revises or updates the SOM. CMS announces the revisions or updates by issuing to State Survey Agencies a separate memo (previously called "Survey & Certification Memos"), rather than by revising the main online document. These memos are directed to "State Survey Agency Directors" and have a code in the upper right-hand corner (for example, Ref: QSO-19-09). At a later date, CMS updates the online document in accordance with the memo — this may take months. Therefore, hospitals should not rely on the online manual only. Instead, hospitals should also check for any relevant memos that were issued since the last revision date of the relevant part of the online SOM (chapter or appendix) tht the hospital is interested in. The first page of each online document comprising the SOM tells its last revision date. *(See "CMS Memos to Surveyors," page 3.10, for more information.)*

The SOM provides guidance to surveyors and sets out CMS policy regarding survey procedures as well as the specific requirements hospitals must meet. State Survey Agencies are expected to refer to and comply with the SOM. The SOM is therefore an important resource for hospitals, even though it is written for surveyors.

The SOM has eight chapters, hundreds of exhibits, and 24 appendixes. The most important portions of the SOM with regard to hospital surveys are chapters 2, 3 and 5, as well as the appendixes.

Chapters

1. Chapter 1: Program Background and Responsibilities
2. Chapter 2: The Certification Process
3. Chapter 3: Additional Program Activities
   (This chapter discusses sanctions for noncompliance with the CoPs, including the process for terminating a hospital's participation in the Medicare and Medicaid programs.)
4. Chapter 4: Program Administration and Fiscal Management
5. Chapter 5: Complaint Procedures
6. Chapter 6: Special Procedures for Laboratories
7. Chapter 7: Survey and Enforcement Process for SNFs and NFs
8. Chapter 8: Standards and Certification

Exhibits

The exhibits are model letters and forms for the surveyors to use. Hospitals may wish to review Exhibit 7A, Principles of Documentation. This exhibit is a tool to assist surveyors in drafting the Form CMS-2567 "Statement of Deficiencies and Plan of Correction." However, it includes a disclaimer advising that it is "merely guidance" for surveyors and that it does not impose obligations on either providers or surveyors.

Appendixes

The SOM contains numerous appendixes. Each appendix pertains to a particular type of facility or service (except for Appendix Q which guides surveyors in determining when a deficiency constitutes an immediate jeopardy under federal law). The appendixes are very important, and are discussed in more detail below.

SOM Appendixes: Interpretive Guidelines

As mentioned above, each appendix to the SOM pertains to a particular type of facility or service (except for Appendix Q, which guides surveyors in determining when a deficiency constitutes an immediate jeopardy under federal law). Each appendix repeats the language of the CoPs applicable to the relevant facility or service, and the standards that comprise those CoPs. In addition, CMS has included additional guidance and a recommended survey procedure for each CoP. Hospital managers need to be familiar with not only the CoPs and the related standards, but also the *Interpretive Guidelines*. The *Interpretive Guidelines* provide valuable insight into the agencies' evaluation process and what the hospital must do to comply with each CoP.

The appendixes that are most relevant for hospitals are:

1. A: Hospitals
2. B: Home Health Agencies
3. C: Laboratories and Laboratory Services
4. D: Portable X-Ray Service
5. E: Outpatient Physical Therapy or Speech Pathology Services
6. G: Rural Health Clinics

7. H: End-Stage Renal Disease Facilities
8. I: Life Safety Code
9. K: Comprehensive Outpatient Rehabilitation Facilities
10. L: Ambulatory Surgical Services
11. M: Hospice
12. Q: Determining Immediate Jeopardy (applies to all facility types)
13. T: Swing-Beds
14. V: Responsibilities of Medicare Participating Hospitals in Emergency Cases (EMTALA)
15. W: Critical Access Hospitals
16. X. Survey Protocol and Interpretive Guidelines for Organ Transplant Programs
17. Z: Emergency Preparedness for All Provider and Certified Supplier Types

NOTE: The SOM governs hospitals as well as numerous other types of health care facilities and services such as hospices, home health agencies, nursing facilities, and intermediate care facilities. In referring to the SOM, be sure to look at the appropriate facility or service provisions.

Continuing with the Radiologic Services example, we see that Appendix A, Hospitals, contains 25 pages of *Interpretive Guidelines* and survey procedures regarding the Radiologic Services CoP. The *Interpretive Guidelines* provide background on definitions regarding radiologic services, the necessary level of services to be provided and a general overview of CMS's expectations regarding the hospital's radiologic services, including safety requirements. The *Interpretive Guidelines* also provide information about nationally recognized standards and recommendations regarding radiologic services. Finally, the survey procedures outline the steps that the surveyors will undertake. For example, some of the procedures that surveyors are directed to undertake with respect to assessing compliance with the Radiologic Services CoP are:

1. Verify that radiological services are integrated into the hospital-wide QAPI program.
2. Observe locations where radiological services are provided. Are they safe for patients and personnel? Are any hazards to patients or personnel observed?
3. Review the inspection records (logs) to verify that periodic inspections are conducted in accordance with manufacturer's instructions, federal and state laws, regulations, and guidelines and hospital policy.
4. Verify that the hospital requires periodic checks on all radiology personnel and any other hospital staff exposed to radiation and that the personnel are knowledgeable about radiation exposure for month, year, and cumulative/entire working life.
5. Review medical records to determine that radiological services are provided only on the orders of practitioners with clinical privileges and to practitioners outside the hospital who have been authorized by the medical staff and the governing body to order radiological services, consistent with state law.

6. Determine which staff are using differing pieces of radiological equipment and/or administering patient procedures. Review their personnel folders to determine they meet the qualifications established by the medical staff for the tasks they perform.

The complete *Interpretive Guidelines* for the Radiologic Services CoP, including the survey procedures, are found online *(see B. "State Operations Manual," page 3.7)*.

Tags

The appendixes also contain "tags." For Appendix A (Hospitals), the tags under the Radiologic Services CoP are A-0528, A-0529, A-0535, A-0536, A-0537, A-0538, A-0539, A-0546, A-0547, and A-0553. These tag numbers will be used by the surveyors in the Form CMS-2567: "Statement of Deficiencies and Plan of Correction" to identify as specifically as possible which requirement(s) the hospital failed to fulfill.

(The tags for Appendix W, Critical Access Hospitals, start with a "C" — for example, C-0168. The tags for Appendix C, Laboratories, start with a "D" — for example, D5301. Tags for other provider types or services may start with different letters.)

The tags do not precisely correspond to the conditions or the standards. A standard, for example, may have one tag or may have several tags.

Hospitals should be familiar with the CoPs, their component standards, and the *Interpretive Guidelines*. In preparing for surveys, hospitals should assign staff to "act like a surveyor" and take each step noted in the survey procedures *(see D. "Perform Mock Surveys," page 4.5)*. As mentioned above, the CoPs, standards, *Interpretive Guidelines*, and survey procedures are all found in the appendixes to the SOM.

CMS Memos to Surveyors

CMS frequently sends memos to State Survey Agency directors to clarify issues that may be misunderstood by surveyors, to update surveyors on changes to the SOM, and to provide survey tools to surveyors. These memos can be very helpful to hospitals in understanding various aspects of the survey process as well as substantive areas of compliance. The memos are referenced with a code and date (for example, QSO-19-09, dated Mar. 5, 2019) and are posted on the CMS website at www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions.html. Hospitals should check this website a couple of times per month to determine whether any new items posted are relevant to their facility type or services provided.

C. EMTALA

Although the Emergency Medical Treatment and Labor Act (EMTALA) statute and regulations are in a different part of the law from the CoPs, hospitals are required to comply with the EMTALA requirements in order to participate in the Medicare and Medi-Cal programs.

The EMTALA statute is found at 42 U.S.C. Section 1395dd. The EMTALA regulations are found at 42 C.F.R. Sections 489.20 and 489.24. (*See "Where to Find Laws Referenced in the Manual"* at the beginning of the manual, for information about where the exact text of these laws may be found on the Internet.) Appendix V to the SOM, "Responsibilities of Medicare Participating Hospitals in Emergency Cases," contains the *Interpretive Guidelines* and the survey procedures related to EMTALA compliance *(see "Appendixes," page 3.8)*.

The enforcement of EMTALA is a complaint-driven process. The investigation of a hospital's policies and procedures and any subsequent sanctions are initiated by a complaint. The survey process generally follows what is described in this manual for other complaint surveys (that is, entrance conference, surveyor observations, exit conference, CMS-2567, plan of correction, etc.). An EMTALA survey may also include a referral of medical records to the CMS-contracted quality improvement organization (QIO; in California, this is Livanta) for a physician to review to determine whether the medical screening exam was adequate, stabilizing treatment was appropriate within the capability of the hospital, a transfer was made with qualified personnel and transportation equipment, a transfer was appropriate, etc.

If the results of the complaint investigation indicate that a hospital violated one or more EMTALA requirements, the hospital may be put on a termination track *(see VIII. "The Termination Process," page 3.34)*. In addition, civil monetary penalties of up to $111,597 per violation may be imposed against individual physicians and/or the hospital ($55,800 for hospitals under 100 beds). *(See D. "Financial Penalties," page 3.27.)*

CHA publishes a manual dedicated to EMTALA compliance and enforcement titled, *EMTALA: A Guide to Patient "Anti-Dumping" Laws*. Visit www.calhospital.org/emtala-manual for more information about the manual or to order it.

D. Life Safety Code

The CoP for Physical Environment requires compliance with the Life Safety Code (LSC) and Health Care Facilities Code (HCFC). The LSC is a set of fire protection requirements designed to provide a reasonable degree of safety from fire. It covers construction, protection and operational features designed to provide safety from fire, smoke and panic. The HCFC is a set of requirements intended to provide minimum requirements for the installation, inspection, testing, maintenance, performance and safe practices for facilities, material, equipment and appliances. These documents are published and revised periodically by the National Fire Prevention Association (NFPA). The basic requirement for facilities participating in the Medicare and Medicaid programs is compliance with the 2012 edition of the LSC and HCFC.

In the past, CDPH contracted with the State Fire Marshal to provide the LSC surveyors. However, CDPH now sends some of its HFENs to special life safety training given by CMS in Baltimore, and those HFENs assess the hospital's compliance with the LSC. *(See B. "CDPH Staffing/Surveyors," page 2.1, for more information regarding HFENs.)*

The surveyors will inspect floor-to-floor separations, corridor wall construction, smoke and fire barriers, vertical opening construction, exit stairs and doors, signage, fire alarm system, sprinkler system, emergency power generator set, emergency lighting, medical gas storage, electrical outlets, extension cords, flammability of wastebaskets/drapes/etc., fire extinguishers, corridor obstructions, storage of flammable liquids and gases in laboratories, fume hood ventilation, and the facility fire plan including fire drill records and staff training.

Waivers

CMS has the authority to grant waivers of LSC and HCFC provisions for facilities participating in Medicare and Medicaid. If a hospital is unable to resolve a particular life safety deficiency that was cited during a survey, the hospital can submit a request for a waiver or an equivalency. CMS must find that (a) if the LSC were rigidly applied it would result in an unreasonable hardship and (b) the deficiency does not adversely affect patient health and

safety. Note that the deficiency must have been cited during a survey to be eligible for a waiver or equivalency. A hospital that wants a waiver or equivalency should review the issue with its surveyor for inclusion in the Statement of Deficiencies (Form 2567). Only the CMS regional office can approve a waiver or equivalency request.

Waivers and equivalencies approved by CMS are valid only until the next survey (no more than 3 years), then the deficiency must be cited again during the survey, and the hospital must choose to either resolve the deficiency, or submit a new waiver or equivalency request again. Remember that the decision by CMS to approve a waiver or an equivalency request is made by an individual. There is no guarantee that the same decision will be made again by the same individual, or another person in the same position.

Waivers and equivalencies should not be used for minor deficiencies that can be and should be resolved. Waiver or equivalency requests are appropriate for issues that are truly an operational or financial hardship to resolve.

A waiver request must include the following information:

1. Hospital name, address and CCN
2. Contact information for hospital representative (name, title, telephone number and email address)
3. Detailed description of the deficiency, including the section number
4. Explanation of why the hospital cannot resolve the deficiency and whether the hardship is financial or operational. If financial, provide a budget figure to resolve the deficiency to demonstrate the hardship.

CMS may also issue a time-limited waiver. This may be appropriate if a hospital has been cited for a LSC deficiency that it wants to resolve, but cannot do so within the required time period (60 days of the end of the survey). A time-limited waiver request is, in essence, a request for an extension date to fix the deficiency. The same process for submitting a waiver request should be used, except instead of explaining the hardship in resolving the deficiency, the hospital explains the modifications or actions are required to resolve the deficiency. The hospital should include a copy of a contract with a vendor, building permits, and/or construction schedules to prove corrective action is underway.

An equivalency request is an NFPA document that scientifically demonstrates an equivalent level of safety by assessing the remaining features of life safety through a mathematical formula. An approved equivalency is valid only until the next survey. Hospitals will likely need to hire an experienced consultant to conduct the required engineering study and help them prepare the equivalency request.

Resources

A complete discussion of the LSC and LSC surveys is beyond the scope of this manual. Hospital facility managers should review 42 C.F.R. Section 482.41 (Physical Environment CoP), Appendix I to the SOM (Survey Procedures and *Interpretive Guidelines* for Life Safety Code Surveys) and NFPA publications.

IV. FEDERAL SURVEY PROCESS

Surveyors will assess the hospital's compliance with the CoPs for all services, areas and locations in which the hospital receives reimbursement for patient care services billed under its CMS Certification Number *(see III. "Which Laws are Federal Surveyors Assessing Compliance With?," page 3.3)*. This may include inpatient and outpatient services, both on- and off-campus. The surveyors will accomplish this through observations, interviews and document/record review. Most of the surveyors will be from CDPH, which has a contract with CMS to provide surveyor services *(see B. "CDPH Staffing/Surveyors," page 2.1, and I. "CMS Organizational Structure and Staffing," page 3.1, for more information)*.

Although surveys generally occur during daytime working hours (Monday through Friday), surveyors may conduct the survey at any time, including evening and weekends. All surveys are unannounced. A hospital that refuses to allow immediate access to the premises and relevant documents to a State Survey Agency or CMS surveyor(s) upon reasonable request may be excluded from participation in the Medicare and Medicaid programs [42 C.F.R. Sections 488.7, 489.53 and 1001.1301]. (Regulations discussed in this manual regarding the federal survey process may be found at 42 C.F.R. part 488, subpart A.)

Before the survey team arrives at the hospital, they will have familiarized themselves with the hospital's ownership, physical plant, previous survey results, waivers and variances that exist, types of services offered, media reports, the hospital's website, complaints and other information.

A. Overview

The survey process, in general, consists of an entrance conference, observations by the surveyor(s) and an exit conference. After the exit conference, the hospital will develop preliminary corrective action steps while the surveyors are writing up their survey findings on the CMS-2567 form. After the hospital receives its 2567 form, the hospital will prepare and submit its final plan of correction. Finally, the surveyors may (and in some cases, must) return to the hospital to verify that the plan of correction was implemented. Information about these steps in the survey process is provided below.

In many parts of this manual, the most extensive type of survey is described — a full state licensure or federal certification or validation survey, which can be a week-long (or longer) experience with multiple surveyors in the facility at the same time, with potentially serious consequences. The hospital will need to devote significant high-level staff time responding to this type of survey. However, many surveys will be abbreviated versions of those described in this manual, and the hospital will want to adjust its response and procedures accordingly.

B. Entrance Conference

The entire survey team will enter the hospital together. Upon arrival, the surveyors will usually go to a front desk or to Administration, present identification (which they expect to be checked) and advise the hospital CEO (or designated person in charge) of their intention to conduct a survey. For a validation survey, a surveyor will present the hospital a letter announcing the validation survey, as well as a form titled "Authorization by Deemed Provider/Supplier Selected for Accreditation Organization Validation Survey." The hospital's CEO or other authorized individual will be asked to sign the authorization document, acknowledging that the hospital must permit the validation or complaint survey to take place,

as well as state agency monitoring of the correction of any substantial noncompliance found through the survey. If the hospital refuses to permit the survey to take place, the surveyor will inform the hospital that its deemed status will be removed (if it has deemed status) and the hospital may be subject to termination from the Medicare and Medicaid programs.

The hospital should issue temporary IDs to the surveyors if this is hospital policy. The surveyors will then initiate an entrance conference during which they introduce themselves, identify the team leader, describe the purpose of the survey, and provide an overview of the expected procedure. According to the SOM, the surveyors will provide information about the following:

1. Clarification that all hospital areas and locations under the hospital's CMS Certification Number may be surveyed.
2. Explanation that all interviews with patients, staff and visitors will be conducted privately unless otherwise requested by the interviewee.
3. Discussion of how the facility will assure that the surveyors are able to obtain copies of records and other documentation needed during the survey.
4. Identification of the names and contact information of key staff members.
5. Discussion of the estimated time, location, and possible attendees of any meetings that might be held during the survey.
6. Proposal of a tentative date and time for the exit conference.

See A. "First Impressions," page 4.7, and B. "Entrance Conference," page 4.7, for tips regarding the entrance conference.

If the survey is for the purpose of investigating a complaint, the surveyors will mention only the general nature of the complaint. For example, if the complaint is that a patient developed a life-threatening infection in a post-surgical wound, the surveyors will be vague, merely indicating that it is a situation related to infection control for surgical patients. They will not identify the complainant. However, the hospital may be able to guess the complainant from the patient records that the surveyors choose to review.

At the end of the entrance conference, the survey team will conduct its own team meeting without hospital representatives present.

What to Provide the Survey Team

The materials requested by the surveyors will depend on the type and focus of the survey. Generally, the survey team will ask for the following:

1. A conference room or other location where the team may meet privately during the survey. The room must be lockable and have appropriate power outlets/strips, internet access, and a printer.
2. A telephone for team communications, preferable in the team meeting location.
3. A list of current inpatients, including each patient's name, room number, diagnosis(es), admission date, age, attending physician, and other significant information. The surveyors will want this information ASAP, and in no case later than 3 hours after the request is made.

4. A list of department heads with their locations and phone numbers. (It's a good idea to also provide the name and phone number of the hospital's LCA team leader.)
5. A copy of the facility's organizational chart.
6. The names and addresses of all off-site locations operating under the same CMS certification number. (This is the number used to bill hospital services to Medicare; a rural health clinic or skilled nursing facility will probably have a different certification number.)
7. The hospital's infection control plan.
8. A list of all employees.
9. The medical staff bylaws and rules and regulations.
10. A list of contracted services.
11. A copy of the facility's floor plan, indicating the location of patient care and treatment areas. (It's a good idea to prominently indicate on the floor plan where the surveyors' conference room or work room is located, and the telephone number(s) of the phones in the room.)
12. Any waivers the hospital has obtained.
13. For state surveys, the surveyors will want copies of program flexes that have been granted. CDPH has prepared a list of documents it may request for relicensing surveys, available at https://www.cdph.ca.gov/Programs/CHCQ/LCP/CDPH%20Document%20Library/GACHRLS-GeneralEntranceList.pdf.
14. CDPH surveyors must have a flu vaccine or wear a mask in designated patient care areas during the annual flu season. CDPH employees who have received a flu vaccine will have a sticker on their CDPH identification badge. If the surveyor hasn't been vaccinated, the hospital must provide a mask. *(See All Facilities Letter 20-82, dated Oct. 30, 2020, for more information.)*

In a hospital using electronic health records (EHRs), the survey team will request that the hospital provide a terminal(s) where the surveyors may have unrestricted access to the medical records. In the case of a hospital with terminals at multiple care locations, surveyors must be provided access to a terminal at each care location *(see "Access to EHRs," page 3.20)*. The hospital must designate a staff member who is proficient at using the EHR to help the surveyors.

If the surveyors are conducting an EMTALA complaint survey, they will ask for the following information as they deem appropriate:

1. Dedicated ED logs for the past 6-12 months;
2. The dedicated ED policy and procedures manual;
3. Consent forms for transfers of unstable individuals;
4. Dedicated ED committee meeting minutes for the past 12 months;
5. Dedicated ED staffing schedule (physicians for the past 3 months and nurses for the last 4 weeks) or as appropriate;
6. Bylaws/rules and regulations of the medical staff;

7. Minutes from medical staff meetings for the past 6-12 months;
8. Current medical staff roster;
9. Physician on-call lists for the past 6 months;
10. Credential files, including the director of the ED and ED physicians;
11. QAPI plan;
12. QAPI minutes;
13. List of contracted services;
14. Dedicated ED personnel records;
15. In-service training program records;
16. Ambulance trip reports and memoranda of transfer; and
17. Ambulance ownership information and applicable state/regional/community EMS protocols.

The hospital should have a person assigned to complete each of the tasks or obtain the information listed above as soon as possible upon notification of the surveyor's presence. A back-up person (or more than one) should also be assigned in case the primary person responsible is sick, on vacation or otherwise unavailable.

C. Surveyors' Procedures

Sample Size and Selection

The surveyors will review the patient list provided by the hospital and select patients who represent a cross-section of the patient population and services provided. They may also use patient logs (ER, OB, OR, restraint, etc.). They usually select patients who are in the facility during the time of the survey (i.e., open records). This allows them to validate the information obtained through record reviews with observations and patient/staff interviews.

The number of patients selected for a CMS certification or validation survey depends upon the hospital's average daily census. The sample will be at least 10 percent of the average daily census, but not fewer than 30 inpatients. For small hospitals with an average daily census of 20 patients or less, the sample should not be fewer than 20 inpatient records. At least one patient from each nursing unit (e.g., med/surg, ICU, OB, pediatrics, specialty units, etc.) will be chosen. In addition to the inpatient sample, a sample of outpatients will be selected.

If a complaint is being investigated, the surveyors will include patients who are part of the complaint. Issues identified through complaints may be an area of focus when selecting the patient sample. Approximately 20-50 records will be reviewed for an EMTALA complaint survey.

The surveyors will give patients (and any staff or visitors that are interviewed) in the sample a unique identifier. The surveyors are required to keep identifying information (medical record numbers, Social Security numbers, billing record numbers, care unit, etc.) on a separate identifier list.

Comprehensive Review

The surveyors will undertake a comprehensive review of care and services received by each patient in the sample. A **"comprehensive review"** includes all three methods of surveying for each patient: observations of care and services provided, interviews with the patient/family/staff, and medical record review (described below).

During the comprehensive review, the surveyors will look at actual and potential patient outcomes, as well as required processes. They will assess the care and services provided, including the appropriateness of the care and whether the care provided meets the needs of the individual patient.

Information Gathering by Surveyors: Observation/Interviews/Record Review

Observation

Surveyors will visit patient care settings, including inpatient units, outpatient clinics, anesthetizing locations, emergency departments, imaging, rehabilitation, remote locations, satellites, etc. They will also visit areas where patients are not present, such as dietary, laboratory, central supply, etc.

The SOM directs the surveyors to:

> Maintain open and ongoing dialogue with the facility staff throughout the survey process. Conferences with facility staff may be held in order to inform them of survey findings. This affords facility staff the opportunity to present additional information or to offer explanations concerning identified issues.

However, the SOM goes on to state that, "Survey information must not be discussed unless the investigation process and data collection for the specific concerns is completed."

The SOM states that surveyors are encouraged to station themselves as physically close to patient care as possible. The surveyors are told to pay particular attention to the following:

1. Patient care, including treatments and therapies in all patient care settings;
2. Staff member activities, equipment, documentation, building structure, sounds and smells;
3. People, care, activities, processes, documentation, policies, equipment, etc., that are present that should not be present, as well as those that are not present that should be present;
4. Integration of all services, such that the facility is functioning as one integrated whole;
5. Whether quality assessment and performance improvement (QAPI) is a facility-wide activity, incorporating every service and activity of the provider and whether every facility department and activity reports to, and receives reports from, the facility's central organized body managing the facility-wide QAPI program; and
6. Storage, security and confidentiality of medical records.

Surveyors are advised to have observations verified by the patient, family, facility staff, another survey team member, or by another mechanism. For example, if a surveyor finds an outdated medication in the pharmacy, the surveyor may ask the pharmacist to verify that the drug is outdated.

Patients have the right to decline to be observed *(see "Patient Privacy Rights," page 3.22)*.

Patient and Employee Interviews

Surveyors will conduct informal interviews throughout the duration of the survey. The SOM directs surveyors to, among other things, do the following:

1. Maintain detailed documentation of each interview conducted. Document the interview date, time and location; the full name and title of the person interviewed; and key points made and/or topics discussed. To the extent possible, document quotes from the interviewee.
2. Interviews with facility staff should be brief. Use a few well-phrased questions to elicit the desired information. For example, to determine if a staff member is aware of disaster procedures and his/her role in such events, simply ask, "If you smelled smoke, what would you do?"
3. When interviewing staff, begin your interviews with staff that work most closely with the patient.
4. Conduct patient interviews regarding their knowledge of their plan of care, the implementation of the plan, and the quality of the services received. Other topics for patient or family interview may include patient rights, advanced directives, and the facility's grievance/complaint procedure.
5. Interviews with patients must be conducted in privacy and with the patient's prior permission.
6. Use open-ended questions during your interview.
7. Validate all information obtained.

Staff interviews may assess the staff's knowledge of the patient's needs, plan of care and progress towards goals. Interviews may also assess the staff's knowledge of the hospital's policies and procedures as well as the staff's clinical proficiency. Staff are allowed to have their supervisor (or another hospital representative) present during the interview. However, the hospital cannot insist that a hospital representative be included in every staff interview. Employees have the right to discuss possible regulatory violations or patient safety concerns with surveyors privately during a CDPH investigation or survey [Health and Safety Code Section 1278.5].

Patient interviews will focus on the patient's condition, reason for admission, quality of care, and the patient's knowledge of their plan of care. For example, a surgical patient may be asked about the process for preparation for surgery, the patient's knowledge of and consent for the procedure, pre-operative patient teaching, post-operative patient goals and the discharge plan. Family members may be interviewed if appropriate (for example, for pediatric patients), as well as ambulance workers or other witnesses.

Patients, family members and other witnesses have the right to decline to be interviewed *(see "Patient Privacy Rights," page 3.22)*.

Document/Record Review

Surveyors may inspect both written and electronic records, including, but not limited to:

1. Patient clinical records;
2. Personnel files;

3. Credentialing and privileging files;
4. Equipment maintenance records;
5. Staffing documentation;
6. Policy and procedure manuals; and
7. Contracts.

Surveyors will make or request photocopies of documents needed to support survey findings (the surveyors may need access to a photocopier where they can make their own copies). The surveyors are required to make the hospital a copy of all items they photocopy if the hospital so requests — the hospital should make this request in a clear manner. If a hospital employee makes copies for surveyors, the employee should make an extra set for the hospital's survey file.

A hospital may be terminated from participation in the Medicare and Medicaid programs if it fails to permit examination or photocopying of any records or other information by, or on behalf of, CMS, as necessary to determine or verify compliance with participation requirements [42 C.F.R. Section 489.53(a)(13)].

Peer Review Documents

CDPH and CMS take the position that they are legally entitled to access peer review information, even if it is protected from discovery during court proceedings by the California Evidence Code. There is some legal support for this position, as CDPH and CMS must assess whether the hospital is complying with regulations governing the medical staff, the hospital governing body, and quality assurance. CMS, in particular, reminds hospitals that as a federal government agency it need not recognize this state law. CMS has the authority to exclude hospitals from participating in Medicare if they fail to provide information that CMS or the State Survey Agency (CDPH) finds necessary to determine Medicare payment liability or compliance with the Conditions of Participation [42 U.S.C. Sections 1320a-7(b)(11) and (12)].

If CMS or CDPH requests peer review information protected by Evidence Code Section 1157 during a survey, the hospital should clearly indicate every report, document and interview that is entitled to 1157 protection, ask the surveyors to note this in their records and reports, and inform them that the hospital intends to assert the applicability of peer review protection. Paper and electronic documents can be labeled "Peer Review Document: Do Not Copy/Do Not Cite in 2567" or something similar. Generally, the surveyors will not copy these documents. Information that is protected from discovery under Evidence Code 1157 may remain protected even if it is disclosed to CDPH in the course of an investigation by CDPH [*Fox v. Kramer*, 22 Cal.4th 531 (2000)]. CHA's *Consent Manual* includes a detailed discussion of incident reports and various legal privileges in chapter 19.

Attorney-Client Privileged Documents

CDPH and CMS do not assert that they are entitled to access documents protected by the attorney-client privilege. California courts have held that incident reports may be regarded as confidential attorney-client communications if the hospital can show that the purpose and intent of the reports is to provide a confidential communication between the hospital and its attorney. CHA's *Consent Manual* includes a detailed discussion of incident reports and the attorney-client privilege in chapter 19.

Patient Safety Work Product Documents

The Patient Safety and Quality Improvement Act (PSQIA) of 2005 was enacted 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 data to identify and better understand underlying causes of risks or ham, and share those findings back to participating providers.

The PSQIA alleviates health care providers' fears that trial lawyers, government agencies, or others might obtain and misuse information about these events by providing federal legal confidentiality protections to the information that is assembled and reported by providers to a PSO. The confidentiality protections preempt any state or local law that allows or requires disclosure of information defined as "patient safety work product." Thus, surveyors should not ask hospitals for access to patient safety work product documents, and hospitals should not provide access to these documents. This applies whether the surveyors are conducting a state survey or a federal survey.

"Patient safety work product" 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 patient safety evaluation system for reporting to a PSO, and such documentation includes the date the information entered the patient safety evaluation system; 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 patient safety evaluation system.

However, patient safety work product 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 patient safety evaluation system. Such separate information or a copy thereof reported to a PSO shall not by reason of its reporting be considered patient safety work product.

A complete discussion of PSOs, including the confidentiality of PSWP, is included in chapter 13 of CHA's *California Hospital Compliance Manual*. Hospitals with questions about which documents may or may not be released to surveyors pursuant to the PSQIA should consult legal counsel.

Access to EHRs

CMS has sent two memorandums to State Survey Agencies regarding the surveying of facilities that use electronic health records (EHRs) [S&C 09-53, dated Aug. 14, 2009, and S&C 14-31 dated May 16, 2014, available at www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions.html].

This memo states that if a surveyor requests access to an EHR, the hospital must:

1. Provide the surveyor with a tutorial on how to use its particular electronic system, and
2. Designate an individual ("navigator") who will, when requested by the surveyor, access the system, respond to questions, and assist the surveyor as needed in accessing electronic information in a timely fashion. The navigator is expected to have sufficient system access permissions to retrieve complete medical records, including, when requested, information from built-in audit features that enable identification of the date, time and author for entries or changes made to the record. The navigator should know which portions of the medical record, if any, are not captured in the EHR and to retrieve those paper-based portions as well.

Each surveyor is allowed to determine the EHR access method that best meets the need for the survey. During the entrance conference in a hospital using EHRs, the survey team must request that the hospital provide a terminal(s) where the surveyors may access records, and will establish the process they will follow in order to have unrestricted access to the medical record. In the case of a hospital with terminals at multiple care locations, surveyors must be provided access to a terminal at each care location.

If the hospital is unable to provide direct print capability to the surveyor, the hospital must make available a printout of any record or part of a record upon request in a time frame that does not impede the survey process. Whenever possible, the hospital must provide surveyors electronic access to records in a read-only format or other secure format to avoid any inadvertent changes to the record. The hospital is solely responsible for ensuring that all necessary back-up of data and security measures are in place.

Providing electronic access to surveyors will not eliminate the need for a surveyor to print a paper copy or to request a paper copy of certain parts of certain records. However, the surveyor is required to make reasonable efforts to avoid, where possible, the printing of entire records. The surveyor should print or request a paper copy of only those parts of records that are needed to support findings of noncompliance, unless protocols for particular types of surveys require otherwise (e.g., copying complete medical records to be submitted for an EMTALA physician review).

CDPH sent a memo to its surveyors following the CMS memo S&C 09-53, stating that CDPH surveyors should interview administrative staff at hospitals to get a general overview of the facility's EHR system and specifically should ask:

1. What records are kept electronically vs. paper?
2. Are electronic records ever purged from the system?
3. Are electronic signatures used?
4. What are the off-site back-up systems, disaster plans and procedures for downtime?
5. What quality assurance monitoring is performed to ensure there is no unauthorized access?

CDPH's memo reminded surveyors that they are not responsible for assessing compliance with HIPAA privacy and security rules (they are enforced by the federal Office for Civil Rights)

[DOM 09-06, Oct. 23, 2009]. The surveyors will focus only on breach reporting under California law (Health and Safety Code Section 1280.15) and whether the hospital's use of EHRs is consistent with the Medicare CoPs. Surveyors will:

1. Tour nursing stations and patient rooms to evaluate where terminals are located, and to see if computer screens showing clinical records are left unattended and readily observable or accessible by patients/visitors.
2. Determine if the terminals log off within a certain period of time, if they are not being used.
3. See if passwords are kept in a visible area.
4. Seek evidence that hospital staff shared information from an EHR with unauthorized individuals.
5. Ask for pertinent policies and procedures.
6. Review EHR system training records for all staff, including registry staff and consultants.
7. Review signed confidentiality agreements or oaths (including volunteers).
8. Review contracts with third parties that have access to electronic records (particularly the confidentiality clauses).

State law requires a hospital to provide access to electronically stored patient records to CDPH staff promptly upon request [Health and Safety Code Section 123149].

Patient Privacy Rights

Surveyors are required to respect patient privacy and maintain patient confidentiality at all times. Surveyors are required to obtain the patient's permission prior to observing the patient receiving treatment. (If the patient lacks the capacity to give permission, the patient's legal representative should be contacted for permission.) A patient may decline/refuse to allow the surveyors to observe and may decline/refuse to be interviewed. A hospital representative may wish to confirm that the patient is comfortable with the surveyor's observation and/or interviewing. The hospital representative may say to the surveyor something like, "Let me go into the patient's room with you and make sure the patient is comfortable with this, and then I'm happy to step out." The patient may request that a hospital staff member stay with them during an interview. The surveyors are required to have a hospital staff member witness any interaction where private parts of the patient's body are exposed.

Surveyors are required to protect the privacy of patients (and others) who are interviewed or observed. Their names will not be used in the 2567, and in some cases, even identifiers will not be used on the 2567 if the interviewee expresses the wish that the hospital not know the source of the information provided to the surveyor. However, the patient (or other person) cannot be guaranteed that the information will remain anonymous, because a court may require that the source of the information be disclosed.

Surveyors may not examine patients by themselves. If it is necessary to determine a patient's health status and whether appropriate health care is being provided, the surveyor may (with patient permission) request that a hospital staff member examine the patient in the surveyor's presence.

Daily Meetings

The surveyors will meet daily (likely at the end of each day), without hospital staff present, to share their findings and any concerns. They will ask fellow surveyors to be on the lookout for similar deficiencies or issues in other areas of the hospital. For example, if one surveyor finds an outdated medication on a crash cart in the emergency department, she will inform her fellow surveyors of that finding, and the other surveyors may check for outdated medications on crash carts in other areas of the hospital during the rest of the survey.

The hospital's licensing, certification and accreditation team should also meet at least daily *(see "LCA Team Meetings During Survey," page 4.9)*.

D. Decision Making by Survey Team

At the end of the period of observation, interviews and document review, the surveyors will meet (without hospital staff present) and discuss each applicable CoP. They will share their findings, evaluate their evidence, and make team decisions regarding compliance with each CoP.

The federal regulations regarding the survey process state:

> The decision as to whether there is compliance with a particular requirement, condition of participation, or condition for coverage, depends upon the manner and degree to which the provider or supplier satisfies the various standards within each condition [42 C.F.R. Section 488.26].

Condition-Level vs. Standard-Level Deficiency

When noncompliance with a CoP is found, the determination of whether the lack of compliance is at the "standard" or "condition" level depends upon the nature (how severe, how dangerous, how critical, etc.) and extent (how prevalent, how many, how pervasive, how often, etc.) of the noncompliance. The determination of whether a hospital has a condition-level deficiency or a standard-level deficiency is left to the discretion of the survey team and CMS to determine. There is no black-and-white rule.

A deficiency at the condition level may be due to noncompliance with requirements in a single standard or several standards within the condition. A deficiency at the condition level may also be due to noncompliance with the requirements of a single part (tag) representing a severe or critical health or safety breach. According to the SOM, "Even a seemingly small breach in critical actions or at critical times can kill or severely injure a patient, and represents a critical or severe health or safety threat."

A deficiency at the standard level may occur when there is noncompliance with any single requirement or several requirements within a particular standard that are not of such character as to substantially limit a facility's capacity to furnish adequate care, or which would not jeopardize or adversely affect the health or safety of patients if the deficient practice recurred.

It is possible for a hospital to have some standard-level deficiencies yet still be found in overall compliance with the CoPs. In such a case, the hospital will not be scheduled for termination from the Medicare and Medicaid programs. Instead, the hospital will be required to complete a plan of correction (PoC) and be put on State Survey Agency monitoring until the deficiencies are corrected.

On the other hand, it is possible that substantial noncompliance with one or more standards will result in a finding that the hospital is out of compliance with one or more conditions. The surveyors will make a recommendation to CMS, which has significant latitude to make the final determination regarding whether the hospital will be found out of compliance with a condition. It is not possible to remain a participant in the Medicare and Medicaid programs if there is sustained noncompliance with any condition *(see V. "Federal Survey Outcome," page 3.26)*.

Deficiency Determined to Have Occurred Prior to Survey

When noncompliance is determined to have occurred prior to an on-site federal survey, and the hospital states to the surveyors while they are still on-site, that it has corrected the deficiency, the survey team will consider the following:

1. Is the corrective action superficial or inadequate, or is the corrective action adequate and systemic?
2. Has the hospital implemented the corrective intervention(s) or action(s)?
3. Has the hospital taken a QAPI approach to the corrective action to ensure monitoring, tracking and sustainability?

The survey team uses its judgment to determine whether the hospital's corrective action is sufficient to prevent the deficiency from recurring. If the surveyors are satisfied with the corrective action, they will not cite a deficiency. However, if noncompliance is noted during a survey, even if the hospital corrects it during the survey, it will be cited on the Form CMS-2567 *(see VI. "The Form CMS-2567: Statement of Deficiencies and Plan of Correction," page 3.30)*.

E. Exit Conference

At the end of the survey, the survey team will conduct an exit conference. The SOM states that the purpose of the exit conference is to informally communicate preliminary survey team findings and provide an opportunity for the interchange of information, especially if there are differences of opinion. The SOM states that all findings should be discussed at the exit conference. The hospital should seek as much clarification about deficiencies as needed to understand what was done wrong and how to correct it. If any complaints or facility-reported incidents were investigated, the survey team should inform the hospital about their status.

Although the exit conference may appear casual, it is not. The hospital must take this meeting very seriously. At the exit conference, the surveyors are required to describe all the deficiencies they found during the survey. Sometimes, however, deficiencies that are mentioned during the exit conference will not be included in the final report because CMS may not agree with State Survey Agency findings in the ultimate report. The surveyors are directed by the SOM to not state whether deficiencies are at the condition-level or the standard-level — however, it doesn't hurt to ask.

The hospital determines which hospital representatives will attend the exit conference. However, as discussed in "Discontinuation of Exit Conference," page 3.25, if an attendee is hostile or intimidating or misbehaves in some way, the surveyors have the authority to discontinue the exit conference completely. In such a case, it may be better for the hospital to agree to exclude the offensive staff member and continue the exit conference.

During the exit conference, the SOM directs the surveyors to state that "the provider will have an opportunity to present new information after the exit conference for consideration after the survey." The SOM states that:

> The provider has a right to disagree with the findings and present arguments to refute them. Surveyors should be receptive to such disagreements. If the provider presents information to negate any of the findings, surveyors should indicate their willingness to reevaluate the findings before leaving the facility. The survey team's reasonableness demonstrates their fairness and professionalism. The degree of receptivity displayed by providers during the exit conference often depends upon the attitudes and survey style of the survey team.

However, it is not unusual for the surveyors to discourage the hospital from providing substantive feedback during the exit conference. Sometimes they will ask if there are any questions. Usually, though, they expect any disputed items to have been dealt with during the survey or to await the 2567. This occurs most frequently when the exit conference takes place late in the day and the surveyors have scheduling or transportation issues.

Nonetheless, if there are known errors of fact or missing information, the hospital should courteously attempt to get the correct information to the surveyors before they leave the facility. It may be possible for the hospital to reschedule the exit conference if necessary to get the information to the surveyors.

It's worth repeating that the exit conference is intended to share preliminary — not final — findings. The hospital may offer additional information during the exit conference. Even if the hospital doesn't offer additional information, the surveyors may, upon later reflection, decide to omit some deficiencies mentioned during the exit conference. Official findings will be sent to the hospital in writing on the 2567 form.

(See E. "Checklist for Exit Conference," page 4.10, for tips regarding the exit conference.)

Complaint Survey Exit Conference

For a complaint survey, the State Operations Manual states that the surveyors should inform the hospital of the survey findings, including a general description of any deficiencies found. The description should be detailed enough to inform the hospital of the types of activities that require corrective action. However, the surveyors are directed not to comment on whether the deficiencies identified were condition- or standard-level. Surveyors must also not make reference to any "tags" related to deficiencies identified *(see "Tags," page 3.10)*. They are also directed not to provide a list of patients interviewed, observed, or whose medical records were reviewed, and not to identify specific patients whose cases are associated with specific deficiencies. However, hospitals have the right to request a copy of any documentation the surveyors copy to support deficiency findings; therefore the hospital should have enough information after the exit conference to begin corrective actions.

Discontinuation of Exit Conference

The SOM states that it is the general policy to conduct an exit conference at the conclusion of each survey. However, the SOM also acknowledges that there are some situations that justify the surveyors' refusal to conduct or continue an exit conference. For example, the surveyors may end the exit conference if the hospital is represented by counsel who tries to turn it into an evidentiary hearing, or if the hospital creates an environment that is hostile, intimidating or inconsistent with the informal and preliminary nature of an exit conference.

V. FEDERAL SURVEY OUTCOME

There are three possible federal survey outcomes:

1. No deficiencies. (A **"deficiency,"** for purposes of federal surveys, means noncompliance with a Medicare requirement.)
2. Standard-level deficiencies.
3. Condition-level deficiencies.

Each is described below. *(See "Condition-Level vs. Standard-Level Deficiency," page 3.23.)*

A. No Deficiencies

Obviously, having no deficiencies is the best possible outcome. The hospital is then done with the survey process — congratulations!

B. Standard-Level Deficiency

If a hospital is found to have only a standard-level deficiency or deficiencies, the hospital may continue to operate if it has submitted an acceptable plan of correction to the State Survey Agency [42 C.F.R. Section 488.28]. The plan of correction must provide for achieving compliance within a reasonable period of time — the SOM describes a reasonable period of time as "generally no longer than 60 calendar days." Depending on the nature of the deficiency, however, the SOM recognizes that some corrections may reasonably take longer than 60 days (for example, if construction is required), while other corrections may reasonably be accomplished in a much shorter time. The amount of time allowed for the hospital to achieve compliance is based on the nature of the deficiency and the State Survey Agency's judgment regarding the capacity of the facility to provide adequate and safe care. A resurvey is not required for standard-level deficiencies. However, the hospital may be monitored by the State Survey Agency until the hospital achieves compliance. If, during monitoring, the State Survey Agency finds the hospital out of compliance with a condition, or discovers an IJ, the hospital may be moved to a termination track *(see VIII. "The Termination Process," page 3.34)*.

C. Condition-Level Deficiency

If the State Survey Agency discovers a condition-level deficiency in the course of a complaint/allegation or validation survey, and if CMS agrees, CMS will notify the provider of the removal of its "deemed status" (if applicable) and place the provider under State Survey Agency survey jurisdiction. CMS may request a full survey of all CoPs. The regional office will determine whether a full survey is appropriate after considering the manner and degree of noncompliance, the hospital's compliance history, recent changes in the provider's ownership or management, whether the resources to conduct a full survey are available in the time frame needed, and the length of time since the hospital's last accreditation survey. Alternatively, the hospital may be put on a termination track *(see VIII. "The Termination Process," page 3.34)*.

A hospital with a condition-level deficiency cannot be certified based on a plan of correction or acceptable progress (that is, what the hospital *will do*). Thus, the hospital will be subject to a resurvey to confirm compliance based on a credible allegation of compliance (that is, what the hospital *has done* to correct the deficiencies) *(see A. "Credible Allegation of Compliance," page 3.33)*.

D. Financial Penalties

Under federal law, financial penalties cannot be imposed for violations of the CoPs. However, financial penalties may be imposed for violations of EMTALA against hospitals for up to $111,597 per violation ($55,800 for hospitals under 100 beds). Penalties may also be imposed against individual physicians for up to $111,597 per violation for wrongfully signing a certification for transfer or failing to respond within a reasonable period of time while serving on-call, under specified circumstances. (Further details about financial penalties for EMTALA violations are found in CHA's *EMTALA: A Guide to Patient Anti-Dumping Laws*, available at www.calhospital.org/emtala-manual. *See also C. "EMTALA," page 3.10, for general information about EMTALA requirements.*)

Value-Based Purchasing

It is possible that a financial penalty may result if a hospital is cited by CMS for an IJ. CMS has stated that a hospital that is cited for immediate jeopardy on at least three federal surveys during the performance period (each time noted on the Form CMS-2567) will be excluded from its Value-Based Purchasing (VBP) program for the applicable fiscal year. Because performance periods can vary by measure, CMS has indicated that a hospital cited for multiple deficiencies during any of the performance periods for a VBP program year will be subject to exclusion.

CMS has further clarified that the survey end date will be used to assign the citation to a performance period unless the Form CMS-2567 contains only EMTALA violations (no violations of CoPs), in which case CMS uses the date the Form CMS-2567 was issued. Two Form CMS-2567s with IJ citations and the same survey end date (simultaneous surveys) are counted as one instance of an IJ citation. CMS acknowledges that the survey end date will often be earlier than the date on which the Form CMS-2567 is issued to the hospital. [42 C.F.R. Section 412.160]

E. Immediate Jeopardy (Federal)

Under federal law, an **"immediate jeopardy"** (IJ) is "a situation in which the provider's or supplier's noncompliance with one or more requirements, conditions of participation, conditions for coverage, or conditions for certification has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident or patient" [42 C.F.R. Section 489.3].

"Likely" means the nature and/or extent of the identified noncompliance creates a reasonable expectation that an adverse outcome resulting in serious injury, harm, impairment, or death will occur if not corrected. Serious injury, serious harm, serious impairment or death are adverse outcomes which result in, or are likely to result in:

1. Death;
2. A significant decline in physical, mental, or psychosocial functioning (that is not solely due to the normal progression of a disease or aging process);
3. Loss of limb, or disfigurement;
4. Avoidable pain that is excruciating, and more than transient; or
5. Other serious harm that creates life-threatening complications/conditions.

[SOM, Appendix Q]

CMS has identified three key components of immediate jeopardy:

1. Noncompliance: the hospital has failed to meet one or more federal health, safety, and/or quality regulations;
2. Actual or likely serious adverse outcome: as a result of the identified noncompliance, serious injury, serious harm, serious impairment or death has occurred, is occurring, or is likely to occur to one or more identified patients at risk; and
3. Need for immediate action: the noncompliance creates a need for the hospital to take immediate corrective action to prevent serious injury, serious harm, serious impairment or death from occurring or recurring.

The survey team must consult its district office manager or Sacramento headquarters before determining that an IJ exists. They may also call CMS and confer with them. If an IJ is called, the survey team will provide written notice to the hospital, which must immediately mobilize to address the circumstances deemed to have created the IJ. The survey team must use the special template found at the end of Appendix Q to notify the hospital of the IJ. Several consequences can follow. These are addressed below.

The hospital must provide a removal plan to the surveyors as soon as it has identified the steps it will take to ensure that no patients are suffering or are likely to suffer serious injury, serious harm, serious impairment or death as a result of the noncompliance. A removal plan is not the same as a Plan of Correction – the removal plan focuses on immediate action steps rather than a more thorough, long-term plan that addresses all aspects of the noncompliance. The removal plan must:

1. Identify the patients who have suffered, or are likely to suffer, a serious adverse outcome as a result of the noncompliance;
2. Identify all actions the hospital will take to immediately address the noncompliance and detail how it will keep patients safe and free from serious harm or death caused by the noncompliance. Unlike a plan of correction, the removal plan need not completely correct all noncompliance associated with the IJ; rather, it must ensure serious harm will not occur or recur.
3. Specify the action the entity will take to alter the process or system failure to prevent a serious adverse outcome from occurring or recurring, and when the action will be complete.
4. Include a date by which the hospital asserts the likelihood for serious harm to any patient no longer exists.

Although there is no strict requirement that the IJ be removed prior to the exit conference, that is certainly the goal a hospital wants to achieve. Removing the IJ before the surveyors leave will avoid the hospital being placed on the 23-day termination track, and the requirement to submit a separate written response to the 2567 regarding the IJ in addition to the response to the condition-level and standard-level deficiencies. Surveyors may use their discretion to delay the team's exit until a removal plan is accepted and the IJ is determined to be removed, if the hospital is capable of removing the IJ while the surveyors are onsite. There is no requirement, however, that surveyors remain on-site until the IJ is removed.

The SOM's Appendix Q, "Core Guidelines for Determining Immediate Jeopardy," provides detailed information and lists factors that surveyors should consider in making their decision. *(See "Appendixes," page 3.8, for information about the appendixes to the SOM.)*

State law also uses the term "immediate jeopardy." While state law defines this term only slightly differently, CDPH has interpreted the term much differently in practice. In addition, under state law, a deficiency constituting immediate jeopardy may result in a financial penalty. This is not the case under federal law, unless there is an EMTALA violation or impact on the hospital's participation in the Value-Based Purchasing program. *(see V. "State Survey Outcome," page 2.9, regarding the state definition and application of the term "immediate jeopardy")*. CHA has created a chart showing the differences between state and federal IJs; it may be found at the end of this manual as Appendix HS-15, "Federal vs. State Immediate Jeopardy Definition and Implementation Comparison."

Hospital Corrects IJ While Surveyors are On-Site

Even if the hospital corrects the IJ while the surveyors are still on-site, and that correction fully addresses any condition-level noncompliance associated with the IJ incident, the IJ incident will still be reported on the Form CMS-2567 — but it will be noted that the deficiency was removed. The hospital will not be put on a termination track.

The hospital's Form CMS-2567 response in this circumstance should describe what was done to correct the IJ (all corrective actions taken), the date of full correction, any monitoring that may be called for and the hospital employee responsible for maintaining compliance.

Hospital Corrects IJ While Surveyors are On-Site, But Deficiencies Remain: 90-Day Termination Track

If the hospital corrects the IJ while the surveyors are still on-site, but an associated condition-level deficiency or deficiencies remain (notwithstanding resolution of the IJ circumstances), then CMS or the State Survey Agency will cite a condition-level deficiency and the removal of an IJ on the Form CMS-2567 report, and will place the hospital on a 90-day termination track *(see C. "Condition-Level Deficiency," page 3.26)*.

If the hospital corrects the IJ while the surveyors are still on-site, but an associated standard-level deficiency or deficiencies remain (notwithstanding resolution of the IJ circumstances), then CMS or the State Survey Agency will cite the IJ and the condition-level deficiency, but show the date of removal. The remaining deficiencies will be cited at the standard level on the Form CMS-2567 report, and (assuming no other condition-level deficiencies exist) the hospital will be subject to State Survey Agency monitoring until the deficiencies have been corrected. The hospital will not be put on a termination track.

(See also "Condition-Level vs. Standard-Level Deficiency," page 3.23.)

Hospital Does Not Correct IJ While Surveyors are On-Site: 23-Day Termination Track

If the hospital has not corrected the IJ while the surveyors are still on-site, CMS or the State Survey Agency will issue an IJ and place the hospital on a 23-day termination track. *(See VIII. "The Termination Process," page 3.34.)*

If the hospital submits a "credible allegation" that it has corrected the threat, the State Survey Agency is instructed to resurvey before termination, if possible. A "credible allegation" is one

that is realistic in terms of the possibility of the corrective action being accomplished by the time of the credible allegation and indicates resolution of the problem.

If the hospital does not alleviate the threat before day 23, then Medicare participation will be terminated effective on day 23.

If the hospital alleviates the threat before day 23, but deficiencies still exist at the condition level, the hospital will shift "tracks" to the 90-day termination track (described at CHA Appendix HS-8, "Timeline for 90-Day Termination Track"), in effect giving it 67 more days to bring itself into compliance.

VI. THE FORM CMS-2567: STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

A. Statement of Deficiencies

After the survey, the surveyors will complete the surveyor's portion of the Form CMS-2567, "Statement of Deficiencies and Plan of Correction" (a copy of this form is found at the back of this manual as CHA Appendix HS-7 and at http://cms.gov/cmsforms/downloads/CMS2567.pdf). The CMS-2567 is the record of the survey where the survey team documents and justifies its determination of compliance or noncompliance.

Each surveyor will draft his or her section of the CMS-2567, so the style and detail may vary within the document. The State Survey Agency (CDPH) is not required to include all of the deficiencies mentioned during the exit conference. However, the State Survey Agency is not supposed to include any deficiencies that were not mentioned during the exit conference. (A recording of the exit conference may prove critical in documenting such discrepancies for an informal or formal appeal. *See "Consider Recording the Exit Conference," page 4.11.*) The state surveyors will send the CMS-2567 to the CMS regional office for review before the hospital receives it.

CMS may accept the CMS-2567 as written, or may work with the State Survey Agency to make changes; CMS clearly has the authority to reject and/or modify State Survey Agency recommendations. CMS makes the ultimate decision regarding which, if any, conditions and standards are not met. After CMS has approved the CMS-2567, CMS will mail it to the hospital. It is supposed to be sent to the hospital within 10 working days after the exit conference. However, this deadline is frequently missed. CMS is also supposed to alert the hospital of the pending report as soon as possible in the case of an IJ, and within 30 days for other cases. CMS may phone the hospital and fax the CMS-2567. (If CMS calls, the hospital should request that CMS fax the CMS-2567 as soon as possible. Be aware that the CMS-2567 can be very lengthy — sometimes 150 pages or more, since CMS uses only a small part of each page.)

The Form CMS-2567 is a five-column document:

1. The first and third columns (identical) include the tag associated with each deficient condition and standard. These tag numbers are found in the State Operations Manual appendix for the applicable facility or service *(see "Tags," page 3.10, for more information about tags)*.
2. The second column includes the following:

a. A cite to the regulation. The Code of Federal Regulations citation refers to the actual standard or condition at issue as it is stated in the federal regulations.

b. An explicit statement that the condition or standard is not met and how that determination was made.

c. A detailed description of the findings. The statement of the evidence describes the circumstances the surveyors found that led them to conclude that a deficiency exists. The statement may be short or lengthy and may be broken out into separate findings that separately or together demonstrate noncompliance. It is not unusual for this statement to be highly repetitive and difficult to follow. Be careful to take the time to read each finding to ascertain what exactly is being cited as a deficiency and what may be superfluous information.

- In a condition tag, each finding is usually followed by a reference to the standard tag implicated.
- In a standard tag, if an interview supported the finding, the details of that interview will be described, but the form will usually not identify specific individual interviewees or patients (because of confidentiality issues and the fact that the Form CMS-2567 is a public document.) That is why the suggestions for documentation during the survey are so important *(see chapter 4)*. Also, if the hospital has failed to abide by one of its policies and procedures, then that particular policy will be mentioned and summarized to further demonstrate the deficiency.

3. The fourth and fifth columns of the Form CMS-2567 are blank when the hospital receives it. While column four is called "Plan of Correction," the actual response required for this column may be a plan of correction (meaning the steps the hospital has already taken *and* the steps the hospital will take after the 2567 response is submitted to achieve compliance) or a "credible allegation of compliance" (meaning all steps to correct deficiencies have been completed) *(see A. "Credible Allegation of Compliance," page 3.33)*, depending on the type of survey, the findings and the instructions in the cover letter. *(See chapter 5 for more information on preparing the hospital's response.)*

The hospital's response is usually due to the State Survey Agency (CDPH) within 10 calendar days after the hospital receives it.

B. Cover Letter From CMS Accompanying CMS-2567

The Form CMS-2567 is usually accompanied by a cover letter from CMS. Like the CMS-2567, this is usually a template that CMS tailors to fit the circumstances particular to the hospital in question. The cover letter is a critical document and must be reviewed very carefully. The letter includes the following information:

1. **Termination Date**. If the hospital is found out of compliance with one or more CoPs, the cover letter will state the ultimate date that the hospital's CMS certification will terminate if the hospital does not come back into compliance in the required amount of time. The cover letter will also include the date that CMS

will give notice to the public regarding the termination *(see C. "Public Notice," page 3.36)*.

2. **Date Hospital's Response is Due**. This date is usually a fairly quick turnaround (10 calendar days normally). If the date falls on the weekend or a holiday, be sure to get CDPH/CMS confirmation that receipt of the hospital's CMS-2567 response by the next working day is acceptable. CMS may be willing to extend the deadline by a few days; if so, the extension should be documented.
3. **Review of Hospital's Response/Right to Resurvey**. The CMS cover letter will explain that CMS will authorize the State Survey Agency to perform a resurvey only if the hospital's CMS-2567 response is timely, responsive to all deficiencies, and credible.
4. **Ability to Resurvey**. Some CMS cover letters explain the process that would occur if authorities could not resurvey the hospital prior to the termination date. This language is disturbing because it ignores CMS prescribed timelines. Legal counsel should be consulted immediately if the hospital's cover letter includes this language.
5. **CMS and/or State Survey Agency Contact**. The cover letter should include a contact name and phone number that the hospital may call with questions.
6. **List of Noncompliance Conditions**. This list summarizes the CoPs with which the hospital is not in compliance, if there are any. The Form CMS-2567 may include standards that the hospital has not complied with that, although they are deficiencies, do not cause the hospital to be out of compliance with the entire condition.
7. **Elements to Address in the Hospital's Response**. The cover letter will spell out specific elements that CMS expects the hospital to address in its CMS-2567 response, for each deficiency. Be careful — these elements vary with each cover letter. There is no one formula to a hospital's CMS-2567 response because CMS sometimes alters the required elements for the hospital's response.

These variances in cover letter instructions can further complicate the hospital's move from its preliminary response/plan of correction to its final CMS-2567 response/plan of correction. The important point here is that the hospital's CMS-2567 response must specifically address each point listed in the cover letter. *(See chapter 5 for more information on preparing the hospital's response.)*

C. Plan of Correction

Chapter 5 contains information about steps to take after the survey has concluded, including initial steps to take immediately after the exit conference, developing preliminary corrective action steps, and drafting the Plan of Correction.

D. Public Availability of CMS-2567

The Form CMS-2567 is made available to the public no later than 90 calendar days following completion of the survey. The purpose of disclosure is to notify the public of the hospital's deficiencies and the actions the hospital is taking to remedy them. If the federal government receives a Freedom of Information Act request, the Form CMS-2567 may be released much sooner than the usual 90 days. Because of this, the hospital should be prepared for media inquiry as soon as the survey ends *(see D. "News Media," page 5.3).*

The Association of Health Care Journalists posts deficiencies on CMS-2567s from complaint investigations on its website at www.hospitalinspections.org. The database is searchable by state, city or key work (such as "abuse" or "medication error.") However, the hospital's response or plan of correction is not included.

VII. CDPH/CMS ACTIONS AFTER POC SUBMITTED

A. Credible Allegation of Compliance

Upon receiving the hospital's 2567 response, the surveyors must determine whether the hospital has made a credible allegation of compliance. A **"credible allegation of compliance"** is a statement or documentation:

1. That is realistic in terms of the possibility of the corrective action being accomplished between the exit conference and the date of the allegation of compliance (for example, the date of the hospital's plan of correction); and
2. That indicates resolution of the problems.

The SOM states that the alleged corrective action:

1. Should be detailed;
2. Must have removed the deficiency; and
3. Must be of the kind that could have been accomplished between the survey date and the date of the allegation of compliance (the date of the hospital's plan of correction).

Sometimes CMS will approve the PoC without a resurvey. Other times, a resurvey is required. CMS will grant a resurvey only if the State Survey Agency determines that the hospital has made a credible allegation of compliance in its 2567 response.

CDPH and CMS are not required to communicate to the hospital when a determination has been made regarding whether the hospital has successfully made a credible allegation of compliance. Often the only confirmation the hospital receives that such a determination has been made is the appearance of surveyors to resurvey. Nonetheless, if too much time passes without word (how much is too much will depend on the circumstances, whether termination dates are impending, etc.), the hospital should call CDPH and/or CMS to ask the status of the survey process and to specifically ask if a credible allegation of compliance has been found or if any additional information or clarification is needed. If CMS has decided to approve the PoC without a resurvey, the hospital may wish to request a confirmation letter.

B. State Monitoring

CMS may place a hospital on **"state monitoring."** This refers to visits by the State Survey Agency to oversee a hospital's compliance status:

1. During bankruptcy, when CMS authorizes such visits.
2. After a change of ownership, when CMS authorizes such visits.
3. During or shortly after removal of an IJ when the purpose of the visit is to ensure the welfare of patients by providing an oversight presence, rather than to perform a structured follow-up visit.
4. In other circumstances, when CMS authorizes such visits.

C. Resurvey

When CMS believes that the hospital's 2567 response has made a credible allegation of compliance, the hospital may be entitled to a resurvey, depending on which track the hospital is on and where the hospital is in the investigation process. Because it is not always clear when the hospital is entitled to a resurvey, the hospital should pin down CMS on this subject during telephone calls or during the survey itself. (The terms "resurvey," "revisit," and "revisit survey" are used interchangeably.) If CMS determines that a resurvey is needed, the hospital should request a prompt resurvey from CMS/CDPH well before the threatened termination date (if applicable). Communication with CMS an CDPH can be critical regarding the timing of the resurvey in relation to the hospital's decertification. If the resurvey process is not completed before the deadline, the hospital may wish to consider judicial action to halt or delay the termination *(see B. "Filing a Lawsuit," page 3.38)*. On rare occasions, CMS has extended the termination date for hospitals, but this is discretionary and a hospital should not rely on this option. (For a complaint survey requiring a resurvey, the resurvey should take place within 45 days of the complaint survey if no full survey is required by CMS.)

The scope of the resurvey will also vary depending on which track the hospital is on and where in the process the resurvey occurs. The resurvey may be a full survey of all CoPs or limited to reviewing only those CoPs previously found out of compliance. Even if the scope is limited, the surveyors have the authority to cite the hospital for other deficient CoPs that they observe. This is because the hospital is required to be in compliance with all CoPs at all times.

The resurvey process is very similar to the initial survey. Ideally, the survey team will be smaller, the length of the survey will be shorter, and any resulting 2567 report will be shorter. However, the hospital should not be lulled into a secure feeling by the scaled-back nature of some resurveys. The surveyors themselves may make the resurvey process more casual (e.g., coming out on different days rather than as a team, not holding an exit conference, etc.). The SOM does not support such actions, particularly with respect to the exit conference. This is not an optional meeting, but part of CMS policy. If the surveyors fail to hold an exit conference but still submit a CMS-2567 Statement of Deficiencies, the hospital should work with its attorneys on how best to respond.

Following a resurvey, the surveyors will again produce a 2567 report detailing any deficiencies found. Upon receiving the report, the hospital must undertake all the same steps to respond as they did with the original report. In preparing a response the hospital should also review its prior responses. If prior corrective action steps and monitoring were not sufficient to correct the problem, then obviously the same response will not suffice. The hospital should infer that it is expected to take a more aggressive approach to solving the problem and eliminating the deficiency.

VIII. THE TERMINATION PROCESS

CMS may terminate a hospital's participation in the Medicare and Medicaid programs because of noncompliance with one or more CoPs or failure to provide an acceptable plan of correction for noncompliance with other requirements (such as violations of EMTALA and other obligations in the provider agreement). There are other reasons for termination, such as billing irregularities, that are not related to surveys and thus beyond the scope of this manual.

The notice (letter) of suspension or termination of a hospital's provider agreement can be 23 days (if the violations constitute an immediate jeopardy) or 90 days (if the violations do not constitute immediate jeopardy), as described below. When one or more condition-level deficiencies are identified during a survey, the State Survey Agency (CDPH) is required to send the notice and a Form CMS-2567, "Statement of Deficiencies and Plan of Correction," report to the hospital within 10 working days. (CDPH does not always adhere to its deadline.) The hospital then has 10 calendar days to submit its response. *(See IV. "Drafting the Hospital's Final 2567 Response and PoC," page 5.7, for more information on preparing the hospital's response.)*

When an immediate jeopardy to patient health or safety is documented, the State Survey Agency and the CMS Regional Office will complete termination procedures within 23 calendar days. The termination procedures will be postponed or stopped only if compliance is achieved and documented through an on-site resurvey. If the hospital makes a credible allegation of compliance, the State Survey Agency is required to conduct a resurvey prior to termination if possible. (*See CHA Appendix HS-9, "Timeline for a 23-Day Termination Track," for a timeline of important steps in the 23-day termination process.)*

When a hospital is out of compliance with one or more CoPs (that is, condition-level deficiencies exist), but the noncompliance does not constitute immediate jeopardy, the State Survey Agency and CMS will complete termination procedures within 90 calendar days. The termination procedures will be postponed or stopped only if compliance is achieved and documented through an on-site resurvey. If the hospital makes a credible allegation of compliance, the State Survey Agency is required to conduct a resurvey. The resurvey will determine whether the hospital is in fact in compliance, or if it has achieved acceptable progress. A second resurvey may be conducted between the 46th and 90th calendar days after the survey, if necessary, and if the hospital submits a second credible allegation of compliance. *(See CHA Appendix HS-8, "Timeline for a 90-Day Termination Track," for a timeline of important steps in the 90-day termination process.)*

The termination process will not be postponed to accommodate informal hearings or meetings or to give the hospital additional time to achieve compliance. However, informal hearings or meetings must take place within these time limits as deemed appropriate by the CMS Regional Office. The termination process will also not be postponed for changes of ownership, receivership or any other cause not explicitly required by law.

The State Survey Agency may switch from the 90-day procedures to the 23-day procedures at any time there is an immediate threat to patient health and safety.

A. Notice of Termination

As noted above, a condition-level deficiency, as well as any circumstance found to create an immediate jeopardy, may cause CMS to initiate termination of provider certification.

In such case, CMS must notify the hospital in writing [42 C.F.R. Section 498.20]. The notification must include at least the following information:

1. The basis or reasons for the decision to terminate.
2. The effect of the decision to terminate.
3. Information regarding the hospital's right to a hearing.

B. Hospital's Response

The hospital then has three options after receiving a notice of termination:

1. Correct the deficiencies and submit a PoC; and/or
2. Contest the deficiencies and submit a PoC; and/or
3. Contest the deficiencies without submitting a PoC.

Correcting the deficiencies and submitting a PoC the safest alternative. However, a hospital can attempt to informally contest the accuracy of the findings, but generally success will only be had at this stage if it can be readily shown that the State Survey Agency got its facts wrong. If a hospital disagrees with a finding of a cited deficiency, the hospital may, in lieu of submitting a PoC, state on Form CMS-2567 the factual basis for disagreeing that a deficiency occurred. Whenever possible, the hospital must reference the specific regulatory provision involved in the disputed issue and what factual evidence was available at the time of the survey to demonstrate compliance. The hospital must also provide documented evidence that successfully refutes the validity of the deficiency. It is not acceptable for the hospital to provide evidence of corrective actions taken *after* the survey started as a basis for removal of a deficiency citation. It also is not acceptable for the hospital to base its disagreement on a different interpretation of the regulatory requirements than that found in CMS guidance, or by refuting the professional judgment of the surveyor regarding the level, extent, scope or severity of the deficiency.

The original termination date will not be changed by the hospital's disagreement with one or more of the deficiency citations. The CMS Regional Office reviews all of the documentation, including the survey findings and the documentation presented by the hospital before making a determination. If CMS determines that a deficiency did not exist, it is removed from Form CMS-2567.

The trouble with waiting to appeal the deficiencies is that termination will likely take effect before the appeal can be conducted. Thus, even if the hospital ultimately prevails, it will have a break in Medicare certification, causing significant confusion, billing problems and negative public relations implications. Depending on the facts and circumstances, a hospital that receives a notice of termination may wish to pursue more than one of the above options simultaneously *(see A. "Effect of an Early Appeal," page 3.38)*.

C. Public Notice

CMS will place a notice in the local newspaper stating:

MEDICARE NOTICE TO THE PUBLIC
Notice is hereby given that the agreement between the [Hospital/Address], and the Secretary of Health and Human Services, as a provider of services in the Health Insurance for the Aged and Disabled Program (Medicare) is to be terminated at the close of [date of termination].

CMS may use radio or television announcements if publication in the newspaper cannot be done in a timely manner.

If CMS receives credible evidence that the cause for the termination has been removed, CMS will immediately contact the newspaper to stop the scheduled notice. CMS will also publish a public notice of termination retraction as appropriate. It will state that:

> Notice is hereby given that [name and address of facility] has achieved compliance with the Medicare Conditions of Participation/Requirements for Participation pertaining to [fill in title of CoP or requirement]. As a result, the Secretary of Health and Human Services is continuing the agreement with [the facility] in the Medicare program.

IX. APPEALING A FINAL DETERMINATION TO TERMINATE MEDICARE/ MEDICAID CERTIFICATION

A hospital has the right to appeal a final determination to terminate Medicare/Medicaid certification. Until such a determination has been made, the hospital is limited to pursuing such informal options as requesting meetings with key agency officers, seeking clarification of findings, and otherwise cooperating with CMS and the State Survey Agency (CDPH) to achieve a mutually satisfactory outcome.

To request an appeal, the hospital must:

1. File a request in writing.
2. Submit the request within 60 days from receipt of notice from CMS of an initial or revised determination. (An extension may be obtained upon a showing of good cause.)
3. Identify the specific issues, and the findings of fact and conclusions of law with which the hospital disagrees.
4. Specify the basis for contending that the findings of fact and conclusions of law are incorrect.

Failure to comply with these requirements may result in dismissal of the hospital's appeal. In addition to meeting the above requirements, the request should:

1. Put CMS on notice of all matters in dispute.
2. Enable the Administrative Law Judge (ALJ) to rule on the relevancy of evidence.
3. Indicate whether facts are at issue, or whether the dispute is limited to legal issues, in which case a hearing would not be necessary.

At the hearing, CMS has the burden of demonstrating why the hospital should be terminated. At the conclusion of the hearing, both the agency and the hospital have the right to request a Departmental Appeals Board (DAB) review if dissatisfied by the decision of the ALJ. A request for review must usually be filed within 60 days from receipt of notice of the decision and must specify the issues, the findings of fact or conclusions of law with which the party disagrees, and the basis for contending that the findings and conclusions are incorrect. The DAB may dismiss the request or grant a review by a panel of three individuals. Upon review, the DAB may remand the case to an ALJ or issue a decision. Judicial review is the final option if the hospital is dissatisfied with the decision of the DAB.

Once the option to appeal is under consideration, it is crucial that the hospital enlist the assistance of counsel, if that has not already been done. Counsel should participate in the drafting of the request and should make sure that no rights are inadvertently waived and that all of the requirements for the request are met. *(See 42 C.F.R. Section 489.53 and Part 498 regarding termination and appeal rights.)*

A. Effect of an Early Appeal

Filing an appeal at the earliest possible time after receipt of notice of termination can shorten the period during which the hospital is technically ineligible to participate in the Medicare and Medicaid programs. In the best case scenario, the hospital will be found in compliance with all Conditions of Participation upon resurvey and the request for appeal can be withdrawn. However, the possibility always exists that the hospital will not be found back in compliance after the first resurvey, and since there are no statutory or regulatory provisions for securing an expedited appeal, its exposure is limited by getting the appeal process started early. It is highly unlikely (if not impossible) that an ALJ will have an opportunity to review the decision to terminate and issue a decision in time to actually prevent termination. Thus, retroactive reinstatement is the most the hospital can likely achieve. Limiting the amount of time that the hospital is decertified is the best way to mitigate damages, including less obvious damages such as the medical staff losing confidence in the hospital and an adverse public perception.

Submitting an early appeal may have the additional benefit of demonstrating seriousness on the part of the hospital. It may also cause the agencies to reconsider tenuous positions and to encourage compliance with time lines and procedures. It also may help maintain confidence of the medical staff and the public.

The major circumstance in which it may not be feasible to file an early appeal is if the deficiency is one that will necessarily take time to correct or to get far enough in the correction process to make a credible allegation of compliance (e.g., a deficiency that requires entering into contracts and obtaining designs for construction, or training significant numbers of employees and staff members of a large facility). In such a case, it may be necessary to carefully assess the earliest point at which a credible allegation of compliance can reasonably be made. The good faith of the organization is at stake if the credible allegation of compliance is premature. Obviously, when a 23-day termination is at issue, the need to move expeditiously cannot be overemphasized.

B. Filing a Lawsuit

If CMS will not provide sufficient time for a hospital to demonstrate compliance with the CoPs prior to termination of its provider status, a hospital may decide to file a lawsuit seeking to delay termination. The court will consider the likelihood of irreparable harm to the hospital if it is terminated from the Medicare program, the likelihood of harm to CMS if the hospital's termination is delayed, the likelihood that the hospital's legal arguments are correct, and the public interest. A hospital should seek legal counsel immediately upon the first inkling that it might need to go to court. Time is short in the decertification process, and the hospital must file the suit before the 23- or 90-day termination track period ends.

4 Tips for Achieving a Successful Survey

I. Preparing for a Survey 4.1

A. Establish a Survey Readiness/Response Team 4.1

Identify Key Leaders 4.1

Prepare Survey Kits 4.1

Establish a Communication Structure 4.1

B. Train Appropriate Personnel 4.2

Identify and Train Escorts, Scribes and Runners 4.2

Train Hospital Staff 4.3

Involve the Medical Staff 4.4

C. Develop Documentation 4.5

Prepare Informational Binders 4.5

Prepare Quick-Review Checklists 4.5

Develop Policies and Procedures 4.5

D. Perform Mock Surveys 4.5

II. During the Survey 4.7

A. First Impressions 4.7

Greeting the Survey Team 4.7

Surveyors' Identification 4.7

Communication Center 4.7

B. Entrance Conference 4.7

C. Communication Within the Facility 4.8

Assign Escorts, Scribes and Runners 4.8

Key Personnel 4.9

Debrief All Staff Who Interact With Surveyors 4.9

LCA Team Meetings During Survey 4.9

D. How to Handle an IJ During the Survey 4.9

E. Checklist for Exit Conference 4.10

Participants in the Exit Conference 4.10

When to Consult Legal Counsel 4.10

Take Notes During the Exit Conference 4.10

Ask the Surveyors to Identify Tag Numbers, Interviewees 4.10

Consider Recording the Exit Conference 4.11

Collect Temporary IDs 4.11

F. How to Handle Unusual Problems with Surveyors 4.11

4 Tips for Achieving a Successful Survey

I. PREPARING FOR A SURVEY

The potential for an unannounced licensing, certification or accreditation survey exists every day. Hospitals should plan carefully for this inevitability. This portion of the manual provides helpful information about survey preparation and response. The information discussed in this chapter applies to both state and federal surveys.

A. Establish a Survey Readiness/Response Team

Every hospital should establish a licensing, certification and accreditation (LCA) team and designate a team leader. This team is responsible for planning for successful surveys, training staff, responding when surveyors arrive and preparing plans of correction. The LCA team may include members of the executive staff, medical staff, department heads, medical directors, medication safety officers, patient safety officers, the compliance officer, the chief risk officer and the QAPI coordinator. Other key individuals, including legal counsel, may be added as appropriate.

Identify Key Leaders

Identify key leaders (and back-ups in their absence) from each department and service to prepare their unit for surveys and to be called if their department or service is at issue or if the surveyors want to inspect their unit.

Prepare Survey Kits

Prepare survey kits that contain the contact information of LCA staff, key employees, medical staff members and management of any on-site contracted services. Include the location and phone numbers of the hospital "command center" *(see "Establish a Communication Structure," page 4.1)* and the work room that the surveyors will use.

The LCA team should also have contact information for their CMS/regional office personnel and for their CDPH district office personnel, including the names of the surveyors' supervisors, as well as contact information for CDPH Sacramento headquarters, in the rare event that a problem arises that needs the attention of CMS or CDPH executive management. Know who is in charge at your district office, and their back-ups during vacation, sick leave, etc. It is a good idea to have this information in advance so that if an urgent problem arises, no time is wasted trying to find out which CDPH person/phone number to call.

The survey kits should also contain any documents, forms or policies necessary or useful for the hospital's LCA team.

Establish a Communication Structure

The hospital will want to establish a command center for effectuating communication throughout the survey. The command center should be set up immediately upon entrance

of surveyors by a predetermined leader. The command center will be the central hub for communication and coordination of all survey activities, including producing and copying documents and scheduling daily briefings. A communication plan should be developed and tested in advance.

The first priority will be to immediately notify the LCA team leader and team members of the surveyors' presence, as well as the staff members responsible for going through the quick-review checklists *(see "Prepare Quick-Review Checklists," page 4.5)* and the tasks listed under "What to Provide the Survey Team," page 3.14. The communication plan should include a method for verifying that these employees are working on their pre-assigned tasks, so that a back-up can be contacted quickly if necessary.

The communication plan for other key leaders and the rest of the hospital staff should quickly be implemented. A representative of the medical staff (a physician) should be notified and should be available to address any medical staff concerns that may arise.

The hospital will want to alert the staff to the presence of the surveyors by phone, email and/or text messaging. Consider establishing a phone tree, automated phone message system, and/or email or text list so that personnel throughout the hospital (inpatient units and outpatient departments, both on- and off-campus) are aware that surveyors are on-site. Every department should be notified. Be sure to include in the communication plan how to alert the next shift that a survey is in progress.

The hospital may wish to make announcements over the public address system, such as, "Our hospital welcomes the survey team from the California Department of Public Health." This announcement can be repeated now and then, especially during shift changes.

B. Train Appropriate Personnel

Identify and Train Escorts, Scribes and Runners

The surveyors have the discretion to allow, or refuse to allow, hospital personnel to accompany the surveyors during a survey. Surveyors vary widely in this regard. Some will not permit any hospital representatives to accompany them in the facility. Others don't care who or how many people accompany them. How the hospital representatives approach the surveyors and the survey process may affect the surveyors' decision in this regard. Obviously, a surveyor will be more likely to allow a pleasant, helpful staff member to accompany him/her than a negative, defensive staff member. The hospital should try to assign a personable, knowledgeable employee who has good judgment and the ability to be assertive when necessary to accompany each surveyor.

The hospital should identify and train escorts, scribes and runners in advance, as described below.

Escort

If possible, an escort should accompany each surveyor during the survey. The escort announces the surveyor's presence in a cordial and welcoming manner as they make their rounds throughout the hospital. An experienced clinician with thorough knowledge of the hospital's operations makes an ideal escort.

Scribe

A scribe will document questions and comments from the surveyors during the survey, and keep track of the medical records, policies and other documents examined or requested by surveyors during the survey.

Runner

A runner will obtain documents and materials requested by the surveyor during the survey, and make a copy for the hospital's file. The runner also alerts the next department or unit of the surveyor's anticipated arrival, issues the surveyor is focused on, and any other information useful to the next department.

Exactly how the escort, scribe and runner function may vary. The scribe and runner can walk behind the surveyor and escort (so the surveyor hardly even knows they are there). At times the scribe and runner may be the same person, and when that person has to leave the vicinity of the surveyor, the escort can assume the scribe's duties. Depending upon the unit of the hospital that the surveyor is in, the escort may step back and let the charge nurse or other unit leader act as an escort. Hospital staff can be flexible in the assignment and function of escorts, scribes and runners.

(See also "Assign Escorts, Scribes and Runners," page 4.8.)

Train Hospital Staff

Hospitals should train all personnel who may encounter surveyors, including clinical staff, medical staff, contract staff, volunteers and employees in dietary, pharmacy, laboratory, central supply, environmental services, etc. Training should include staff in inpatient units and outpatient departments, both on- and off-campus. Training may be done during new employee orientation, annual skills training, or during specialized survey readiness training.

Training should include at least the following elements:

1. Basic information regarding who the surveyors are and what the surveyors' job is.
2. Surveyors should be treated professionally, courteously, and with respect *(see A. "First Impressions," page 4.7).*
3. How to respond during surveys. Training should cover obvious do's and don'ts:
    - Do answer questions truthfully and provide facts.
    - Don't give your opinion or babble out of nervousness.
    - Avoid acknowledging violations.
    - Don't self-report areas of concern or incidents that the surveyors have not identified.
    - Don't raise issues that the surveyors have mot asked about.
    - Say "Let me find someone to assist you," as opposed to "I don't know" or "No one ever told me that."
    - Understand that your statements may be quoted by surveyors as evidence of deficiencies.

4. Make sure employees understand that surveyors are not like police — that is, they are not asking questions because they think the employee did something wrong. The surveyors are interested in finding out what the employee knows or how the employee usually does something.
5. What to do if a hospital staff member feels that a surveyor is behaving in an intimidating, harassing or inappropriate manner, or is interfering with patient care. Remember that some employees may feel that surveyors are equivalent to police officers, authority figures or judges. This may be due more to the employee's feelings than the surveyor's behavior. Nevertheless, if an employee becomes so nervous at being observed by a surveyor, this may result in a patient care error. Employees should be taught what to say to the surveyor and whom to call if they are feeling extremely nervous, flustered or scared.
6. Employees should feel free to use any tools, information or additional staff they would normally use when doing their job. For example, if a surveyor asks a nurse to prepare an injection, the nurse should feel free to let the surveyor know that ordinarily she would get her reading glasses before preparing the injection, and to go get her reading glasses. (This may not be optimal if the surveyor calls a mock code, but it is better than preparing an incorrect injection.)
7. Employees should not perform a task at the direction of the surveyor if the employee does not perform that task pursuant to hospital policy and procedure. For example, if the hospital's policy for pediatric codes requires the physician to draw the medications, the surveyor should not insist that the nurse demonstrate how she would draw the medications. Again, employees should be trained how to handle these unusual situations.
8. Patients' privacy rights with respect to surveyors *(see "Patient Privacy Rights," page 3.22)*.
9. Staff rights during observation or interviews *(see "Information Gathering by Surveyors: Observation/Interviews/Record Review," page 3.17)*.
10. Who to debrief after the interaction with the surveyor is over.

In addition, hospital personnel at every entrance should be trained regarding whom to call when surveyors arrive (days, nights, weekends, holidays, etc.).

The bottom line is that all hospital staff members should be courteous and respectful to the surveyors at all times, but should also feel empowered to take appropriate action to maintain safe, high-quality patient care.

Involve the Medical Staff

Involve the medical staff in planning and training for surveys. There should be ongoing communication about emerging issues with regard to compliance with licensing, certification and accreditation requirements, as well as how to respond during surveys. Make the medical staff leadership a part of the hospital's LCA team both to maintain compliance and to avoid negative responses from the medical staff when surveyors raise questions. Meet

with the QAPI committee, quality council, medication safety committee and other medical staff committees as appropriate. Be sure to schedule training for medical staff officers and department and service chiefs as the leadership changes over time.

C. Develop Documentation

Prepare Informational Binders

The hospital should prepare binders (or electronic equivalents) in advance containing the hospital's patient safety plan, medication error reduction plan, infection control plan, diet manual, radiology permits (CT, fluoroscopy, brachytherapy, etc.), supporting policies and procedures and other similar documents. The hospital should determine which information should be kept in the departments, and which in a centralized location. Procedures should be in place to ensure that these documents are kept up to date. Educate appropriate leaders and staff on the contents of the binders and the role they play in the survey process.

Prepare Quick-Review Checklists

Establish checklists for each department to perform a quick review as soon as surveyors arrive at the hospital (before the surveyors reach the department). The checklists might address clutter in hallways, expired medications, outdated patient food, restraint documentation, code cart, staff wearing badges, documentation of consent and H&P, universal precaution/time out, etc. These quick-review checklists are, of course, in addition to more detailed planning documents and tools.

Develop Policies and Procedures

The hospital should have policies and procedures regarding surveys that cover required training, preparation for surveys, procedures during surveys, etc. Note, however, that the California Department of Public Health (CDPH) may cite hospitals for not complying with their policies, even if the policies contain requirements that would not otherwise legally be required. In other words, 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. CHA has developed an "FAQ on Writing Hospital Policies and Procedures," reprinted as CHA Appendix HS-13.

D. Perform Mock Surveys

Hospitals should perform various types of mock surveys. These surveys should be unannounced and the mock survey team should act like, and be treated like, an actual CDPH survey team. To prepare for federal certification surveys, hospitals should assign staff to "act like a surveyor" and perform each step in the survey procedures found in the applicable appendix or appendixes to the State Operations Manual *(see B. "State Operations Manual," page 3.7)*. To prepare for state surveys, hospitals should assess readiness with the surveys described under II. "Types of State Surveys," page 2.3. Because surveyors will review a hospital's past three years' deficiencies prior to coming on-site, hospitals will also want to review past 2567s and evaluate their compliance with their past PoCs. Hospitals should also review their past three years' of complaints and entity-reported events (such as adverse events), because the surveyors will have these in mind, also. Finally, hospitals should review new laws as well as recent AFLs issued by CDPH, as the CDPH surveyors may focus on these areas. *(See III. "Which Laws are State Surveyors Assessing Compliance With?," page 2.6, regarding AFLs.)*

During mock surveys, mock surveyors should observe staff performng patient care and other tasks, interview staff and patients, and perform record review — just as the surveyors will do. It may be helpful for hospitals that are part of a system — or even unrelated hospitals — to team up and survey each other. (Unrelated hospitals that consider taking this approach will need to enter into a business associate agreement to comply with federal privacy laws unless no patient-identifiable information will be shared.)

Mock surveys should be conducted at least annually, and again three to four months before a potential survey. Reports should be generated and presented during a mock exit conference. The hospital's LCA team is responsible for following up regarding corrective action plans, auditing, and tracking/trending outcomes.

Hospitals may wish to solicit feedback from staff regarding the mock survey. Internal mock survey feedback questions may include:

1. The mock survey helped me understand what a real survey would be like
2. The mock survey helped me understand what to do during an actual survey
3. Talking to the mock surveyors was good practice for me
4. The mock survey was helpful in identifying areas to work on prior to our actual survey
5. The mock surveyors were knowledgeable
6. I learned something new during the mock survey
7. I would like to learn more about the survey process
8. What can we do to improve the survey process?

The first seven questions can have a response such as:

1. Agree strongly
2. Agree somewhat
3. Neither agree nor disagree
4. Disagree somewhat
5. Disagree strongly

The last question should be open response — just include blank space for staff to write their ideas.

Documentation During the Mock Survey

Documentation during the survey is very important, and this should be practiced during mock surveys. A common problem that hospitals encounter in preparing the 2567 response is the inability to identify the precise individual or document to which a deficiency relates. Be aware that the surveyors also may not keep adequate notes of the individuals or documentation at issue, or may lose them. It is difficult to prepare an effective response to the 2567 or to correct obvious surveyor errors without good notes.

Thus, training and mock surveys should include an emphasis on documenting everything that happens throughout the survey.

II. DURING THE SURVEY

A. First Impressions

First impressions count! Be cordial and respectful of the surveyors and the survey process.

The surveyors are well aware that hospitals are not completely thrilled to see them. They know that their arrival means extra work for hospital staff, extra stress and perhaps cancelled vacations. It will not increase the chances for a successful survey if hospital staff act hostilely, condescendingly, cynically or defensively with the surveyors who, after all, are just doing their job. Showing respect for what the surveyors do can improve the entire interaction.

All hospital personnel should take the attitude that the surveyors are partners in achieving high-quality patient care. The surveyors serve as another set of eyes on quality, to identify practices that can be improved that the hospital might not have considered. It cannot be emphasized enough how important it is for the members of the LCA team and other key leaders to model a constructive attitude toward surveyors. This will accrue to the benefit of the hospital.

Greeting the Survey Team

The chief executive officer and/or chief operating officer (or their designees in their absence) should be the "executive greeter" and be available for the entrance conference. Depending upon the organizational structure of the hospital, this person may also lead the hospital's LCA team.

Hospitals may wish to provide parking validation or temporary parking passes to surveyors.

Surveyors' Identification

Be sure to check the surveyors' identification, which is issued by CDPH or CMS. Surveyors are required to show their identification when they arrive at the facility and to wear it (and/or the hospital-issued ID) at all times they are in the facility. If doubt exists about the identity of a person claiming to be a surveyor, call the CDPH district office or CMS regional office to verify.

Imposters have attempted to gain access to hospital facilities in the past. If individuals falsely identify themselves as CDPH or CMS employees in an attempt to access a hospital facility, notify CDPH, CMS and local law enforcement immediately.

Obtain a business card from each surveyor, and make copies of the cards for each person on the LCA team. Finally, be sure to attend to appropriate amenities for surveyors — provide workspace, temporary badges, etc. *(See "What to Provide the Survey Team," page 3.14.)*

Communication Center

Implement the communication plan as soon as possible. *(See "Establish a Communication Structure," page 4.1.)*

B. Entrance Conference

As mentioned above, it is important for the entire hospital staff to be cordial and respectful of the surveyors and the survey process. This is especially true for hospital staff members who participate in the entrance conference. The attitude of the hospital representatives at the entrance conference can set the tone for the entire survey.

The entrance conference provides a forum for the hospital to coordinate with the surveyors regarding their survey protocol. The hospital should take careful notes of the entrance conference. Pay attention to the issues with which the surveyors seem particularly concerned during the entrance conference. Clarify whether the survey to be performed is a state survey or a federal survey. This will help the hospital's response team match any identified deficiencies to the statutes and regulations implicated, and thus help the hospital develop its plan of correction.

CDPH uses the same surveyors for both state and federal surveys. Although the surveyors may be the same people, there are differences in processes and potential outcomes, as described throughout this manual. To make matters more confusing, surveyors may figuratively "switch hats" while in the hospital. For example, CDPH may receive a self-report of an adverse event and begin a state survey. If the surveyors detect noncompliance with a federal requirement, they may call CMS while still at the hospital and request authority to conduct a survey on behalf of CMS.

Hospitals should seek clarification from the surveyors if it is not clear whether they are representing the state or CMS. Hospital should also clarify what type of survey will take place *(see II. "Types of State Surveys," page 2.3 and II. "Types of Federal Surveys," page 3.2)*.

As the entrance conference proceeds, try to identify as soon as possible the departments and services that are at particular issue. Include the applicable department and service leaders at the earliest appropriate time in the survey process.

At the end of the entrance conference, the hospital should feel free to ask questions or request clarification about anything related to the survey process. The hospital should also restate any action steps that either the surveyors or hospital representatives have agreed to take, any agreements made during the entrance conference, or other key points.

C. Communication Within the Facility

Assign Escorts, Scribes and Runners

Assign an escort, scribe, and runner to accompany each surveyor on the rounds, making sure they offer whatever assistance and amenities the surveyor requires *(see "Identify and Train Escorts, Scribes and Runners," page 4.2, for a description of roles)*. Within the bounds of the survey protocols for privacy for patients, staff and visitors, have the escort, scribe and runner keep careful track and take notes of:

1. The identity of all individuals (patients, staff, others) whom the surveyors interview or question.
2. All records the surveyors review, including patient records, logs, policies, procedures and protocols, and any surveyor comments that relate to a particular record.
3. All situations in which the surveyors take particular interest, and any comments surveyors make regarding particular issues.

Escorts, runners and scribes should track dates and times in their notes. They should be debriefed as soon as possible when they are finished with the surveyors, while the survey is still fresh in their minds.

As a finding is discovered, ask the surveyors to cite to the applicable tag number, CoP, standard and/or condition (for a federal survey) or Title 22 or Health and Safety Code Section (for a state survey). The surveyors are not required to provide this information at this time in the process, but it doesn't hurt to ask for as much information as they will provide.

Don't be confrontational, but ask questions and advocate, when appropriate, for your facility's practices.

Key Personnel

During the survey, there should be key personnel available in the department/unit when the surveyors are present to ensure a quick and efficient review and to address any questions or concerns.

Debrief All Staff Who Interact With Surveyors

Debrief each hospital staff member who interacts with a surveyor to learn what issues the surveyor was interested in and the surveyor's reaction to what he/she observed. This will help identify trends and surveyors' areas of focus.

LCA Team Meetings During Survey

As mentioned under "Daily Meetings," page 3.23, the surveyors will meet daily (often at the end of each day), without hospital staff present, to share their findings and any concerns. They will ask fellow surveyors to be on the lookout for similar deficiencies or issues in other areas of the hospital. For example, if one surveyor finds an outdated medication on a crash cart in the emergency department, she will inform her fellow surveyors of that finding, and the other surveyors may check for outdated medications on crash carts in other areas of the hospital during the rest of the survey.

The hospital's LCA team should also meet at least daily to identify trends and share any comments, concerns, issues, or pointed questions raised by the surveyors. The team should address any problems or potential problems identified by the surveyors as soon as possible, and throughout the entire hospital, as applicable. For the example given above (surveyor finds outdated medication on crash cart in emergency department), the hospital should check all of the other crash carts in the hospital for outdated medications, and check the hospital's applicable policies and procedures. The hospital should try to determine whether the presence of the outdated medication was a fluke, a symptom of a missing or poorly written policy, or a well-written policy that was not implemented. If it appears that one employee did not perform his or her job as anticipated, it might be a good idea to check other responsibilities of that employee. It is important that the hospital undertake this type of review as soon as possible upon discovery by a surveyor, and make corrections as soon as possible.

D. How to Handle an IJ During the Survey

As discussed in detail under E. "Immediate Jeopardy (Federal)," page 3.27, a hospital should try to correct any IJs found during a survey before the surveyors leave the facility. By doing so, the hospital can avoid formally being placed on the 23-day termination track and having

to submit a separate written response to the Form CMS-2567 write-up of the IJ (if the survey is a federal survey). It is therefore crucial that the hospital be assertive and persistent in bringing all corrective action steps to the surveyors' attention in order to get their feedback on whether or not the IJ has been cleared and, if not, what else the surveyors require to be done. Constant communication is important, and an attitude of concern and cooperation is paramount. (State IJs are handled differently; *see D. "Deficiencies Constituting Immediate Jeopardy," page 2.10, and Appendix HS-15, "Federal vs. State Immediate Jeopardy Definition and Implementation Comparison."*)

E. Checklist for Exit Conference

At the end of the survey, the survey team will conduct an exit conference to informally communicate preliminary findings. The hospital will be given the opportunity to provide additional information. The purpose, content and guidelines regarding the exit conference are described in E. "Exit Conference," page 3.24. This portion of the manual provides additional tips.

Participants in the Exit Conference

The hospital determines which hospital representatives will attend the exit conference. Hospitals should carefully consider which staff members to include. If initial reports indicate deficiencies in a certain area, the hospital may wish to include management staff from that area in the exit conference.

The surveyors will note the hospital's reactions to survey findings/deficiencies. The participants in the exit conference should maintain a professional and constructive demeanor at all times. It is appropriate to ask questions, provide additional information to the surveyors, politely point out any errors surveyors may have made, and to explain the hospital's perspective. It is not constructive for hospital representatives to become argumentative, hostile, or defensive. The surveyors may end the exit conference prematurely if participants become hostile or intimidating.

When to Consult Legal Counsel

If it appears that the outcome of a survey could result in termination of participation in the Medicare and Medicaid programs, monetary fines, or other serious repercussions, a hospital should consider immediately involving a health care attorney experienced in assisting hospitals with licensing and certification issues. Although legal counsel do not usually attend the exit conference, a telephone or in-person consultation with experienced counsel can be very useful in assisting hospital leadership to assess the potential risks and to prepare for and take best advantage of the exit conference. *(See also E. "Consider Involving Legal Counsel and/or Consultants," page 5.5.)*

Take Notes During the Exit Conference

The hospital representatives participating in the exit conference should take note of the names of the surveyors and which surveyor is speaking about each deficiency or point described.

Ask the Surveyors to Identify Tag Numbers, Interviewees

Although the surveyors are not required to, nor supposed to, disclose the tag numbers that may be implicated at this stage of the survey process, it does not hurt to ask for as much information as they will provide about deficiencies, and which CoPs, tags, and Title 22 or Health or Safety Code provisions are implicated. If there are particular patient records

or interview situations involved, try to clarify the identity of the patient(s) or interviewee(s) involved. However, the surveyors are not required to, nor supposed to, disclose the names of patients or employees. It may be possible to gain enough information from the surveyors for the hospital to make an educated guess regarding the patient and/or employee, so the hospital can investigate and remediate any problems. The 2567 is required to contain sufficient information for the hospital to correct the deficient practice, and to contest the deficiency if it desires. The hospital may have to wait until it receives the 2567 to get the necessary information.

Consider Recording the Exit Conference

The hospital may wish to record the exit conference or have a scribe take notes. Audiorecording the exit conference is permitted, if a copy of the recording is given to the surveyors at the end of the conference, or the surveyors have the ability to make their own simultaneous recording. Videorecording is also permitted if it is not disruptive to the conference, in the opinion of the surveyor(s). Again, a copy must be given to the surveyors at the end of the conference. It is a good idea to test the recording device(s) prior to the exit conference.

The decision regarding whether to record the exit conference should be made by the LCA team, in consultation with risk management and legal counsel. The team should consider the risks and benefits of recording the conference. If the exit conference is recorded, the discussion may become more formal and guarded, and the surveyors may be less forthcoming in sharing information or less willing to change their minds about deficiencies. The hospital representatives also may be reluctant to have an open discussion and would want to be careful to avoid admitting liability of any kind.

On the other hand, because the hospital may not receive the 2567 for some time after the exit conference, the hospital may want to have a complete and accurate source of the agencies' findings right away. Handwritten notes and memories may not be sufficient for this process. If something is confusing, it may be helpful for attorneys/consultants hired by the hospital to assist in developing the plan of correction to listen to the exact words of the surveyors. A recording may provide proof that a particular deficiency was never mentioned in the exit conference; this may be critical in a formal or informal appeal.

If the conference is recorded, the hospital will want to prepare a transcript of the recording and begin as soon as possible to address any deficiencies identified by the surveyors. It is not a good idea to wait until the 2567 is received to begin to address the deficiencies.

Collect Temporary IDs

If the hospital has issued temporary IDs to the surveyors, they should be collected at the end of the exit conference.

F. How to Handle Unusual Problems with Surveyors

Surveyors, like hospital personnel, have different styles and personalities. Some are more competent/experienced than others, and some are more pleasant than others. This is to be expected. All surveyors should be treated courteously and respectfully. This type of treatment will accrue to the hospital's benefit. Remember, the surveyors are just doing their job. They and the hospital have the same goal: assuring safe, high-quality patient care.

Surveyors should also treat hospital personnel courteously and respectfully, and behave professionally. They are expected to follow infection control protocols, respect patient privacy, and dress and behave appropriately.

CDPH employs more than 600 surveyors as well as consultants, management and support staff. Conflicts and misunderstandings can occur with any human interaction. In addition, like any large employer, occasionally CDPH will have a problem employee. If a hospital has a serious issue with a CDPH employee, it must be handled professionally and confidentially. Obviously, safe patient care is paramount and must take precedence over upsetting or angering a surveyor.

In the rare case in which a surveyor behaves inappropriately, the hospital should document the facts (not conclusions). For example, if a surveyor appears intoxicated on the premises of the hospital, the hospital should have the employee or employees who observed the surveyor document that "surveyor X slurred her words, stumbled, and smelled of alcohol," not "surveyor X appeared drunk." Document quotes as appropriate, as well as the names of any witnesses. If possible, the CDPH survey team leader should be called to observe the allegedly inappropriate surveyor. If it is necessary to remove the surveyor from a patient care area, do so tactfully — for example, ask to meet with the surveyor in a private conference room. The hospital should have two trusted employees interact with the surveyor, so there is a witness.

A hospital executive should explain the situation factually to the on-site CDPH survey team leader as soon as possible. If that person does not resolve the problem (or is part of the problem), the hospital executive should call the appropriate supervisor in the CDPH district office; if that doesn't work, then escalate to a district administrator or the district manager. In some cases, the hospital may need to involve CDPH executive management in Sacramento. If the surveyor is conducting a CMS survey, CMS may be contacted — CMS has indicated to CHA staff that it wishes to be informed of significant problems with surveyors.

Occasionally, a hospital will have a problem with a surveyor that isn't as urgent as indicated above, but still needs to be resolved. An example might include a surveyor who seems to have a biased attitude against the hospital, or is somewhat threatening, hostile or insulting. The hospital may wish to have a high-level employee who has excellent "people skills" meet with the surveyor privately to review the documented facts, and devise a solution together. If this approach does not resolve the issue, the hospital may then involve the district office supervisor, CDPH executive management and/or CMS.

Situations with surveyors may evolve over time. The hospital should document any unusual or negative incident that occurs with a surveyor, in case this documentation is later needed to demonstrate a pattern of behavior.

Many hospitals fear retaliation from surveyors if they question/challenge the surveyors or bring issues to the attention of the surveyors' supervisors. This is an understandable concern. CHA staff has worked closely with CDPH executive management in Sacramento, and knows that CDPH leadership is genuinely interested in learning about inappropriate behavior on the part of surveyors so that they can correct it and improve the survey process. Just as a hospital would want to know if one of its employees is not representing the hospital well, CDPH wants to know about its personnel. It is difficult for CDPH leadership to act upon complaints about surveyors when the hospital involved declines to be identified or

to identify the particular surveyor involved. CDPH has been clear that it does not tolerate retaliation. CDPH can — and has — reassigned surveyors who behave inappropriately or act in a retaliatory fashion. Nevertheless, it is not possible for CHA to completely alleviate this understandable concern.

5 After the Survey: Preparing the Plan of Correction

I. Communicating Survey Results 5.1

A. Governing Body 5.1

B. Employees 5.2

C. Medical Staff 5.2

D. News Media 5.3

II. Initial Steps 5.4

A. Begin Immediately After the Exit Conference; Deadlines 5.4

B. Debrief Staff 5.4

C. Transcribe the Recording of the Exit Conference 5.4

D. Convene the Response Team 5.5

E. Consider Involving Legal Counsel and/or Consultants 5.5

F. Submitting Information After the Exit Conference 5.6

III. Develop Preliminary Corrective Action Steps 5.6

IV. Drafting the Hospital's Final 2567 Response and PoC 5.7

A. Reconvene the Response Team Upon Receipt of 2567 ..... 5.7

B. Questions 5.8

C. Turn the Preliminary Corrective Action Steps into the 2567 Response 5.8

D. Drafting the Hospital's 2567 Response 5.9

Complete Response Needed for Each Deficiency 5.10

Remember That the Response Will be Publicly Available 5.10

Include All Actions — Even the Obvious Ones 5.10

Describe New or Revised Policies 5.10

Consider Whether to Attach Documents 5.11

Be Cautious in Disclosing Disciplinary Action 5.11

Describe Staff Education and Training 5.12

Describe Monitoring 5.12

Date of Corrective Action 5.13

E. Hospital Disputes Factual Findings in 2567 ..... 5.13

F. Cover Letter Accompanying Hospital's Response 5.14

V. After the 2567 Response is Submitted 5.15

A. Documentation 5.15

B. Continuous Improvement 5.16

C. Hospital Forgets to Include Something in the PoC 5.16

D. Follow-Up Questions from Surveyors 5.16

E. Final Actions by Surveyors 5.17

5 After the Survey: Preparing the Plan of Correction

Once the exit conference is over and the surveyors have left the facility, there is still plenty of work to do. The hospital must respond to questions about the survey, communicate survey results, and develop preliminary corrective action steps. After the Statement of Deficiencies (the CMS or State 2567) is received, the hospital must prepare and submit its plan of correction, and possibly appeal any adverse actions. This chapter focuses on these tasks.

I. COMMUNICATING SURVEY RESULTS

A. Governing Body

The survey results should be promptly communicated to the chair of the hospital's governing body/board. Together, the chair and the hospital CEO should determine how much and how soon additional communication to the full governing body may be needed. While there may be an inclination to spare the governing body specific details, and a reluctance to involve them in specific remedial actions, it is important to keep in mind their overall responsibility for the hospital, and that they may receive inquiries from a variety of sources (inside or outside the hospital). They will not want to be caught off guard. The Centers for Medicare & Medicaid Services (CMS) and the California Department of Public Health (CDPH) expect the governing body to be aware of survey results and to take them seriously.

Moreover, in some cases — and especially where the Governing Body Condition of Participation (CoP) is or may be involved — early and proactive governing body participation may be called for. Key factors to look at are:

1. If the Governing Body CoP, or any related standards, are cited as out of compliance, then the governing body must be made aware of these right away. In this circumstance, the governing body will likely need to demonstrate improvement in its oversight functions in order for the hospital to come back into compliance with the condition or standard(s).
2. Consider the need for a governing body task force, or at least a delegation of authority to a group or committee as may be needed to effectuate prompt corrective actions.
3. If the survey findings suggest that many policies and procedures will need to be revised and have governing body approval, the governing body may need to be put on-call to be available, when needed, to approve these revisions. (Check the meeting notice requirements of the hospital's corporate bylaws.) The hospital may wish to consider whether the governing body should be asked to delegate approval authority to key individuals. If there is a delegation of authority, there still needs to be ultimate accountability to the governing body. However, most actions can be implemented upon approval by the authorized representative(s), and later ratified by the governing body.

B. Employees

Hospital leadership may wish to communicate to employees the results of the survey; its potential implications for ongoing licensure, certification or accreditation; and the importance of prompt and effective corrective action. However, if negative findings are anticipated, the hospital should take care not to create an atmosphere of alarm or confusion. Moreover, the hospital should expect that anything said in open staff forums or written in memos may ultimately make its way into the media and/or other venues. Thus, how and when the survey results are communicated are crucial to getting the staff on board with accepting and effectuating any significant changes that may need to be made in a short period of time.

The initial focus should be on pulling together as a team to correct any deficiencies. Avoid blame, which can undermine morale and interfere with the compliance process.

Staff meetings may be held to acknowledge the survey and the apparent negative results (based on the exit conference), if there are any. The level of detail communicated will depend upon the scope of the problems (if any) as well as the particular forum.

If many areas of the hospital's operations have been found deficient, general staff meetings may be needed to communicate what is happening, answer questions and quash rumors. Avoid specifics for these meetings, as confidentiality issues may be at play, while addressing the general areas that require improvement and what the general process will be. Focus these discussions on how improvements will benefit hospital operations and patient care.

Encourage employees to ask their managers if they have any questions, but to be circumspect in speculating and discussing possible survey results unnecessarily.

Additional staff meetings will likely be necessary to "drill down" to the individuals whose actions and cooperation will be needed to effectuate corrections. For these meetings:

1. Be straightforward about areas of deficiencies (although confidentiality as to specific details may still be important).
2. Give the staff an idea of what the process will be (plans of correction, new policies and procedures, more surveys, etc.).
3. Try to develop an "ownership" mentality, emphasizing the importance of staff cooperation and active participation. This is an important step to effectuate change. Encourage the staff to be part of the solution by letting them know that as new draft policies and procedures are produced, their feedback and comments are a necessary part of the improvement process.

C. Medical Staff

If the deficiencies involve issues within the purview of the medical staff, the hospital should promptly notify the chief medical officer and the chief of the medical staff. Early convening of the Medical Executive Committee may also be needed. Key leadership should have been previously educated regarding maintaining compliance with licensing, certification and accreditation requirements, as well as the survey process (including how to work with surveyors). Similarly, if deficiencies involve issues within the purview of medical staff committee(s) or department(s), the committee or department chair(s) should be informed and meetings convened as early as possible. Each affected committee or department should consider whether delegation of immediate action authority to one or more representatives will be necessary to facilitate prompt corrective action.

The medical staff response to the survey is one of the more difficult issues to manage, and hence is an area where leadership is key. Early mobilization of key staff leaders is critical to effective corrective actions. While it is generally true that the corrective measures will involve policy and procedure changes and other generic changes to medical staff operations, it is sometimes true that remedial action may require practitioner-specific corrective action pursuant to the medical staff bylaws.

Issues within the medical staff purview cannot be resolved by hospital administration alone. It is important early on to evaluate what is really at issue, and to work with the medical staff leadership to identify specific actions that effectively address and resolve the identified problems(s).

D. News Media

The hospital should have policies and procedures in place for handling all requests for information from the news media. Typically, either someone in the hospital's public relations department or hospital administration is designated as the hospital's official media spokesperson.

The hospital should anticipate that the news media will likely learn of the survey results. This is especially true if an immediate jeopardy (IJ) has been declared or a fine will be assessed. The hospital spokesperson should be informed of the survey results at the same time that key hospital leadership is provided the information. This affords the spokesperson the best opportunity to develop appropriate messages in a timely manner, and to be prepared to respond to media inquiries. Depending on the specific results, consideration should be given as to whether a senior executive with clinical expertise (Chief Nursing Officer, Chief Medical Officer, etc.) should participate in media interviews. This may help to diffuse concerns about the impact of any identified deficiencies on the quality of care provided to patients.

It is recommended that the hospital spokesperson develop a comprehensive set of Talking Points to use in response to media inquiries. The tone of the Talking Points should be straightforward and honest, without assigning blame to anyone involved. Nor should the Talking Points seek to discredit the surveyors. If the hospital disagrees with the survey results, a matter-of-fact statement to that effect — and why — may be appropriate.

If the media learn of the survey results prior to the hospital being able to fully analyze and investigate the information, a comment such as the following should be made. "We are still investigating these issues to more fully understand the surveyors' concerns. We are committed to ensuring the delivery of high quality, safe patient care."

Should the media inquiry come as the result of a publicly announced IJ or administrative penalty, it is recommended that the hospital be as forthcoming as possible without putting itself in any legal jeopardy. Straightforward answers that acknowledge the incident, discuss what corrections/changes the hospital has made to correct the issue, and reconfirm the hospital's commitment to the delivery of safe patient care will provide the hospital with the best opportunity to regain the public's trust.

(See D. "Public Availability of CMS-2567," page 3.32, D. "Public Availability of CMS-2567," page 3.32 and C. "Public Notice," page 3.36, regarding the information CDPH and CMS will make available to the public.)

II. INITIAL STEPS

A. Begin Immediately After the Exit Conference; Deadlines

Once the surveyors have left the facility, there may be an inclination to wait for CMS's or CDPH's next move — i.e., to await the written survey results and see what they "really meant" by their exit comments. That would be a mistake. As mentioned earlier, the surveyors are supposed to discuss all findings during the exit conference. Thus, the hospital should (but may not always) know of every deficiency that could be cited in the final CMS-2567 or State-2567 report, and should begin taking action immediately. Keep in mind that in some instances the hospital may not even receive the 2567 report for a month or two after the survey. The hospital cannot sit back and wait to take corrective action steps until that time. The hospital should begin work on its corrective action steps immediately after the exit conference — if not before. Those corrective actions that can be taken during the survey, while the surveyors are still on-site, should be taken.

Keep in mind, too, that all of the hospital's deadlines regarding federal surveys are based on calendar days, rather than working days (although deadlines that apply to CDPH and CMS are usually based on working days). Thus, the hospital's clock starts ticking the day of the exit conference — very often a Friday — and the ticking does not lapse for weekends or holidays.

Hospitals may wish to be cautious, however, about taking corrective action steps that require a large expenditure prior to receiving the 2567. Hospitals may wish, instead, to make as many preparations as possible, but not legally commit to the expenditure until receipt of the 2567. It is possible that the surveyors will decide, after the exit conference, not to put a particular deficiency on the 2567 after all, even though it was discussed during the exit conference.

B. Debrief Staff

After the exit conference (or, better yet, each day after surveyors have left), interview escorts and any staff that interacted with surveyors to determine what was actually said. This may help clarify complicated fact-specific issues and may also help identify any factual errors or misunderstandings by surveyors. These interviews may also reveal opportunities to educate staff to improve responses to surveyors. Keep in mind that it is unlawful to retaliate against patients, employees, members of the medical staff, or other health care workers for cooperating with CDPH or CMS surveyors [Health and Safety Code Section 1278.5].

C. Transcribe the Recording of the Exit Conference

The exit conference is the hospital's primary source of initial direction regarding preparation of the plan of correction. If the conference was recorded, the written transcription of the actual comments made by the surveyors at the exit conference (rather than each participant's notes of what they think they heard) may be a useful tool in guiding the development and implementation of the PoC. The transcript should be prepared and distributed to the response team as soon as possible.

D. Convene the Response Team

To develop a satisfactory PoC within the required time frames, the hospital should assemble a team immediately following the exit conference to dissect what occurred, why it occurred, what will be done to correct the occurrence, what will be done to prevent recurrence, and to implement the measures developed. Coordinate the matters raised in the exit conference with the notes key leaders made during the survey. Where there are particular records involved, carefully review the applicable records to identify any surveyor errors or missing information that might change the findings.

The composition of the response team will depend upon the deficiencies identified by the surveyors. For example, if many of the deficiencies are related to pharmacy, then the hospital's pharmacist in charge should be part of the response team. Likewise, if nurse education was an issue, the hospital should include representatives from nursing administration, staff training and education, or other appropriate areas of the hospital. If the hospital has an in-house legal department, in-house counsel should be included as part of the response team.

E. Consider Involving Legal Counsel and/or Consultants

If it appears that the outcome of a survey could result in termination of participation in the Medicare and Medicaid programs, a hospital should immediately consider involving a health care attorney experienced in assisting hospitals with licensing and certification issues. Ideally, counsel should be involved immediately after the exit conference or during the survey if an IJ is identified. The primary role of counsel is to review the documents with an eye to the specific CoPs, standards, tags, *Interpretive Guidelines* and other statutes and regulations involved. Counsel can also advise on the best way to develop the plan of correction, especially when full compliance cannot be achieved immediately, such as when equipment purchases, construction or major education efforts are required. In addition, having an attorney involved in the development of the hospital's response allows much of the work product to be protected by the attorney-client privilege.

In certain cases, especially where the hospital's staff may not have the requisite expertise or experience, it may be advisable to involve consultants. This is especially the case where complex processes are involved or the competence of the current director of a function is at issue. Examples of a complex process may include a need to reorganize the medical records function or respond to highly technical laboratory deficiencies. Consultants need to be selected carefully, but quickly, in accordance with the applicable deadlines for the 2567 response. Counsel may have worked with consultants in prior cases and may be helpful in identifying and contracting with them.

When outside consultants are used, confidentiality of the information the consultants obtain is always an issue. If individually-identifiable protected health information will be shared with outside legal counsel or with consultants, a business associate agreement that complies with the Health Insurance Portability and Accountability Act regulations will be required. *(See CHA's* California Health Information Privacy Manual *for more information.)*

It is advisable to structure the consulting engagement to make the consultants a part of the hospital's medical staff quality assurance system to take maximum advantage of state confidentiality laws relating to peer review and/or medical staff quality assurance. Counsel can be helpful with these agreements. Consideration should also be given to whether

consultants should be engaged by and report to counsel in order to take advantage of the attorney work product privilege.

When consultants are involved, counsel can help assess whether it would be helpful to disclose their participation to CMS and/or CDPH. If CMS or CDPH is familiar with, and has confidence in, the particular consultants, this may improve the prospects for a finding of a credible allegation of compliance at a stage before the consultation process is fully completed.

If a consultant is a former surveyor, there may be conflict of interest or other legal prohibition that should be explored before the consultant is engaged. The consultant should certify that he/she knows of such conflicts or prohibitions. Hospitals should be aware that The Joint Commission does not permit its surveyors to act as consultants.

F. Submitting Information After the Exit Conference

A question that occasionally arises is whether the hospital may submit additional information to CMS or CDPH for consideration after the exit conference but before the CMS- 2567 or State-2567 is prepared by the surveyors or received by the hospital. Unfortunately, there is no formal avenue for doing this. However, if the hospital has additional information that was not originally available to the surveyors, but that might avert a final determination of a deficiency, the hospital should try to get that information to the surveyors as quickly as possible. Similarly, the hospital should try to get information to the surveyors regarding significant errors before the 2567 report is issued.

III. DEVELOP PRELIMINARY CORRECTIVE ACTION STEPS

The hospital should develop preliminary corrective action steps based on the deficiencies noted during the survey and the exit conference. The response team should review each deficiency identified by the surveyors. If the survey was a CMS survey, the team should review the Medicare CoP that is implicated, its component standards, and the associated *Interpretive Guidelines (see III. "Which Laws are Federal Surveyors Assessing Compliance With?," page 3.3)*. This review will help the response team identify what the hospital needs to do to correct the deficiency and become compliant with the conditions and standards. The team should keep in mind that one deficiency may implicate more than one CoP. It may be especially difficult for the response team to guess when the "Governing Body" and "Medical Staff" conditions may be implicated by a deficiency. Nevertheless, an early review of the conditions and standards will guide the hospital in developing its preliminary corrective action steps.

If the survey was a state survey, the team should review the Title 22 or Health and Safety Code provisions that may be implicated *(see III. "Which Laws are State Surveyors Assessing Compliance With?," page 2.6)*.

The hospital may have to make some educated guesses regarding how the surveyors will use each deficiency to support noncompliance with which standard and/or condition (for CMS surveys) or which Title 22 or Health and Safety Code provision (for state surveys).

Once the team has identified to its best ability what needs to be done to correct each deficiency, a written document should be produced. The document should list:

1. Each action step, including any new policies and procedures needed, revisions to existing policies and procedures, and training needed.
2. The hospital employee(s) responsible for implementing the step.
3. The deadline for implementation.
4. How the fact of completed implementation will be communicated back to the team leader.

Potential corrective action steps include development or revision of policies and procedures and forms; peer review activities; performance improvement projects; and staff education.

The hospital should also develop an auditing or monitoring plan to ensure that new policies or procedures are followed after they are put in place. The hospital may wish to monitor more frequently when new policies and procedures are first implemented, and reduce the frequency as the new policies and procedures become routine. In addition, the efficacy of the action steps should be evaluated, and changes made as appropriate.

The team leader should follow up regarding implementation of action steps and schedule team meetings as necessary to keep everyone on track.

The hospital should keep detailed notes of all its corrective action steps (including minutes of meetings) so that, once the final 2567 report is received, the hospital has documentation of its progress since the survey.

IV. DRAFTING THE HOSPITAL'S FINAL 2567 RESPONSE AND POC

A. Reconvene the Response Team Upon Receipt of 2567

Upon receiving the 2567 report, the hospital should make multiple copies for the response team, and set aside the original for use in producing the final response. The team leader should quickly review the 2567 report with an eye toward determining whether any additional members will need to be added to the response team. The response team should be convened as soon as possible.

The team should read and analyze the full 2567 report. For each finding, the team should determine whether:

1. The finding is new and needs to be addressed for the first time,
2. The finding has already been fully addressed by the hospital's preliminary corrective action steps, or
3. The finding has been addressed in the preliminary corrective action plan, but the plan needs modification or further action.

The 2567 report will list the conditions and standards (if a CMS survey) or the Title 22 and Health and Safety Code provisions (if a state survey) implicated. The team should review any of these that were not reviewed in developing the preliminary corrective action steps.

The response team should also review the cover letter that accompanies the 2567 report. The hospital's response must specifically address each category listed in the cover letter *(see B. "Cover Letter From CMS Accompanying CMS-2567," page 3.31)*.

B. Questions

The team should gather all of the questions it has and determine how to approach each one. Strategize the pros and cons of calling CMS and/or CDPH, other hospitals, CHA, and/or outside consultants. If the team decides to seek clarification from CMS or CDPH, formulate the questions to assure you get clear answers. If the response is not clear, ask for clarification. Respect the chain of authority, but if it is not working properly, escalate the matter politely. Identify who the hospital should work with in the future if additional questions arise.

C. Turn the Preliminary Corrective Action Steps into the 2567 Response

After receipt of the 2567, the hospital will want to turn the preliminary corrective action steps into the final 2567 response. The preliminary corrective action steps usually comprise an immediate-response plan that is not tailored to the 2567 report completed by the surveyors (because the corrective action steps are developed before the 2567 is received). The preliminary corrective action steps may be used as a resource for drafting the final 2567 response, but the pertinent information may need to be reorganized and augmented to show how the hospital's actions have addressed the specific findings cited by the surveyors. It is important to follow the exact order of the findings in the 2567 report, and to respond to each and every finding.

The response team should not become wedded to its preliminary corrective action steps. Sometimes there is a tendency to want to simply restate the corrective action steps rather than to isolate the specific issue involved in each finding, as well as the specific corrective measures that address the specific issue.

Once the 2567 report is received, the response team needs to approach the issues differently. This is because the surveyors take general factual findings (which they reported to the hospital in the exit conference) and they "unbundle" them into many different conclusions. A single fact may be used to support a conclusion that the hospital is out of compliance with a whole series of standards within a condition, as well as a conclusion that the hospital is out of compliance with more than one condition (or, if a state survey, more than one Title 22 or Health and Safety Code requirement). Thus, even though the surveyors may repeat a certain fact throughout their 2567 report, the gist of the conclusion will shift slightly from standard to standard, and significantly from condition to condition. The hospital's response must likewise be tailored to address the specific standard and/or condition (or Title 22 and/or Health and Safety Code requirement) at issue.

In addition, despite the fact that the surveyors are supposed to have reported all findings during the exit conference, there may be new findings the hospital has never heard of, or the 2567 report may exclude some findings the team was expecting to see and was prepared to respond to, and/or the report may present expected findings but with facts that are slightly different than anticipated. The hospital must respond to, and only to, the findings in the 2567 report.

The hospital should do the following:

1. If there is a new issue presented, develop corrective action steps immediately.
2. If there are findings described during the exit conference that are not included in the 2567, all references to corrective actions taken regarding them should be excluded from the final 2567 response/PoC.
3. If the findings contain some surprises or different facts, adjust the hospital's 2567 response accordingly. Forget the old facts that were originally anticipated when developing the corrective action steps.
4. Rebundle the information from the initial corrective actions as necessary to address each finding within the context of the specific standard, condition or state requirement. Augment with any needed additional information or corrective actions.

The final PoC will include immediate measures taken to address the specific problems cited, as well as such structural and process measures that may be necessary to achieve long-term correction and prevent recurrence.

D. Drafting the Hospital's 2567 Response

The hospital is required to prepare and submit a PoC — that is, the steps the hospital has already taken and/or will take to correct the deficiencies noted in the 2567 and prevent future violations. For federal surveys (the CMS-2567), the PoC must be sent to the State Survey Agency (CDPH) within 10 calendar days after the hospital receives the statement of deficiencies. *(See VI. "The Form CMS-2567: Statement of Deficiencies and Plan of Correction," page 3.30, regarding state time frames.)* The hospital may complete the two right-hand columns of the 2567 form itself, or attach a separate document.

While column four is called "Provider's Plan of Correction," the actual response required for this column may be a plan of correction (meaning the steps the hospital has already taken and the steps the hospital will take after the 2567 response is submitted to achieve compliance) or, using a CMS term, a "credible allegation of compliance" (meaning that the hospital has completed all steps it believes necessary to achieve compliance when the 2567 response is submitted).

The CMS State Operations Manual requires a PoC to include the position of the person who will monitor the corrective action and the frequency of monitoring, as well as the dates each corrective action has been or will be completed.

Hospitals should not use individuals' names — either employees, patients, medical staff members, or others — on the PoC. If the surveyors have used an identifier to refer to an individual, the hospital should use the same identifier to refer to that individual in its response. If the hospital wishes to refer to individuals not identified by the surveyors, the hospital may refer to employees by their position, discipline, or job title or be assigned an identifier. Patients, family, surveyors and others should be assigned an identifier of some type.

The hospital should indicate how the hospital's governing body and executive management — including the board of directors/trustees — and the quality assurance and performance improvement functions are engaged in the corrective action plan.

The CEO or other appropriate individual must sign and date the 2567 before returning it to the State Survey Agency (CDPH). It must meet the approval of the State Survey Agency for it to be acceptable.

Complete Response Needed for Each Deficiency

Every response to a deficiency should stand on its own. The entire answer, complete with all the detail, must be in the hospital's response to each deficiency. This requirement can result in a lot of repetition. However, this is important because the hospital's 2567 response may be broken up among the surveyors for review, making cross-references difficult for them to evaluate.

The goal of the hospital's 2567 response is to include enough detail about the corrective action steps so that a reader unfamiliar with the hospital (and who is not a clinician) can envision the "fix" — the actions taken and how these steps will prevent recurrence.

Remember That the Response Will be Publicly Available

Keep in mind that the hospital's 2567 response will be publicly available. The hospital will want to minimize adverse publicity, clarify misperceptions, and generally reassure the public about the facility. Care must be taken not to offend the surveyors (there is significant agency discretion in accepting the PoC), yet not to permit incorrect or unwarranted conclusions to go unanswered.

Include All Actions — Even the Obvious Ones

Think of the most obvious fix to a problem. Include this action. Then describe other action steps taken.

Illustration:

Finding on 2567: "The light fixture in Linen Closet X was burned out."
Incomplete response: "On [date], the hospital's policy and procedure regarding how often light bulbs should be checked was amended."
Preferable response: "The burned-out light fixture in Closet X was immediately replaced on [date – the date of the survey]. The hospital's policy and procedure regarding how often light bulbs should be checked was amended on [date] to require [daily or weekly] checking and documentation of [daily or weekly] checking. A sign was placed in all linen closets informing staff to call Environmental Services at extension XXXX upon finding a burned-out light bulb."

Describe New or Revised Policies

Provide detailed descriptions of new or revised policies and procedures, rather than just stating that "a new policy and procedure regarding XXX was developed" or "the policy and procedure regarding XXX was revised." If the relevant language of a revised policy is short, it may be good to quote that language. It is not enough to simply attach the new/revised policy and let the surveyors find the "fix." If you do attach a policy (in addition to including a specific description of what is new or different in the policy), highlight the relevant portions. *(See the illustration above, which states that the policy was amended "to require [daily or weekly] checking and documentation of [daily or weekly] checking.")*

Consider Whether to Attach Documents

Consider carefully whether to attach documents, such as policies and procedures, to the hospital's 2567 response. Surveyors differ in their view of whether documents should be attached. Some surveyors do not accept attachments, while others will request additional documents (such as revised policies and procedures) if they are not attached to the 2567. Even if the hospital includes attachments, the hospital must make sure that the plan of correction can stand on its own (as if there were no attachments). The 2567 response must be drafted with this requirement in mind. CMS has told CHA staff that CMS will review attachments, but will later discard them. If CMS subsequently accesses its copy of the hospital's plan of correction for some reason, the attachments will not be available.

When determining whether to submit attachments to the 2567, the hospital should consider that, if documents are attached, the surveyors may take the opportunity to scrutinize them and find other deficiencies. In addition, the documents may be made publicly available — the hospital may or may not have an issue with this. Finally, if the documents are attached, the surveyors may not feel it necessary to do a resurvey. This may deprive the hospital of the opportunity to make a good appearance at the resurvey. On the other hand, if the surveyors do a resurvey, they may find new deficiencies.

If documents are attached to the 2567, the attachments should be clearly marked so the surveyors can easily identify which responses they relate to. If documents are not attached, the hospital should note in its cover letter or in the PoC that copies are available upon request.

Be Cautious in Disclosing Disciplinary Action

The hospital should consult legal counsel before disclosing on a 2567 response specific details of disciplinary actions taken against employees or medical staff members, as this document may be publicly available. If legal counsel cautions against such disclosure, it may be sufficient to put some version of the following language in the 2567 response:

"The hospital carefully reviewed and documented its review of any allegations made as to employees and/or medical staff members to determine whether any disciplinary or corrective action was warranted. These reviews were completed as to employees on [date] and as to members of the medical staff on [date].

Employee matters are reviewed under the policies and procedures of the Human Resources Department (approved on [date] by the Board of Trustees/Directors). These include a system of progressive disciplinary actions for which the Vice President of Human Resources is ultimately responsible. Complete records of any such actions taken during the period from [date] to [date] are maintained and are available for on-site inspection in the office of the Director of Human Resources.

Medical staff matters are reviewed by the medical staff department and service chiefs and applicable committees under the direction of the Chief of Staff. Any actions are ultimately subject to approval or disapproval by the Board of Trustees/Directors, which has overall responsibility for the quality of care rendered in the institution. The medical staff has bylaws, rules and regulations that deal with peer review and corrective action as to medical staff members (approved by the medical staff on [date] and by the Board of Trustees/Directors on [date]). Complete records detailing any corrective actions that took place during the period from [date] to [date] are maintained and are available for on-site inspection in the office of

the Medical Staff Coordinator. The Board of Trustees/Directors is subject to the procedures specified in the documents listed above, and is also bound by its own bylaws (approved by the Board of Trustees/Directors on [date]). Complete records detailing any corrective actions undertaken by the Board of Trustees/Directors are maintained and are available for inspection in the hospital's administrative offices."

If legal counsel approves the disclosure of disciplinary action, the hospital should describe all levels. For example, if a nurse is first verbally counseled for failing to record vital signs, but later he or she is given a written counseling and required training, all three actions should be detailed, including the dates. The identifier used by the surveyors should be used, not the employee's name.

Describe Staff Education and Training

When the response calls for staff education and training, include all types of education, whether individualized or group, whether the education is written or oral, etc. Be clear in describing which staff will be trained (for example, "all RNs working in the neonatal ICU"). Do not say "all staff" unless you really mean that. Include all dates that the education occurs, not just the first or last date. CDPH requires that all staff development programs be documented by:

1. A record of the title, length of course in hours, and objectives of the education program presented;
2. Name, title, and qualifications of the instructor or the title and type of other educational media;
3. A description of the content;
4. A date, a record of the instructor, process, or media and a list of attendees; and
5. Written evaluation of the course content by attendees.

[Title 22, California Code of Regulations, Section 70214(d)]

You may wish to note in the 2567 Plan of Correction that these records are available.

Describe Monitoring

The hospital must describe the monitoring it will undertake — that is, what review, quality assurance measures, monitoring procedures, etc. are being done so that the particular deficiencies cited in the 2567 do not and cannot happen again. The 2567 response should describe who is responsible for monitoring (title of person), how often they monitor, what they monitor for, who the results are reported to, what happens with the results (whether good or bad), and what procedures are in place to alert key personnel if a problem occurs again so it can be corrected right away. The monitoring should be integrated into the hospital's larger QAPI processes.

Tiered monitoring may be warranted if serious patient care issues are at stake. The first layer of monitoring may be intense and aggressive — perhaps hourly or daily review. After improvement is seen, monitoring can drop to less frequent review — perhaps weekly. When ongoing compliance has been achieved, monitoring can return to part of the general audit process.

Review the 2567 to determine whether it specifies which person is responsible for the task that was deficient (for example, "The Director of Nursing is responsible for…."). If so, the person responsible for monitoring must be that designated individual.

Date of Corrective Action

The 2567 contains a column where the hospital is required to put a date by which each deficiency is fixed. Only one date should be included, across from the first line of each deficiency. (If a separate document is used for the PoC, it too should contain one final completion date per deficiency.) The date used should be the latest date when all of the collective actions that formed the response were completed. For CMS-2567 forms, this date should be within 30 days of the exit conference, or (with rare exceptions described below) no later than the date the 2567 response is due. Interim dates should be embedded in the explanation of the action items.

The rare exceptions apply to actions, such as plant and equipment changes, that cannot be completed until a later date. When that occurs, it is necessary to fully describe concrete steps already completed, such as starting construction, submitting design plans, or ordering equipment. It may be possible to use the date that the hospital undertook this action as the completion date. However, this must be accompanied by an explanatory note stating when final completion is expected.

If the Medical Executive Committee or Board of Trustees/Directors has not yet approved a policy and procedure, and this cannot be accomplished before the 2567 response is submitted, the hospital should consider stating: *"These policy changes were immediately implemented and approved by the Department of Nursing on [date]. They are scheduled for action by the MEC during its next scheduled meeting on [date] and by the Board of Trustees/Directors during its next schedule meeting on [date]."* It is preferable, however, to have these bodies meet emergently and approve the policies.

If a training program will run for a number of days or weeks, state which dates occurred prior to the due date of the 2567 response, and then state something along the lines of *"training will continue on 4/10-4/15 in order to achieve 100% attendance by all trauma nurses."* Be sure to make provisions to train staff on vacation or otherwise absent during the regular training.

E. Hospital Disputes Factual Findings in 2567

There is no formal procedure for appealing a factual error reflected in a 2567. A hospital that disagrees with a factual finding regarding a cited deficiency has several options:

1. Accept the deficiencies cited and submit a response to the 2567.
2. Document objections to the cited deficiencies, submit a response to the 2567, and provide convincing arguments and evidence that the findings are incorrect.
3. Document objections to the cited deficiencies and provide convincing arguments and evidence that the findings are incorrect. Submit this information to CDPH or CMS in the form of a letter rather than as a response to the 2567.

Which option to select will depend upon the facts and circumstances. Hospitals are encouraged to work with their local district office staff to discuss the perceived error and determine how best to address it. Hospitals may also wish to consult experienced legal counsel.

Option two provides two benefits that hospitals may wish to consider:

1. The hospital's position will be made public whenever the 2567 is released, and
2. The information will be included in the documentation considered during any subsequent reconsideration and hearings.

The hospital choosing option two should document its position in the PoC, and clearly specify why the finding of a deficiency is incorrect or inaccurate. The hospital should also provide necessary clarification or supporting information. When drafting the response, be clear that the hospital is challenging the accuracy of the factual findings that underlie the alleged deficiency, not challenging the legal conclusion that the facts warrant the finding of a deficiency.

Illustrations:

If the surveyor erroneously reported a crack in the meat slicer, the hospital's 2567 response should courteously correct the facts: "The cracked plastic part mentioned in the findings was on the puree blender, not the meat slicer. The cracked part was replaced on [date]. The hospital's policy and documentation forms regarding food preparation equipment inspection were revised on [date] to require [daily or weekly] inspection and documentation of [daily or weekly] inspections of all puree blender parts."

If the surveyor erroneously states that the hospital failed to document a new order on a follow-up form and the hospital can produce evidence that this finding is incorrect, the hospital should attach evidence and then state in the 2567 response: "Hospital disputes the finding that it failed to document the new antibiotic order on the ED follow-up form. There is documentation on the follow-up form that the new antibiotic was ordered and called in to the patient's pharmacy. The patient was notified on [date] at [time]. See Exhibit A."

It is important to note that the presence of an error in the 2567 does not extend the time line for the hospital's submission of its response and plan of correction. *(See CHA's* EMTALA: A Guide to Patient Anti-Dumping Laws *for more information regarding disputing EMTALA-related deficiencies.)*

F. Cover Letter Accompanying Hospital's Response

The CEO or designee should prepare a cover letter to accompany the hospital's response to the CMS-2567 or State-2567. This cover letter should be used to:

1. Confirm the hospital's understanding regarding the next steps (especially if this has been unclear).
2. Capture, in writing, any intentions expressed verbally by the surveyors or by CMS during telephone calls.
3. Explain if there are any disputed findings and summarize how the hospital handled them.

4. Explain any problems in the 2567, such as cross-references that were not accurate, condition tags that referenced a standard not included in the 2567, references to patients not cited elsewhere, etc.
5. Note any omissions or errors, such as missing references.
6. Request clarification regarding the process and timing of the resurvey.

A sample cover letter may be found as CHA Appendix HS-10, "Sample Cover Letter for Hospital's CMS-2567 Response (for a CMS survey)," at the end of this manual. This letter is designed to be used in response to a CMS survey. If the hospital underwent a state survey, it should be sent only to CDPH and not to CMS. Obviously, appropriate changes will need to be made to the sample letter so that it applies accurately to the particular situation at issue. It cannot simply be copied and used as is without thoughtful revision.

Note that the CEO must sign both the cover letter and the front page of the hospital's 2567 response.

Given the short time frame for responding to the CMS-2567, the hospital may wish to arrange for courier or overnight delivery. The cover letter may be marked "Hand-Delivered" or "Delivered by Courier" or similar words as appropriate.

V. AFTER THE 2567 RESPONSE IS SUBMITTED

After the 2567 response/PoC is submitted, the hospital should undertake all necessary actions to continue to implement the plan, maintain and monitor compliance with the plan, and assemble documentation that the plan has been successfully implemented to show the surveyors upon resurvey. Actually, much of this work can be done before the plan is submitted — the sooner a deficiency is fixed after identification, the better.

The drafters of the 2567 response should do the following:

1. Communicate to the responsible people identified in the 2567 response what they are responsible for, and help provide adequate resources to achieve these responsibilities.
2. Complete all action items within the stated time frame.
3. Monitor compliance with the corrective actions to ensure that hospital staff members thoroughly incorporate the new policy, procedure, method or whatever the case may be.

A. Documentation

Assemble and maintain documentation that irrefutably demonstrates compliance with the plan of correction. Document all monitoring and the results thereof (as well as the actions that are being monitored). This documentation should be well-organized so that the surveyors can quickly confirm that the hospital did what it said it would do on the 2567 response. The surveyors should not need to go searching for the documentation referenced in the hospital's response.

The hospital should make multiple copies of the relevant documentation, and keep it up-to-date when any change takes place. Where appropriate, highlight specific changes or provisions designed to address the cited deficiencies so the surveyors can see them easily.

B. Continuous Improvement

The hospital should continue to make improvements. As monitoring results come back, the hospital may need to make changes and improve the processes discussed in the 2567 response. Submitting the 2567 response to the surveyors does not preclude the hospital from making improvements as part of its QAPI process. Depending upon the facts and circumstances, it may be appropriate to notify the surveyors of changes in actions or monitoring activities. While sometimes it is sufficient to wait until the surveyors return to resurvey and then explain changes that have evolved, the risk exists that the surveyors won't agree with the change in direction and will cite the hospital for failing to implement the PoC as represented. Generally speaking, any significant deviations from the activities described in the 2567 response should be reported to CDPH and/or CMS. If this is done by phone, it should be documented.

C. Hospital Forgets to Include Something in the PoC

During the PoC implementation and monitoring process, someone may determine that an important element of the hospital's 2567 response was not included. The hospital should make a decision about whether an amended version of the response should be submitted to CDPH and/or CMS along with a cover letter explaining the missing information. If this is done, the hospital should make sure the date that the fix occurred is still prior to the date the hospital's 2567 response was due (in other words, do not use the date that the amended version was submitted). The hospital should make sure that if the missing information affects several deficiencies (often one deficiency will be cited under several requirements, such as Quality or Governing Body), that all are amended as necessary.

Alternatively, the hospital may determine that an amendment is not necessary and can instead either show the surveyors the change upon resurvey or call the surveyor. Checking with CDPH and/or CMS may be appropriate.

D. Follow-Up Questions from Surveyors

While reviewing the hospital's 2567 response, the surveyors may ask follow-up questions. These questions may come by way of a telephone call or a written notice. The hospital should try to ascertain as much information as possible about what level of detail is required for the response, what the response should look like, when the response is due, etc. If the inquiry is by telephone, the hospital should take excellent notes during such a call, so as to enable full compliance with the request for further information.

It is important to take these follow-up questions very seriously. In drafting a follow-up response, the hospital should carefully review its original 2567 response as well as the initial findings cited in the 2567 report. This background will help determine what the surveyor believes is missing in the response. Re-reading the requirement that the surveyors felt was not met is especially important to make sure the follow-up question asked is appropriate given the subject matter of the deficiency cited.

In some cases, the answer to the follow-up question may already have been addressed in the original 2567 response, but may have been overlooked by the reviewing surveyor. If the information was already communicated in the 2567 response, then a letter that clarifies the answer (e.g., showing where it appears in the 2567, and perhaps restating the pertinent information) can be effective.

If the answer was not addressed in the original 2567 response, or if it appeared only in response to a different deficiency, then the hospital may need to amend its 2567 response and resubmit it.

E. Final Actions by Surveyors

After the Plan of Correction is submitted, CDPH/CMS will review it and may resurvey the hospital or accept the POC without a resurvey. The hospital may be put on state monitoring. *See VII. "CDPH/CMS Actions after PoC Submitted," page 3.33, for more information about these actions.*

Index

SYMBOLS

2567, 2.11, 3.30, 5.13

A

Accreditation, 1.4
Adverse event, 2.4, 2.5
All Facility Letters (AFLs), 2.6
American Osteopathic Association (AOA), 1.3
Attorney-client privilege, 3.19

B

Breach of privacy—*See Privacy breach*

C

California Code of Regulations, 2.6
California Department of Public Health (CDPH), 1.1, 1.3
    Licensing and Certification (L&C) Program, 1.1
        District offices, 2.1
    Organization chart, 2.1
California Hospital Association (CHA)
    Catalog of administrative penalties, 2.15
CALS—*See Consolidated Accreditation and Licensure Survey (CALS)*
CDPH—*See California Department of Public Health (CDPH)*
Centers for Medicare & Medicaid Services (CMS), 1.2, 3.1
    Regional offices, 3.1
Certification, 1.2
Certification survey, 3.2
CHA—*See California Hospital Association (CHA)*
CMS—*See Centers for Medicare & Medicaid Services (CMS)*
Code of Federal Regulations, 3.3, 3.30
Complaint survey, 1.4, 2.4, 3.2
Condition-level deficiency, 3.7, 3.23, 3.26
Conditions of Participation (CoPs), 1.2, 3.3
Critical access hospital, 1.2

D

Deemed status, 1.2
Deficiency, 3.23, 3.26
Departmental Appeals Board, 3.37
Det Norske Veritas Healthcare, Inc.—*See DNV Healthcare*
DNV Healthcare, 1.3, 1.4—*See Det Norske Veritas Healthcare, Inc. (DNV Healthcare)*

E

EHRs, 3.15, 3.20
EMTALA, 1.2, 1.4, 2.24, 3.15
Entrance conference, 3.13, 4.7
Exit conference, 3.24, 4.10

F

Frontier hospital, 1.2

G

Governing body, 5.1

H

Health and Safety Code, 2.6
Health Facilities Evaluator Nurses, 2.2
HFAP, 1.3, 1.4

I

Immediate jeopardy
    Federal, 3.27
    State, 2.10
Interpretive Guidelines, 3.7
Interviews, 3.18

J

Joint Commission—*See The Joint Commission (TJC)*

L

L&C—*See California Department of Public Health (CDPH), Licensing and Certification (L&C) Program*
Licensing, 1.1
Life safety code, 3.11

M

Media, 5.3
Medicaid, 1.2
Medi-Cal, 1.2
Medical staff, 4.4, 5.2
Medicare, 1.2
Medicare/Medicaid certification
    Appeal of final determination to terminate, 3.37
MERP—*See Medication Error Reduction Plan (MERP)*

N

National Fire Prevention Association (NFPA), 3.11

P

Patient privacy rights, 3.22
Peer review, 3.19
Penalties, 2.12, 2.23, 2.24, 3.27
Plan of correction, 2.11, 3.31, 5.4, 5.16
    Form CMS-2567, 3.30
Privacy breach, 2.4, 2.5, 2.24
Privacy rights—*See Patient privacy rights*
PSLS—*See Patient Safety Licensing Survey (PSLS)*
Public notice, 2.25, 3.36

R

Recertification survey, 1.4
Record review, 3.18
Resurvey, 3.33, 3.34

S

S&C Memos, 3.10
Sole community hospital, 1.2
SOM—*See State Operations Manual (SOM)*
Specialty hospital, 1.2
Standard-level deficiency, 3.7, 3.23, 3.26
Statement of deficiencies
    Form CMS-2567, 3.30
State monitoring, 3.33
State Operations Manual (SOM), 2.9, 3.7
State survey agency, 1.3
Survey, 4.9
Surveyors, 2.1
Survey procedures, 2.8, 3.7

T

Tags, 3.10
Termination
    From Medicare/Medi-Cal, 3.34
The Joint Commission (TJC), 1.3, 1.4
Title 22, 2.6
TJC—*See The Joint Commission (TJC)*

U

Unusual occurrence, 2.4, 2.5

V

Validation survey, 1.3, 3.3

List of Forms and Appendices

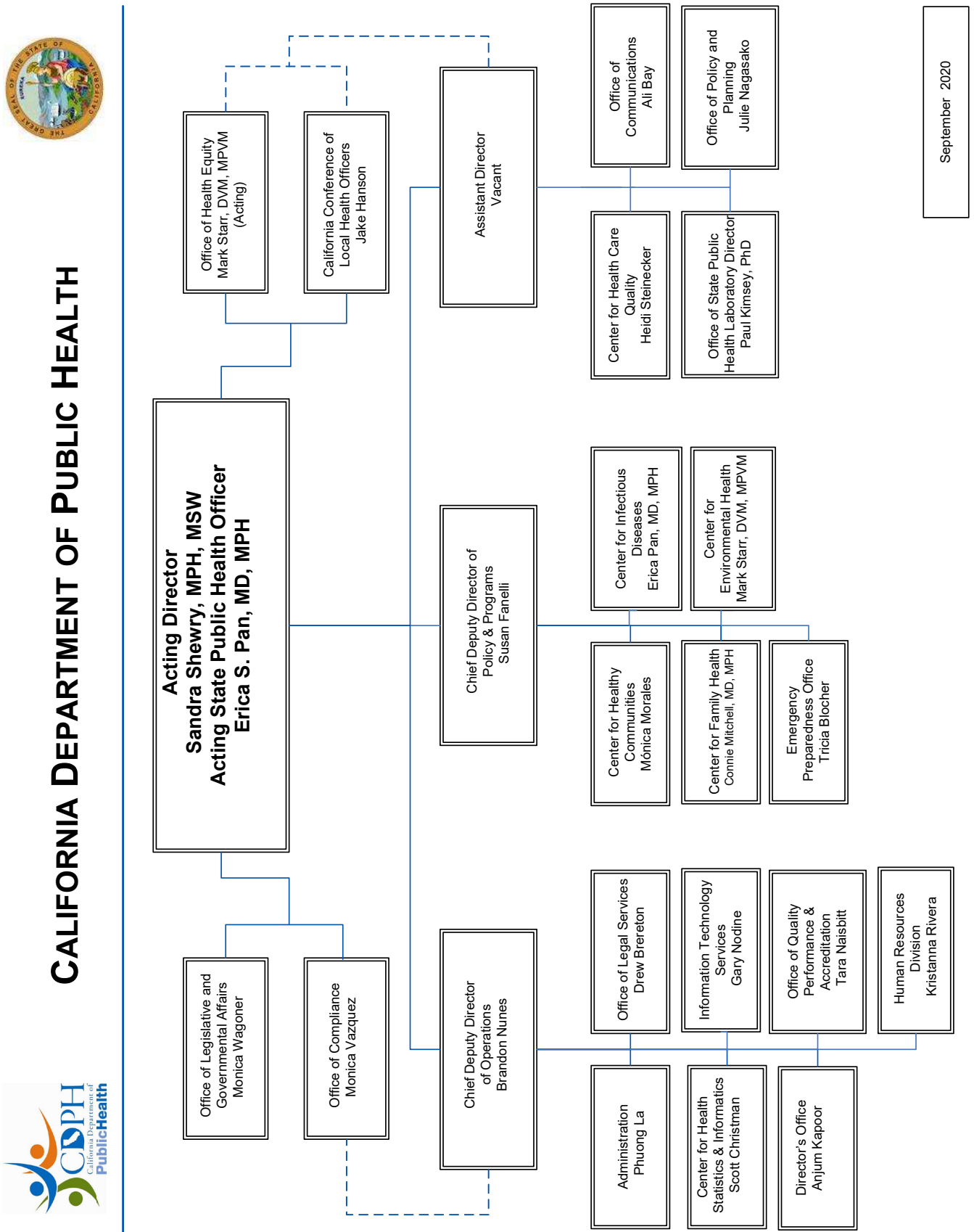
These documents are provided in English in the back of the manual. All forms can be found online for CHA members at www.calhospital.org/free-resources.

HS-1 California Department of Public Health Organization Chart
HS-2 Adverse Event Reporting Requirement
20-1 Adverse Event Report Form — Sample
HS-3 Privacy Breach Reporting Requirement
HS-4 Unusual Occurrences Reporting Requirement
HS-5 State-2567: Statement of Deficiencies and Plan of Correction
HS-6 Maximum Time Frames Related to the Federal On-Site Investigation of Complaints/Incidents
HS-7 Form CMS-2567: Statement of Deficiencies and Plan of Correction
HS-8 Timeline for 90-Day Termination Track
HS-9 Timeline for 23-Day Termination Track
HS-10 Sample Cover Letter for Hospital's CMS-2567 Response *(for a CMS survey)*
HS-11 Definitions of Hospitals Under California Law
HS-13 FAQs on Writing Hospital Policies and Procedures
HS-14 Instructions for Calculating an Administrative Penalty (for non charity care, non privacy breach violations)
CDPH Administrative Penalties: Scope and Severity Matrix
(for non charity care, non privacy breach violations)
HS-15 Federal vs. State Immediate Jeopardy Definition and Implementation Comparison

* Indicates forms that are new or revised in this edition.

APPENDIX HS-1

California Department of Public Health Organization Chart



APPENDIX HS-2

Adverse Event Reporting Requirement

Adverse Events Reporting

In response to media attention on medical errors, the California Legislature passed, and the Governor signed, legislation requiring general acute care hospitals, psychiatric hospitals, and special hospitals to report specified adverse events to CDPH. [Health and Safety Code Sections 1279.1, 1279.2, 1279.3 and 1280.4]

Outpatient settings must also report adverse events. **"Outpatient settings"** are defined as:

1. Any facility, clinic, unlicensed clinic, center, office, or other setting that is not part of a general acute care facility, as defined in [Health and Safety Code] Section 1250, 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. A clinic or ambulatory surgery center that does not meet this definition — i.e., does not use general anesthesia — is not subject to this reporting requirement.
2. Facilities that offer in vitro fertilization, as defined in Health and Safety Code Section 1374.55(b).

Outpatient settings do not include, among other settings, any 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.

[Health and Safety Code Section 1248 and 1248.15]

CDPH has confirmed that distinct-part nursing facilities (DP-NFs) need not report adverse events under this law. However, other reporting requirements may apply (for example, the "unusual occurrences" reporting requirement may apply); *see "Relationship With Other Reporting Requirements," page 5.*

Types of Events that Must be Reported

For purposes of this reporting requirement, **"adverse event"** includes the surgical events, product or device events, patient protection events, care management events, environmental events, criminal events, and one other item described below. The term **"serious disability,"** which is used in many places in the list of adverse events, means:

> a physical or mental impairment that substantially limits one or more of the major life activities of an individual, or the loss of bodily function, if the impairment or loss lasts more than 7 days or is still present at the time of discharge from an inpatient health facility, or the loss of a body part.

The list of adverse events includes the following.

Surgical Events

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 the obtaining of 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.

Product or Device Events

1. 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.
2. 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 requirement, **"device"** includes, but it not limited to, a catheter, drain, or other specialized tube, infusion pump, or ventilator.
3. 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.

Patient Protection Events

1. An infant discharged to the wrong person.
2. 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.
3. 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.

Care Management Events

1. 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.
2. A patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products.
3. 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.
4. 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.
5. 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 requirement, **"hyperbilirubinemia"** means bilirubin levels greater than 30 milligrams per deciliter.
6. 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. *(See AFL 15-03.1 regarding unstageable pressure ulcers at* https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/AFL-15-03.aspx*.)*
7. A patient death or serious disability due to spinal manipulative therapy performed at the health facility.

Environmental Events

1. 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.
2. 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.
3. A patient death or serious disability associated with a burn incurred from any source while the patient is being cared for in a health facility.
4. A patient death associated with a fall while the patient is being cared for in a health facility.
5. A patient death or serious disability associated with the use of restraints or bedrails while being cared for in a health facility.

Criminal Events

1. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider.
2. The abduction of a patient of any age.
3. The sexual assault of a patient within or on the grounds of a health facility.
4. 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.

Final Item

The list of adverse events specified in the law contains a final item that contains a circular definition. The final "catchall" category to be reported is "an adverse event or series of adverse events that cause the death or serious disability of a patient, personnel, or visitor." However, an **"adverse event"** is defined as those events listed above (surgical events, product or device events, patient protection events, care management events, environmental events, and criminal events). Therefore, the final category arguably does not capture any events that are not already described in the law. Hospitals that are considering reporting an event under the "catchall" category should consult legal counsel to determine whether a report under this law is required. Even if a report under this law is determined not to be required, however, hospitals may need to report the incident pursuant to another reporting requirement. *(See "Relationship With Other Reporting Requirements," page .)*

Required Time Frame for Reporting

The report must be made no later than five days after the adverse event has been detected. However, if the adverse event is an ongoing urgent or emergent threat to the welfare, health, or safety of patients, personnel, or visitors, the report must be made not later than 24 hours after the adverse event has been detected.

How to Report

CDPH has developed a web-based reporting tool that health care facilities may use to report adverse events as well as privacy breaches, called the "California Healthcare Event and Reporting Tool" (CalHEART). Information about the online reporting tool may be found in CDPH All Facilities Letter 13-12 at https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/LNCAFL2013.aspx. Hospitals are not required to use this tool; a paper form may be submitted instead. CHA has developed a form, "Adverse Event Report Form" (CHA Form 20-1), that hospitals may use to report an adverse event to CDPH. CDPH has stated it will accept the CHA form. However, CDPH has issued proposed regulations about adverse event reporting. After the regulations are finalized and in effect, hospitals will be required to report electronically and additional information may be required.

Communication With Affected Patient(s)

The hospital must inform the patient or the party responsible for the patient of the adverse event by the time the report is made. In addition, The Joint Commission requirement regarding informing the patient of unanticipated outcomes of care may apply. *(See CHA's* Consent Manual*, chapter 19.)*

Relationship With Other Reporting Requirements

This law does not change or otherwise affect other hospital reporting requirements regarding reportable diseases or unusual occurrences. Hospitals may also need to report adverse events according to the following requirements:

1. Unusual occurrences — *see CHA Appendix HS-4.*
2. Safe Medical Devices Act — *see CHA's* Consent Manual*, chapter 19.*
3. Restraint death reporting — *see CHA's* Consent Manual*, chapter 19.*
4. Medication errors — *see CHA's* Consent Manual*, chapter 19.*
5. Injuries by firearm or assaultive or abusive conduct — *see CHA's* Consent Manual*, chapter 17.*
6. Violence against hospital personnel — *see CHA's* guidebook, "*Healthcare Workplace Violence Prevention - How to Comply with the Cal/OSHA Regulation," available at https://www.calhospital.org/publication/healthcare-workplace-violence-prevention.*
7. Radiation overdose — *see CHA's* Consent Manual*, chapter 19.*

In addition, a root cause analysis pursuant to The Joint Commission's sentinel event requirements may be required. *(See CHA's* Consent Manual*, chapter 19.)*

CDPH Investigations and Reports

Ongoing Threat of Imminent Danger

CDPH must make an on-site inspection or investigation whenever it receives an adverse event report or a complaint indicating an ongoing threat of imminent danger of death or serious bodily harm. The on-site inspection or investigation must take place within 48 hours or two business days (whichever is greater) after receipt of the report or complaint. The investigation must be completed within 45 days. If CDPH does not meet this timeframe, it must provide written notice to the facility and the complainant (if any) of the basis for the extenuating circumstances preventing it from meeting the timeframe, and the anticipated completion date. Until CDPH determines by on-site inspection that the adverse event has been resolved, CDPH must conduct an unannounced inspection at least once per year of any hospital that has reported an adverse event.

No Threat of Imminent Danger

If CDPH receives a complaint or report but determines from the information available to it that there is no threat of imminent danger of death or serious bodily harm to that patient or other patients, no on-site inspection is required, but an investigation must be undertaken and completed within 45 days. If CDPH does not meet this time frame, it must provide written notice to the facility and the complainant (if any) of the basis for the extenuating circumstances preventing it from meeting the time frame, and the anticipated completion date.

Definition

For purposes of this law, a **"complaint"** means any oral or written notice to CDPH (other than an adverse event report from the hospital) of an alleged violation of any applicable state or federal law, or an allegation of facts that might constitute such a violation.

Follow-Up

CDPH must notify the hospital and the complainant in writing of its determination as a result of its investigation.

CDPH Public Reporting of Adverse Events

CDPH provides information about substantiated adverse events and the outcomes of inspections and investigations on its website by posting the hospital's Statement of Deficiencies (CDPH Form 2567) and the hospital's plan of correction.

The information provided by CDPH names individual hospitals and may include compliance information history. The names of patients, health care professionals and other health care workers will not be divulged by CDPH.

Penalties for Failure to Report

The adverse event reporting law contains specific penalties for failure to report. A hospital that fails to report an adverse event may be assessed a civil penalty in an amount not to exceed $100 per day for each day that the adverse event is not reported following the initial five-day period or 24-hour period, as applicable. If the hospital disputes a determination by CDPH regarding an alleged failure to report an adverse event, the hospital may, within 10 days, request a hearing pursuant to Health and Safety Code Section 100171. Penalties do not have to be paid until all appeals have been exhausted.

CDPH has additional authority to fine hospitals for failing to comply with hospital licensing requirements. It is unclear whether both fines may apply, or if CDPH is limited to assessing penalties under this provision.

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.*

APPENDIX HS-4

Unusual Occurrences Reporting Requirement

Reportable "Unusual Occurrences"

Hospitals are required to notify CDPH immediately, via telephone, of the following:

1. Any discontinuance or disruption of services;
2. Upon the threat of a walkout of a substantial number of employees; or
3. An earthquake, fire, power outage or other calamity that causes damage to the facility or threatens the safety or welfare of patients or clients.

[Title 22, California Code of Regulations, Sections 70746 (general acute care hospitals), 71544 (acute psychiatric hospitals)]

Title 22 also requires general acute care hospitals and acute psychiatric hospitals to report by phone any occurrence such as an epidemic outbreak, poisoning, fire, major accident, disaster, other catastrophe or unusual occurrence that threatens the welfare, safety, or health of patients, personnel, or visitors, as soon as reasonably practicable, to the local health officer and to CDPH. The hospital must furnish other pertinent information related to the occurrence as may be requested by the local health officer or CDPH. [Title 22, California Code of Regulations, Sections 70737 (general acute care hospital) and 71535 (acute psychiatric hospital)].

Exactly which types of incidents constitute an "unusual occurrence" has not been further clarified by CDPH. CDPH is aware that its employees as well as hospital employees have inconsistent interpretations of this requirement. CDPH has indicated that the following events should be reported as unusual occurrences:

1. Sentinel events as defined by the Joint Commission, even if the hospital does not report the event to The Joint Commission. (See CHA's Consent Manual, chapter 19, regarding sentinel events.)
2. A patient death that occurs while a patient is restrained or in seclusion for behavior management.
3. Incidents that are covered by the news media.
4. An emergency or disaster-related occurrence that results in a patient evacuation, transfer, or discharge [All Facilities Letter 17-06 (Mar. 13, 2017)].
5. Public Safety Power Shutoff power outages [All Facilities Letter 18-48 (Nov. 13, 2018)].
6. However, CDPH has not promulgated regulations regarding these informal interpretations.

How to Report

During normal business hours, the hospital should contact the local CDPH Licensing and Certification district office it customarily works with. For after-hours reporting, or if the local district office is non-operational due to an emergency or disaster, hospitals in Los Angeles County should contact the Los Angeles County Operator at (213) 974-1234 and ask the operator to notify the on-call Health Facilities Inspection Division supervisor. Hospitals outside Los Angeles County should contact the CDPH duty officer at (916) 328-3605.

The hospital should document that notification was made.

APPENDIX HS-5

State-2567: Statement of Deficiencies and Plan of Correction

California Health and Human Services Agency
Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE

Event ID:

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVES SIGNATURE	TITLE	(X6) DATE

Any deficiency statement ending with an asterisk (1 denotes a deficiency which the institution may be excused from correcting providing It is determined that other safeguards provide sufficient protection to the patients. Except for nursing homes the findings above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility If deficiencies are cited an approved plan of correction is requisite to continued program participation

State-2567 17 of 16

APPENDIX HS-6

Maximum Time Frames Related to the Federal On-Site Investigation of Complaints/Incidents

Provider Type	**Immediate Jeopardy (IJ)** (Noncompliance caused serious injury, harm, impairment, or death of a patient, or the likelihood of such, and there continues to be an immediate risk unless immediate corrective action is taken.)	**Non-IJ: High** (Noncompliance would not represent an IJ, but indicates a condition-level deficiency)	**Non-IJ: Medium** (Noncompliance is limited in manner and degree and/or caused or may cause harm that is of limited consequence and does not impair the individual's mental, physical and/or psychosocial status or function)	**Non-IJ: Low** (Noncompliance may have caused physical, mental and/or psychosocial discomfort that does not constitute injury or damage)
Deemed hospitals	SA must initiate an on-site survey within 2 business days of receipt of RO authorization.	SA must initiate an on-site survey within 45 calendar days of receipt of RO authorization.	Complaint is referred to the applicable accrediting organization(s).	Complaint is referred to the applicable accrediting organization(s).
Non-deemed hospitals	SA must initiate an on-site survey within 2 business days of receipt of RO authorization.	SA must initiate an on-site survey within 45 calendar days after prioritization of complaint.	SA must investigate no later than the next on-site survey.	SA must track/trend for potential focus areas for the next on-site survey. SA has the discretion to initiate a survey based on trending.
EMTALA	SA must initiate an on-site survey within 2 business days of receipt of RO authorization.	SA must initiate an on-site survey within 45 calendar days of receipt of RO authorization.	N/A	N/A

Provider Type	**Immediate Jeopardy (IJ)** (Noncompliance caused serious injury, harm, impairment, or death of a patient, or the likelihood of such, and there continues to be an immediate risk unless immediate corrective action is taken.)	**Non-IJ: High** (Noncompliance would not represent an IJ, but indicates a condition-level deficiency)	**Non-IJ: Medium** (Noncompliance is limited in manner and degree and/or caused or may cause harm that is of limited consequence and does not impair the individual's mental, physical and/ or psychosocial status or function)	**Non-IJ: Low** (Noncompliance may have caused physical, mental and/or psychosocial discomfort that does not constitute injury or damage)
Death associated with restraint/seclusion used for behavior management	SA must initiate an on-site survey within 2 business days of reciept of RO authorization.	N/A (All such complaints are considered IJs)	N/A (All such complaints are considered IJs)	N/A (All such complaints are considered IJs)
Fire resulting in serious injury or death	SA must initiate an on-site survey within 2 business days of receipt of RO authorization.	N/A (All such complaints are considered IJs)	N/A (All such complaints are considered IJs)	N/A (All such complaints are considered IJs)

NOTES:

1. SA=State Survey Agency, which in California is the California Department of Public Health. RO=Regional Office of the Centers for Medicare & Medicaid Services.
2. Generally, an alleged event occurring more than 12 months prior to a complaint will not trigger a complaint investigation. However, the State Survey Agency may conduct an investigation to determine current compliance status based on concerns identified in the complaint.

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Source: *State Operations Manual*, Chapter 5 — Complaint Procedures, Section 5075.9

APPENDIX HS-7

Form CMS-2567: Statement of Deficiencies and Plan of Correction

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
		A. BUILDING _____ B. WING _____	

NAME OF FACILITY	STREET ADDRESS, CITY, STATE, ZIP CODE

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY SHOULD BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERRED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. *(See reverse for further instructions.)* Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE

FORM CMS-2567 (02/99) Previous Versions Obsolete

If continuation sheet Page _____ of _____

INSTRUCTIONS FOR COMPLETION OF THE STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (CMS-2567)

I. **PURPOSE**
This document contains a listing of deficiencies cited by the surveying State Agency (SA) or Regional Office (RO) as requiring correction. The Summary Statement of Deficiencies is based on the surveyors' professional knowledge and interpretation of Medicare and/or Medicaid or Clinical Laboratory Improvement Amendments requirements.

II. **FORM COMPLETION**
Name and Address of Facility – Indicate the name and address of the facility identified on the official certification record. When surveying multiple sites under one identification number, identify the site where a deficiency exists in the text of the deficiency under the Summary Statement of Deficiencies column.

Prefix Identification Tag – Each cited deficiency and corrective action should be preceded by the prefix identification tag (as shown to the left of the regulation in the State Operations Manual or survey report form). For example, a deficiency in Patient Test Management (493.1107) would be preceded by the appropriate D-Tag in the 3000 series. A deficiency cited in the Life Safety Code provision 2-1 (construction) would be preceded by K8. Place this appropriate identification tag in the column labeled ID Prefix Tag.

III. **Summary Statement of Deficiencies** – Each cited deficiency should be followed by full identifying information, e.g., 493.1107(a). Each Life Safety Code deficiency should be followed by the referenced citation from the Life Safety Code and the provision number shown on the survey report form.

IV. **Plan of Correction** – In the column Plan of Correction, the statements should reflect the facility's plan for corrective action and the anticipated time of correction (an explicit date must be shown). If the action has been completed when the form is returned, the plan should indicate the date completed. The date indicated for completion of the corrective action must be appropriate to the level of the deficiency(ies).

V. **Waivers** – Waivers of other than Life Safety Code deficiencies in hospitals are by regulations specifically restricted to the RN waiver as provided in section 1861(e)(5) of the Social Security Act. The long term care regulations provide for waiver of the regulations for nursing, patient room size and number of beds per room. The regulations provide for variance of the number of beds per room for intermediate care facilities for the mentally retarded. Any other deficiency must be covered by an acceptable plan of correction. The waiver principle cannot be invoked in any other area than specified by regulation.

VI. **Waiver Asterisk(*)** – The footnote pertaining to the marking by asterisk of recommended waivers presumes an understanding that the use of waivers is specifically restricted to the regulatory items. In any event, when the asterisk is used after a deficiency statement, the CMS Regional Office should indicate in the right hand column opposite the deficiency whether or not the recommended waiver has been accepted.

VII. **Signature** – This form should be signed and dated by the provider or supplier representative or the laboratory director. The original, with the facility's proposed corrective action, must be returned to the appropriate surveying agency (SA or RO) within 10 days of receipt. Please maintain a copy for your records.

APPENDIX HS-8

Timeline for 90-Day Termination Track

Applies when the hospital has condition-level deficiencies

Friday, July 1

Last day of survey

↓

Monday, July 18

10 working days past survey (weekends and holidays do not count), CMS sends a warning letter and the CMS-2567 report to the hospital

↓

Thursday, July 28

10 calendar days past survey — Hospital's 2567 response due

↓

Monday, August 15

45 calendar days past survey. If hospital's 2567 makes a credible allegation of compliance, then the State Agency should conduct a resurvey by this date.

↓

If hospital has condition-level deficiencies upon resurvey, it can use this time to submit a second 2567 response. If a credible allegation of compliance is found, CMS may authorize the State Agency to perform a 2nd resurvey.

↓

Friday, September 9

70 calendar days past survey. Official termination notice sent by CMS to the hospital. Public notified. Notice must be sent at least 15 days before termination.

↓

TERMINATION DATE — Thursday, September 29

90 calendar days past survey

APPENDIX HS-9

Timeline for 23-Day Termination Track

Applies when the hospital has not corrected the IJ by the survey conclusion

Last Day of Survey

↓

2nd Working Day

State Agency notifies hospital by overnight mail or fax of immediate jeopardy (IJ) deficiency and that it is recommending termination to CMS, which will issue a formal notice.

↓

5th Working Day

CMS notifies hospital and the public (local newspaper) of impending termination and requests an acceptable PoC.

↓

10th Working Day

CMS-2567 report due to hospital regarding any additional non-IJ deficiencies

↓

Termination will take effect on day 23 unless the hospital has achieved compliance or removed the threat. If the threat has been removed but deficiencies still exist at the condition-level, the hospital will shift to the 90-day termination track.

↓

23rd Calendar Day — Termination

APPENDIX HS-10

Sample Cover Letter for Hospital's CMS-2567 Response (for a CMS survey)

[on hospital letterhead]

[Date]

[Name of CMS official — the CMS cover letter should indicate where the hospital should send its response]

[Title]

[Address]

and

[Name of CDPH official *(if indicated in the CMS cover letter)*]

[Title]

[Address]

Re: [Name of Hospital]

Medicare Provider Number [xx-xxxx]

Dear _____:

Enclosed please find [Name of Hospital]'s responses to the Statement of Deficiencies, Form CMS-2567, that was issued as a result of the CMS survey that ended on [insert survey end date].

In responding to the deficiencies noted, [Name of Hospital] has applied the "credible allegation of compliance" standard that is described in the State Operations Manual. We understand the protocol is that CMS will assess whether [Name of Hospital]'s 2567 responses reflect a credible allegation of compliance sufficient to merit a resurvey to confirm that the corrections were in fact made in a manner that brings the hospital back into compliance with the Medicare Conditions of Participation. [Name of Hospital] has prepared, and has available for review on-site, a compilation of the relevant supporting documentation (policies, forms, monitoring instruments, etc.). Please let us know immediately if some other protocol is expected, or if you have any questions about our submission.

As you will see when you review our submission, much work has been done to respond to each and every finding. [Name of Hospital] has elected not to challenge any of the facts at this time — although this submission should not be viewed as an admission, and the hospital reserves its right to appeal.

On behalf of the many dedicated staff members of [Name of Hospital] who have committed themselves to maintaining [Name of Hospital]'s Medicare certification so that the hospital may

continue to serve Medicare and Medi-Cal patients in our community, we ask that CMS and CDPH use their very best efforts to promptly review our submission, immediately contact us for any clarifications or additional documentation that may be needed, and conduct a resurvey as quickly as possible.

We are available to meet with you, in person or by telephone, to further explain our actions and/or provide any additional information or documentation you may require.

Sincerely,

[CEO Name]

Chief Executive Officer

Enclosures: Form CMS-2567 response

Other attachments as appropriate *(for example, documentation supporting disputed facts)*

APPENDIX HS-11

Definitions of Hospitals Under California Law

General Acute Care Hospital

A "general acute care hospital" is defined in Health and Safety Code Section 1250(a) as:

> a health facility having a duly constituted governing body with overall administrative and professional responsibility and an organized medical staff that provides 24-hour inpatient care, including the following basic services: medical, nursing, surgical, anesthesia, laboratory, radiology, pharmacy, and dietary services. A general acute care hospital may include more than one physical plant maintained and operated on separate premises as provided in Section 1250.8. A general acute care hospital that exclusively provides acute medical rehabilitation center services, including at least physical therapy, occupational therapy, and speech therapy, may provide for the required surgical and anesthesia services through a contract with another acute care hospital. In addition, a general acute care hospital that, on July 1, 1983, provided required surgical and anesthesia services through a contract or agreement with another acute care hospital may continue to provide these surgical and anesthesia services through a contract or agreement with an acute care hospital. The general acute care hospital operated by the State Department of Developmental Services at Agnews Developmental Center may, until June 30, 2007, provide surgery and anesthesia services through a contract or agreement with another acute care hospital. Notwithstanding the requirements of this subdivision, a general acute care hospital operated by the Department of Corrections and Rehabilitation or the Department of Veterans Affairs may provide surgery and anesthesia services during normal weekday working hours, and not provide these services during other hours of the weekday or on weekends or holidays, if the general acute care hospital otherwise meets the requirements of this section.
>
> A "general acute care hospital" includes a "rural general acute care hospital." However, a "rural general acute care hospital" shall not be required by the department [the California Department of Public Health] to provide surgery and anesthesia services. A "rural general acute care hospital" shall meet either of the following conditions:
>
> (1) The hospital meets criteria for designation within peer group six or eight, as defined in the report entitled Hospital Peer Grouping for Efficiency Comparison, dated December 20, 1982.
>
> (2) The hospital meets the criteria for designation within peer group five or seven, as defined in the report entitled Hospital Peer Grouping for Efficiency Comparison, dated December 20, 1982, and has no more than 76 acute care beds and is located in a census dwelling place of 15,000 or less population according to the 1980 federal census.

Acute Psychiatric Hospital

An "acute psychiatric hospital" is defined in Health and Safety Code Section 1250(b) as:

> a health facility having a duly constituted governing body with overall administrative and professional responsibility and an organized medical staff that provides 24-hour inpatient care for persons with mental health disorders or other patients referred to in Division 5

> (commencing with Section 5000) or Division 6 (commencing with Section 6000) of the Welfare and Institutions Code, including the following basic services: medical, nursing, rehabilitative, pharmacy, and dietary services.

Special Hospital

A "special hospital" is defined in Health and Safety Code Section 1250(f) as:

> a health facility having a duly constituted governing body with overall administrative and professional responsibility and an organized medical or dental staff that provides inpatient or outpatient care in dentistry or maternity.

Specialty Hospital

There is no definition in California law for a "specialty" hospital, which is typically a hospital that specializes in cardiac care or orthopaedic care. In California, these hospitals are licensed as general acute care hospitals under Health and Safety Code Section 1250(a). A general acute care hospital is not required to have an emergency department, although most do.

APPENDIX HS-13

FAQs on Writing Hospital Policies and Procedures

What is the purpose of hospital policies and procedures?

Hospital policies and procedures (P&Ps) are tools to guide staff towards accomplishing the hospital's goals, and to ensure compliance with federal and state legal requirements as well as applicable accreditation standards.

What is the difference between a policy and a procedure?

A policy is a written document that guides a particular activity or service by establishing a framework for both management and staff. It is broadly written to address minimum legal requirements and specifies responsibility for action. Given their broad framework, hospital policies are reviewed periodically, but do not typically require substantial changes to remain compliant with current legal requirements.

A procedure, on the other hand, contains more detailed requirements to ensure compliance with the policy. A procedure is a sequence of steps for completing a given activity. A procedure can also outline the manner in which a particular policy should be implemented. Since procedures are more detailed and sequential, they are typically updated and revised more frequently. Hospitals often combine a policy and related procedures into a single document.

Why is it important to critically evaluate hospital P&Ps?

Critically evaluating the need for a hospital P&P, and its content, is important for a number of reasons. First, these documents create hospital-wide standards of care, and establish minimum expectations and responsibilities required for compliance with current law (and accreditation standards). As a written expression of the hospital standard of care, hospital P&Ps can be used in litigation to attack or defend the care or services delivered. Equally important, hospital P&Ps can become, in essence, regulatory requirements: government and accreditation organization surveyors can cite a hospital for failure to follow its P&Ps, even if the steps outlined in the P&P would not otherwise be legally required. When creating a new P&P (or evaluating an existing one), stop and consider if the document should really be a P&P, or if it is an operational objective, departmental goal, or new enterprise or program that does not necessitate a P&P. Limiting the number of P&Ps to those really necessary for compliance with the law and accreditation standards is an important way to manage hospital compliance and risk.

How should a hospital P&P be written?

A hospital P&P should be clear, concise, and easy to understand. It should establish the minimum expectations for a particular activity or service. To the extent possible, hospital P&Ps should be written using the exact wording contained in the regulation or statute, and avoid including any additional requirements or specific responsibilities not required by the law. Keep it practical, and consistent with the essential legal requirements. Above all, it should be written to express the minimum necessary actions required for compliance, as expressed in law.

What are some characteristics of a good hospital P&P?

A good hospital P&P is concise, practical, and able to be performed. It should be written with a critical eye toward implementation and performance. Develop and test the content and wording contained in each hospital P&P, seeking input from clinicians and administrators who are impacted by it, to ensure it is clear, concise, and can be easily understood and implemented, using wording that mirrors the essential legal requirements.

What are some things to avoid in writing a hospital P&P?

Remember, your hospital will be surveyed to ensure that staff is following hospital P&Ps, so the choice of words used is critical. Avoid wording that inadvertently raises the standard of conduct beyond the essential legal requirements. For example, do not use "must" if "may" will suffice. Avoid using specific terms and sequences when the law uses general descriptors or objectives (e.g., do not use the word "physician" when "qualified health care provider" will suffice). Another trap is to insert future requirements or goals into hospital P&Ps. Because hospital P&Ps apply when adopted, make sure the ability to meet them exists when they are adopted. Another trap in writing hospital P&Ps is to include additional information or insert specific requirements that are not legally essential. This additional content should be documented elsewhere, and not in a hospital P&P. Remember, hospital P&Ps effectively become regulatory standards. The lesson here is that hospital P&Ps provide a road map for surveyors to evaluate staff knowledge of the content (less is more), and consistent implementation of legally and self-imposed requirements.

Are there examples of how word choices matter?

Yes, choose words that are consistent with the essence of the legal requirement. If possible, use words and phrases directly from the law. An example of a hospital P&P that went awry, and resulted in a lawsuit and hospital liability, was an emergency department P&P that required every patient to be evaluated by a "triage nurse" and seen by an "emergency physician" prior to discharge. A particular patient that subsequently died was seen by a physician, but he was not a specialist in emergency medicine. The court determined that the hospital was negligent because it didn't follow its own policy, and was therefore liable for the patient's injuries. The lesson here is to choose the words carefully. This hospital may have avoided liability by indicating each patient would be triaged by a "qualified health care professional" and evaluated by a "licensed and credentialed member of the medical staff."

What is an example of a P&P requirement that may be impossible to perform?

A hospital P&P that may be impossible to perform is one that requires the hospital to ensure the performance of actions by a third party. For example, a hospital P&P may state that the hospital shall ensure that each physician on its medical staff provides discharge instructions to the patient prior to discharge. This policy objective is ideal; however, the P&P itself places responsibility directly on the hospital for the action or inaction of third parties (physicians who are not employed by the hospital, and therefore not under its control). The physician may not be the health care professional who reviews the discharge instructions with the patient.

What should a hospital do if it identifies P&Ps that are not required?

If a hospital P&P is not legally required, the hospital should consider withdrawing it or revising it to indicate it is a recommendation for staff, not a mandatory P&P. Remember, a hospital P&P becomes essentially a performance standard of care that it will be surveyed against — and can be used in litigation to sue the hospital for falling below the standard of care.

APPENDIX HS-14

Instructions for Calculating an Administrative Penalty (for non charity care, non privacy breach violations)

Using the attached Scope and Severity Matrix, choose the appropriate initial penalty. Make the following adjustments as applicable:

Initial Penalty Adjustments

1. **Actual patient harm:**

   Increase penalty by **10%** for actual harm to the patient at Severity Level 3 or 5 resulting in a physical or mental impairment that substantially limits one or more of the major life activities of a patient, or the loss of bodily function, if the impairment or loss lasts more than seven days or is still present at the time of discharge from the hospital, or the loss of a body part.

OR

   Increase penalty by **5%** for actual harm to the patient at Severity Level 3 or 5 resulting in a physical or mental impairment that substantially limits one or more of the major life activities of a patient, or the loss of bodily function, if the impairment or loss lasts more than three days.

2. **Financial Harm:** Increase penalty by **1%** for actual financial harm to the patient, based on information acquired by CDPH during the normal course of the investigation.
3. **Beyond the Hospital's Control:** Decrease the penalty by **5%** for factors beyond the hospital's control that restrict the hospital's ability to comply with the requirements of licensure, if the hospital developed and maintained disaster and emergency programs as required by state and federal law that were appropriately implemented during a disaster.
4. **Willful Violation:** Increase the penalty by **10%** if this was a willful violation.

Final Base Penalty Adjustments

5. **Immediate Correction:** Decrease the penalty by **20%** if all of the following can be answered "yes":

a. The noncompliance was an event that the hospital was required to report to CDPH and the hospital self-reported the noncompliance to CDPH before it was identified by CDPH.

b. The hospital identified and immediately corrected the noncompliance before it was identified by CDPH.

c. The noncompliance that was corrected did not constitute immediate jeopardy, or result in the death of a patient.

d. The penalty was not imposed for a repeat deficiency that received a penalty reduction within the prior 12 months.

6. **Single Deficiency in Three Years:** Decrease the penalty by **5%** if this is the only deficiency in the last three years that resulted in patient harm or immediate jeopardy.

7. **Repeat Violations:** Increase the penalty by **5%** if the hospital has had three or more repeated deficiencies that posed a risk of more than minimal harm to patient health or safety within the last three years, including the deficiency that is the subject of this penalty calculation.

Maximum Penalty

8. **Maximum Penalty:** The maximum penalty is $25,000 for a violation not constituting an IJ, $75,000 for a first IJ penalty, $100,000 for a second IJ penalty, $125,000 for a third IJ penalty, and $25,000 for a non-IJ penalty.

CDPH Administrative Penalties: Scope and Severity Matrix

(for non charity care, non privacy breach violations)

	ISOLATED	PATTERN	WIDESPREAD
SEVERITY LEVEL 6 (Immediate jeopardy to patient health or safety, resulting in death)	1st IJ penalty: **$75,000** 2nd IJ penalty: **$100,000** 3rd IJ penalty: **$125,000** (100% of maximum IJ penalty)	1st IJ penalty: **$75,000** 2nd IJ penalty: **$100,000** 3rd IJ penalty: **$125,000** (100% of maximum IJ penalty)	1st IJ penalty: **$75,000** 2nd IJ penalty: **$100,000** 3rd IJ penalty: **$125,000** (100% of maximum IJ penalty)
SEVERITY LEVEL 5 (Immediate jeopardy to patient health or safety, resulting in serious injury)	1st IJ penalty: **$45,000** 2nd IJ penalty: **$60,000** 3rd IJ penalty: **$75,000** (60% of maximum IJ penalty)	1st IJ penalty: **$52,500** 2nd IJ penalty: **$70,000** 3rd IJ penalty: **$87,500** (70% of maximum IJ penalty)	1st IJ penalty: **$60,000** 2nd IJ penalty: **$80,000** 3rd IJ penalty: **$100,000** (80% of maximum IJ penalty)
SEVERITY LEVEL 4 (Immediate jeopardy to patient health or safety, likely to cause serious injury or death)	1st IJ penalty: **$30,000** 2nd IJ penalty: **$40,000** 3rd IJ penalty: **$50,000** (40% of maximum IJ penalty)	1st IJ penalty: **$37,500** 2nd IJ penalty: **$50,000** 3rd IJ penalty: **$62,500** (50% of maximum IJ penalty)	1st IJ penalty: **$45,000** 2nd IJ penalty: **$60,000** 3rd IJ penalty: **$75,000** (60% of maximum IJ penalty)
SEVERITY LEVEL 3 (Actual harm that is not immediate jeopardy)	**$15,000** (60% of $25,000)	**$20,000** (80% of $25,000)	**$25,000** (100% of $25,000)
SEVERITY LEVEL 2 (No actual harm; potential for more than minimal harm, not immediate jeopardy)	**$5,000** (20% of $25,000)	**$12,500** (50% of $25,000)	**$17,500** (70% of $25,000)
SEVERITY LEVEL 1 (No actual harm; potential for no more than minimal harm)	No Penalty	No Penalty	No Penalty
MINOR VIOLATION	No Penalty	No Penalty	No Penalty

Notes:

1 This chart applies to general acute care hospitals (including long term care hospitals (LTCHs) and inpatient rehabilitation facilities (IRFs)) as well as acute psychiatric hospitals. The amount in each cell is the initial penalty; several adjustments will be made by CDPH to determine the final penalty amount. *See "Instructions for Calculating an Administrative Penalty" regarding the adjustments that CDPH may make.*

2 "1st IJ penalty," "2nd IJ penalty," and "3rd IJ penalty" refer to how many penalties the hospital has received in the past. If a hospital goes 3 years without an IJ penalty, the next IJ penalty will be considered the first.

3 A small and rural hospital may request a payment plan and reduction of the penalty if payment would cause financial hardship.

APPENDIX HS-15

Federal vs. State Immediate Jeopardy Definition and Implementation Comparison

State	Federal
Immediate Jeopardy — A situation in which the licensee's noncompliance with one or more requirements of licensure has caused, or is likely to cause, seriuos injury or death to the patient [Health & Safety Code Section 1280.1(c)]	**Immediate Jeopardy** — A situation in which the provider's noncompliance with one or more requirements has caused, or is likely to cause, seriuos injury, harm, impairment, or death to a resident or patient [42 C.F.R. Section 489.3]
	Components of an IJ: ▪ Noncompliance ▪ Actual or likely serious harm ▪ Need for immediate action (SOM Appendix Q)
	Upon recognizing a situation that may constitute an IJ, the investigative process must proceed until it confirms or rules out an IJ. The serious harm, injury, impairment or death may have occurred in the past, may be occurring at present, or may be likely to occur in the future as a result of the jeopardy situation. (SOM Appendix Q)
Based on violation of a state requirement (Title 22 or the Health and Safety Code).	Based on violation of a federal requirement
Use "State IJ guidance for Evaluation to Complete" for to detemine if IJ exists (state surveyor tool).	Use "Federal Critical Path, Does IJ Exist" form (from SOM Appendix Q)
Surveyor does not call an IJ on site, but has a script to read to alert the hospital that the surveyor may have identified an IJ.	Surveyor calls an IJ on site. Threat must be present when surveyor is on-site. Otherwise, it is called "past compliance."