

California Hospital Survey Manual

A Guide to the Licensing and Certification Survey Process

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4th Edition



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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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Information contained in the *California Hospital Survey Manual* should not be construed as legal advice or used to resolve legal problems by health care facilities or practitioners without consulting legal counsel. A health care facility may want to accept all or some of the *California Hospital Survey Manual* as part of its standard operating policy. If so, the hospital or health facility's legal counsel and its board of trustees/directors should review such policies.

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 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/lncfl.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

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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 Medicaid¹ 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.

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