# Outpatient Surgery Services in California:
## Oversight, Transparency, and Quality

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## About the Author

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# Contents

# Introduction

Outpatient settings are settings defined in state law according to the level of anesthesia administered during procedures. Any medical procedures (including surgical procedures) that require general anesthesia or deep sedation, or conscious or moderate sedation, must be performed in an outpatient setting. Patients are required to stay less than 24 hours in the facility. Procedures (including surgical procedures) in which only local anesthesia, peripheral nerve blocks, or antianxiety medication are administered, are not required to take place in an outpatient setting, regardless of the type of procedure performed.

In June 2013, the California HealthCare Foundation (CHCF) published a report[1] highlighting the increased reliance on outpatient, or "same-day" surgery centers, noting the lack of available data about these settings. Unfortunately, little is known about the quality and safety of these facilities, and the fragmented state government oversight of these settings has raised questions about their effectiveness in protecting the public health and safety. Ideally, all outpatient surgery settings, regardless of their category, would be subject to equivalent minimum standards for the provision of equivalent services; publicly available (and comparable) quality data on compliance with minimum requirements as well as quality indicator data; standardized enforcement for violations of minimum standards; and equal accountability for settings and the individual health care practitioners who practice in those settings.

This report provides a close look at the oversight, transparency, and quality of care in California's outpatient surgery settings, and identifies opportunities to benefit the public receiving services in these settings.

State law prohibits an entity from operating, managing, conducting, or maintaining an outpatient setting unless it is one of the settings defined in state law:

- **Medicare-certified ASC.** An ambulatory surgical center that is certified to participate in the Medicare program
- **Tribal clinic.** Any clinic conducted, maintained, or operated by a federally recognized Indian tribe or tribal organization, and located on land recognized as tribal land by the federal government
- **Government-owned clinic.** Any clinic directly conducted, maintained, or operated by the United States or by any of its departments, officers, or agencies (exempt from licensure)
- **Licensed clinic.** Any licensed primary care clinic or surgical clinic
- **IVF clinic.** Any facility that offers in vitro fertilization
- **Hospital-based clinic.** Any health facility licensed as a general acute care hospital
- **Dental-owned clinic.** Any outpatient setting to the extent that it is used by a dentist or physician and surgeon in

compliance with Article 2.7 (commencing with Section 1646) or Article 2.8 (commencing with Section 1647) of Chapter 4 of Division 2 of the Business and Professions Code

- **MBC-accredited clinic.** An outpatient setting accredited by an accreditation agency approved by the Medical Board of California[2]
- **Mobile surgery van.** A mobile van operated by an ambulatory surgery center, primary care clinic, surgical clinic, or hospital.

Outpatient surgery settings are a subset of outpatient settings, as defined in state law. This report focuses only on those outpatient settings in which surgeries are performed. Oversight responsibilities and regulatory requirements for outpatient surgery settings vary greatly. Significant changes in California's oversight of outpatient surgery settings have occurred in recent years which have served to further fragment oversight of these settings. A court decision in 2007 resulted in shifting oversight of over 400 surgery settings from the California Department of Public Health (CDPH) to the Medical Board of California (MBC), with these settings no longer required to submit patient encounter or financial data to the Office of Statewide Health Planning and Development (OSHPD).

As a part of this project, a 50-state environmental scan was conducted to compare California to other states in how oversight is conducted, the public availability of information about providers, and mandates for reporting adverse events or other similar requirements. This information was obtained through a review of state statutes, regulations, and other information that is readily available on state websites. In some instances, state regulatory agencies were contacted to obtain clarification of requirements. The information from the 50-state environmental scan is included in Appendix A.

The only information that Californians and public policy decisionmakers will find available online involves the outpatient surgery settings regulated by the California Medical Board. Consumers can search for a specific outpatient setting, review the text of survey reports, and learn of any sanctions imposed by the accreditation agency.

While nationally recognized professional associations have published some information about the quality of care provided in outpatient settings for their own particular specialties, there have been very few published studies, articles, or analyses about the overall quality of care in outpatient surgery settings. In addition, there is little information about the relative quality and safety of specific outpatient surgical procedures across the categories of settings in which those surgeries are performed.

Quality of care is most often measured by internal facility quality assurance processes, and by information collected by oversight agencies through determining compliance with minimum state, federal, or accreditation standards. Data may be collected by the state and federal government, accreditation organizations, and internal facility quality assurance processes, but this data may not be analyzed in such a way as to reach conclusions about the quality of care, nor is this information readily available to the public. Therefore, it is not possible to reach clear conclusions about the relative quality of care provided across the various categories of outpatient surgical settings.

In order to protect public health and safety, and to provide more information about the health care being provided in outpatient surgery settings, a fresh look at the oversight, transparency, and quality of care across all settings is warranted. Since similar procedures are being performed in multiple categories of settings, the public should have some basic level of confidence that the oversight rigor, enforcement for violations, availability of public information, and quality of care are equivalent. Some of the opportunities will require additional analysis and stakeholder involvement to develop and will take more time than others. However, there is every opportunity to continue making incremental improvements to help safeguard public health and safety.

# Background

## What Are Outpatient Settings / Outpatient Surgery Settings?

Outpatient settings are settings defined in state law according to the level of anesthesia administered during procedures. Any medical procedures (including surgical procedures) that require general anesthesia or deep sedation, or conscious or moderate sedation, must be performed in an outpatient setting, as specified. Procedures (including surgical procedures) in which only local anesthesia, peripheral nerve blocks, or antianxiety medication are administered are not required to take place in an outpatient setting, regardless of the type of procedure performed. In addition to surgical procedures, other invasive procedures must be performed in outpatient settings if the level of anesthesia meets the criteria established in state law. State laws for most categories of outpatient settings prohibit patients from remaining in the facility 24 or more hours.

The level of anesthesia can be linked to the risk inherent in the procedure itself, if community standards of practice are followed. One stakeholder interviewed stated that they have encountered instances where physicians have used a combination of local anesthesia and/or antianxiety medications to perform procedures that traditionally require higher levels of sedation/anesthesia. The stakeholder speculated that this may be a way to circumvent more-extensive regulatory review. The Medical Board of California has stated that it would investigate the individual physician(s) for any such allegations and determine if this is a departure from standard practice.

**OPPORTUNITY 1.** Further clarification may be needed to define that administration of the wrong level of anesthesia (that would normally require sedation/anesthesia that defines an outpatient setting) would be considered a violation of the outpatient setting requirements (i.e., operating an uncertified outpatient setting) and subject to specific sanctions.

## Who Can Operate an Outpatient Setting?

Under California state law,[3] only the following entities can operate, manage, conduct or maintain an outpatient facility:

- An ambulatory surgical center that is certified to participate in the Medicare program
- Any clinic conducted, maintained, or operated by a federally recognized Indian tribe or tribal organization, and located on land recognized as tribal land by the federal government
- Any clinic directly conducted, maintained, or operated by the United States or by any of its departments, officers, or agencies
- Any licensed primary care or surgical clinic
- Any facility that offers in vitro fertilization
- Any health facility licensed as a general acute care hospital
- Any outpatient setting to the extent that it is used by a dentist or physician and surgeon in compliance with Article 2.7 (commencing with Section 1646) or Article 2.8 (commencing with Section 1647) of Chapter 4 of Division 2 of the Business and Professions Code
- An outpatient setting accredited by an accreditation agency approved by the Medical Board of California[4]
- A mobile van operated by an ambulatory surgery center, primary care clinic, surgical clinic, or hospital

Oversight responsibilities and regulatory requirements for outpatient surgery settings vary according to who owns the setting and whether the owners seek Medicare/Medicaid reimbursement. Table 1 provides a high-level summary of state regulatory oversight and number of facilities in each category (settings). (See page 10.)

**Table 1. Setting Categories, Numbers, Oversight, and Designations**

| | NUMBER OF SETTINGS | STATE DEPARTMENT/ BOARD OVERSIGHT RESPONSIBILITY | STATE DESIGNATION REQUIREMENT | FEDERAL CERTIFICATION AS AN ASC TO RECEIVE MEDICARE/MEDI-CAL* | COMMENTS |
|---|---|---|---|---|---|
| **Hospital-Based Outpatient Services** (including surgery services) | Unknown† | California Department of Public Health, Licensing and Certification Program (CDPH) | Optional/supplemental service on hospital license | Hospitals have the option of having their outpatient surgery services federally certified as a hospital service, or certified separately from the hospital though federal certification as an ambulatory surgery center. | According to the most recent reports filed with the Office of Statewide Health Planning and Development (OSHPD), 247 out of 427 hospitals reported to OSHPD that they had an organized surgical program, but 367 of 427 hospitals reported an outpatient surgery to OSHPD. |
| **Surgical Clinics** (not owned by a physician or physician group) | 34 | CDPH | Surgical clinic license‡ | Optional: Federal certification as an ambulatory surgery center (through CDPH or deemed status accreditation). | Four are licensed only, and 30 are licensed and also certified as ASCs. |
| **Ambulatory Surgery Centers (ASCs)** | 740 | CDPH<br>ASCs can also be accredited under the authority of the MBC | May be licensed as a surgery clinic, or outpatient service of a hospital, or operating under a physician, dentist, or podiatrist license | | While 710 are certified-only ASCs, 30 are also licensed as surgical clinics. ASCs may be owned by physicians, dentists, or podiatrists or any other entity that meets federal requirements. ASCs must operate exclusively for the purpose of providing surgical treatment for patients. |
| **Correctional Treatment Center-Based (CTC) Outpatient Surgery Services** | 0 | CDPH | Optional service on CTC license | Not applicable: Health care services provided in a facility owned or operated by a prison or jail are ineligible for Medicare/ Medi-Cal reimbursement. | There are 21 correctional treatment centers licensed in California. Currently, no CTCs have CDPH approval to provide outpatient surgery services. |
| **Other Clinics** | Unknown | CDPH<br>Department of Health Care Services shares oversight of federally qualified health centers (FQHCs) | License as a community/ primary care clinic | State Medicaid Certification only for community clinics<br>Federal Medicare Certification as a rural health clinic or FQHC | The number of clinics that perform procedures that would qualify them as outpatient settings is unknown. There are several other certification categories of clinics including: Community clinics, rural health clinics, and FQHCs. The ownership of these clinics can vary; they can be freestanding, hospital-based, or owned by a health care practitioner. There are approximately 1,200 community/primary care clinics, 250 rural health clinics, and 121 FQHCs. |

*Ambulatory surgery centers (ASC) have two options for becoming Medicare/Medi-Cal certified: certification through a survey conducted by the state survey agency (California Department of Public Health, Licensing and Certification Program) or accreditation by an accreditation organization (AO) that has been approved by CMS, and after receiving CMS approval to have "deemed status." In the case of certification through an AO, the periodic survey is conducted by the AO, but the state survey agency may respond to complaints lodged against a deemed ASC, and may conduct a full or partial certification survey at the request of CMS.

†CDPH cannot easily identify the number of hospitals that provide outpatient surgery services, and the location of those services. CDPH is in the process of reconciling data sources and updating their information systems to be able to retrieve this information.

‡If an outpatient setting that is owned by a health practitioner (physician, dentist, or podiatrist) voluntarily seeks licensure as a surgical clinic, it is not required to seek certification by an accrediting agency approved by the Medical Board of California.

**Table 1. Setting Categories, Numbers, Oversight, and Designations,** *continued*

| | NUMBER OF SETTINGS | STATE DEPARTMENT/ BOARD OVERSIGHT RESPONSIBILITY | STATE DESIGNATION REQUIREMENT | FEDERAL CERTIFICATION AS AN ASC TO RECEIVE MEDICARE/MEDI-CAL* | COMMENTS |
|---|---|---|---|---|---|
| **Outpatient Settings** (regulated by the MBC) | 938§ | Medical Board of California (MBC) | Proof of certification by a board-approved accreditation organization | Settings may choose to be certified as an ASC. | This number includes settings reported to the MBC by accrediting agencies approved by MBC. These settings are wholly or partially owned by physicians, dentists, podiatrists, or other entities that are not otherwise required to be licensed or certified as another category. |
| **Outpatient Settings** (regulated by the DBC) | N/A | Dental Board of California (DBC) for individual anesthesia/sedation permits and the individual practice of dentistry<br><br>MBC for outpatient settings accredited by an accrediting agency approved by MBC or<br><br>CDPH if voluntarily licensed as a surgical clinic or certified as an ASC | Not applicable: Various permits issued to individual dentists, depending on level of anesthesia administered. Dentists who hold permits may practice in their own offices, in addition to outpatient settings regulated by the MBC.<br><br>Certification by an accrediting agency approved by MBC or<br><br>Surgical clinic license | Optional: Federal certification as an ambulatory surgery center (through CDPH or deemed status accreditation) | ***The Dental Board of California does not regulate the settings in which dentists perform surgery.***<br>The DBC requires that *individual* dentists performing surgery obtain a permit based on the level of anesthesia administered. Dentists with permits may have multiple locations in which they perform dental surgeries, and may perform dental surgery in locations owned by other dentists or other licensed facilities or clinics. The dental board does not regulate the settings but rather the individual dentists. However, the board has the discretion to inspect settings owned by permit holders and where dental surgery is performed, but not all locations may be inspected. The board has no authority to inspect settings in which dentists holding oral and maxillofacial surgery permits practice.<br>• 83 oral and maxillofacial surgery permits<br>• 27 elective facial cosmetic surgery permits<br>• 844 general anesthesia permits<br>• 516 conscious sedation permits<br>• 2,425 oral conscious sedation permits |
| **Podiatrist or Podiatry Group-Owned Settings** | N/A | Board of Podiatric Medicine for the individual practice of podiatry<br><br>Medical Board of California for outpatient settings accredited by an accrediting agency approved by MBC or<br><br>CDPH if voluntarily certified as an ASC | Not applicable<br><br>Certification by an accrediting agency approved by MBC | Optional: Federal certification as an ambulatory surgery center (through CDPH or deemed status accreditation) | ***The Board of Podiatric Medicine does not regulate outpatient settings in which podiatrists perform surgery.***<br>Podiatrists may order all anesthetics and sedations. Podiatrists may administer moderate or conscious sedation. *DPMs can perform all surgeries within their scope of practice once sedation/anesthesia is administered.* Section 2472# of the California Business and Professions Code specifies the various peer-reviewed facilities in which ankle surgeries may be performed.<br><br>Podiatrist-owned surgical settings may seek Medicare or Medi-Cal certification as an ASC or may be accredited by an accrediting agency approved by the Medical Board of California. |

*Ambulatory surgery centers (ASC) have two options for becoming Medicare/Medi-Cal certified: certification through a survey conducted by the state survey agency (California Department of Public Health, Licensing and Certification Program) or accreditation by an accreditation organization (AO) that has been approved by CMS, and after receiving CMS approval to have "deemed status." In the case of certification through an AO, the periodic survey is conducted by the AO, but the state survey agency may respond to complaints lodged against a deemed ASC, and may conduct a full or partial certification survey at the request of CMS.

§According to data received from the MBC in September 2014. Note: 82 of the 938 outpatient settings under the authority of the MBC are identified as providing podiatric surgery services, 43 of the 938 outpatient settings are identified as providing oral/maxillofacial surgery, and 6 are identified as providing dental surgery. A certified ASC can also be accredited by an accrediting body approved by the MBC.

#See Appendix C for the text of Business and Professions Code §2472. Information from the Board of Podiatric Medicine 09/30/14.

## What Types of Specialized Services Are Provided in Outpatient Settings?

There is a wide variety of specialty services provided in outpatient settings, such as dental, podiatry, plastic or cosmetic surgery, general surgery, orthopedic, and other specialties. The Medical Board of California tracks the specialty services provided at each outpatient setting location under their authority and posts the information on the board's website for each individual setting. However, the ability to search by specialty type is not easily available to the public and state decisionmakers.[5]

Although the Department of Public Health's Licensing and Certification Program has the authority to approve outpatient services for hospitals, it does not track the specific location or types of outpatient specialty services provided in those settings. Further, although CDPH/L&C has oversight authority of surgical clinics and ambulatory surgery centers, the program does not track the types of outpatient surgical services provided at these locations. This information is particularly important for identifying barriers to providing and promoting community access to care, health care delivery system planning, and for emergency preparedness / disaster response.

**OPPORTUNITY 2.** CDPH/L&C should begin to collect information on the area(s) of specialty services provided at each outpatient setting for which they are responsible, similar to the information related to specialty services collected by MBC. The information collected by both CDPH/L&C and MBC should be publically available online and posted on the hospital or surgical clinic license, if applicable. Information about the specialty services offered at each outpatient setting, hospital outpatient service, surgical clinic, and ambulatory surgery center should be made available online.

### Hospital-Based Outpatient Surgery Services (CDPH)

State licensing regulations do have some limited requirements specific to outpatient surgery services, but this service, like other services, is required to be integrated into the overall hospital system (infection control, medical staff, pharmacy, etc.). There is currently no way to identify those hospitals with approved outpatient surgery services. Further, deficiencies are issued to a hospital as a whole, and it is not possible to easily isolate those deficiencies issued for violations that occur in hospital-based outpatient surgery settings. Therefore, this report will not include compliance or other data covering hospital-based outpatient surgical services.

Hospitals have two ways of certifying their outpatient surgery services for Medicare and/or Medi-Cal: as a part of the hospital or as a whole, the option chosen in the vast majority of cases. Hospitals can also have their outpatient surgery service certified as an ambulatory surgery center (ASC), separate from the hospital's certification.

Hospitals can achieve certification in two ways. The hospital can have a survey conducted by the state survey agency (in California this agency is the California Department of Public Health's Licensing and Certification Program), or it can apply to the federal Centers for Medicare & Medicaid Services (CMS) for deemed status approval for achieving accreditation through an accreditation organization (AO) approved by CMS. Each of the AOs approved by CMS has developed their own standards and protocols for surveying ASC, and these standards have been recognized by CMS as being at least the equivalent of the federal ASC Conditions of Participation (COP) for ASCs.

### Correctional Treatment Center-Based Outpatient Surgery Services (CDPH)

State licensing regulations include standards for CTC outpatient surgery services. Since there are no CTCs with approved outpatient surgical services, this section will not include data covering such services.

The statutes that established correctional treatment centers as a new category of facility has been in statute since the mid-1990s, and the regulations to implement the statute were effective on January 1, 1996. Among many statutory provisions related to CTCs was the option of having outpatient surgery services.

The statutes governing outpatient settings were first established in 1994 and amended over time. These sections of law list the entities that

can operate outpatient settings. Although state regulations provide correctional treatment centers the choice to apply for the optional service of outpatient surgery services, the state law that governs the definition of "outpatient setting" does not list correctional treatment centers as an acceptable setting. Although no CTCs have yet been approved for outpatient surgical services, the omission raises questions about whether CTCs could apply for this optional service and if CDPH has the authority to grant such approvals.

### Surgical Clinics (CDPH)

Surgical clinics are freestanding outpatient settings. Outpatient settings owned by physicians and dentists are exempt from having to be licensed as a surgical clinic.

California surgical clinics have been a licensing category for decades, but no state regulations have been promulgated to establish minimum standards for licensure. CDPH/L&C has historically required surgical clinics to meet federal Medicare requirements for ambulatory surgery centers as a condition of licensure, without specific authority to impose these requirements. This recently changed through department-sponsored legislation to provide the authority for CDPH/L&C to use ASC standards to license surgical clinics.[6] By July 1, 2017, the department is required to hold at least one public hearing and submit a report to the legislature that describes the extent to which the federal requirements are sufficient basis for licensing standards. The department will need to seek legislation to extend the use of the federal requirements prior to January 1, 2018.

### Ambulatory Surgery Centers

The ambulatory surgery center (ASC) is a federal designation for providers seeking Medicare and/or Medi-Cal reimbursement through certification as an ASC. Providers can achieve ASC certification in two ways. The ASC can have a survey conducted by the state survey agency (in California the California Department of Public Health's Licensing and Certification Program) on an exception basis if approved by CMS, or it can apply to the federal Centers for Medicare & Medicaid Services (CMS) for deemed status approval for achieving accreditation through an accreditation organization (AO) approved by CMS.

Each of the AOs approved by CMS has developed its own standards and protocols for surveying ASCs, and these standards have been recognized by CMS as being at least the equivalent of the federal ASC Medicare Conditions of Participation (COP) for ASCs. These standards are different from the standards used for accrediting office-based surgery settings (including those under the authority of MBC).

The federal Medicare Conditions of Participation (COP) set forth minimum standards for facilities to be certified for Medicare and Medi-Cal. Each major COP includes multiple standards. If ASC deficient practices are serious, a COP is found to be not met. Failure to correct deficient practices can lead to termination of certification for Medicare and Medi-Cal. If an ASC with deemed status is found to have a COP not met, the ASC will lose its deemed status and come under the oversight authority of CDPH. A deficiency is written for each violation of federal requirement identified on the survey.

### Other Clinics

Other clinic types may perform procedures that would qualify them as outpatient settings. These include: community/primary care clinics, rural health clinics, and federally qualified health centers. There are approximately 1,200 licensed community/primary care clinics, 250 certified rural health clinics (RHC), and 121 certified federally qualified health centers (FQHC). Some RHCs and FQHCs may be licensed as a part of a hospital, as a community/primary care clinic, or may be owned by a health care practitioner. The number of these other clinics that would meet the definition of an outpatient setting is unknown. Therefore, this report will not include compliance or other data on these settings.

### Outpatient Surgery Settings Under the Authority of the California Medical Board

The California Medical Board regulates outpatient settings that are not otherwise required by law to be licensed or certified as another category of provider (hospital-based outpatient service,

surgical clinic, ambulatory surgical center, primary care clinic, etc.). These outpatient settings can be owned by any entity, not just physicians or medical groups.

Effective January 1, 2012, enhanced oversight authority for outpatient settings was provided to MBC. These standards are different from those used to accredit ASCs. Each of the accrediting agencies has developed its own standards for office-based surgery.

These settings are required to be certified by an accrediting agency approved by MBC.

### Dentist-Owned Surgical Settings

The Dental Board of California issues permits to individual dentists, according to the level of anesthesia/sedation to be administered. The board does not regulate the settings in which dentists perform surgery, but it may conduct an onsite inspection of settings as a part of determining compliance with the terms and conditions of the dentist's permit.

Settings owned by dentists or dental groups may operate independently (in their own offices, with appropriate permits from the board), become accredited by an accrediting agency approved by the Medical Board of California, become certified as an ASC, or have the setting licensed as a surgical clinic.

### Podiatrist-Owned Surgical Settings

The Board of Podiatric Medicine does not regulate outpatient settings. Outpatient surgery settings owned by a podiatrist can be certified as an ASC or by an accrediting agency approved by the Medical Board of California. Podiatrist-owned settings do not have the option of being licensed as a surgical clinic.

## What Do Oversight Through Accreditation, and Deemed Status, Mean?

Accreditation is a process of review that health care organizations participate in to demonstrate their ability to meet predetermined criteria and standards of accreditation established by a professional accrediting agency. The health care organization (in this case, outpatient surgery settings) pays a fee to the accreditation organization (AO) for the costs related to oversight of the setting.

Except for outpatient surgery settings regulated by the Medical Board of California, accreditation is largely voluntary. Some settings may seek to be accredited on a voluntary basis as a quality assurance measure, or to comply with requirements imposed by private insurance payers, including managed care organizations. In addition, some state, federal, or private grants may be tied to accreditation.

Accreditation is also an option for those outpatient surgery settings that seek reimbursement for services provided to Medicare and/or Medi-Cal beneficiaries, by becoming certified as an ambulatory surgery center (ASC). There are two ways to obtain certification as an ASC: through a survey approved on an exception basis by CMS (conducted by the state survey agency CDPH/L&C), or through providing proof of accreditation through a CMS-approved AO. Once accreditation is achieved, the setting owners must seek CMS approval for "deemed status." This means that CMS formally deems that the accreditation standards and process is at least the equivalent of federal Medicare requirements for ambulatory surgery centers. In these cases, the AO conducts the periodic surveys — usually once every three years. Ambulatory surgery centers that are not deemed have the periodic surveys conducted by the state survey agency at an interval set by CMS — now once every four years. However, an outpatient setting can be accredited without requesting deemed status approval from CMS. In these instances, the ASC would be certified by surveys conducted by CDPH.

However, if the state survey agency receives a complaint against an ASC with deemed status, the state will investigate the complaint. If the complaint investigation leads the state to believe that federal Medicare Conditions of Participation are not met, they will submit the information to CMS, Region IX for review. CMS, Region IX may request that the state conduct a "complaint validation survey" to determine if in fact federal

Conditions of Participation are not met. ASCs that have Conditions of Participation not met will have their deemed status (but not necessarily their accreditation) revoked until such time that they can demonstrate compliance with federal Medicare requirements. During the period that deemed status was removed by CMS, the state survey agency has oversight authority over the setting. The AO may also conduct a survey of the ASC and follow their process for determining if the ASC will have their accreditation status revoked or modified.

In addition to responding to certain complaints filed against ASCs, CMS requires the state to survey a sample of ASCs with deemed status, as part of a quality assurance process to determine if the accreditation processes are providing equivalent protections and compliance with federal Medicare regulations. Table 2 illustrates the number of settings that are accredited and the number of outpatient settings regulated by the Medical Board of California that are accredited by an accreditation agency approved by the board. (See page 16.)

## How Has California's Oversight of Outpatient Surgery Settings Changed in Recent Years?

### State Licensure and Oversight

The most significant change in oversight of outpatient surgery settings involves the dramatic changes in surgical clinic licensure.

California law has long provided an exception from licensure for clinics "operated by licensed health care practitioners."

Historically, CDPH/L&C had interpreted the law to require a surgical clinic license if the setting was partially owned (rather than wholly owned) by licensed health care practitioners, or if the owners permitted physicians or dentists outside the practice to perform surgery at the setting. In September 2007, this interpretation was challenged in court by a physician who wanted to permit physicians outside the practice to perform surgical procedures in the clinic. In the case, *Capen vs. Shewry,* the California Court of Appeals held that all ASCs that are owned by a physician or group of physicians are excluded from licensure by CDPH. Based on that ruling, CDPH/L&C issued an All-Facilities Letter to licensed surgical clinics that the department would immediately stop issuing any new surgical clinic licenses for clinics with any degree of physician or dentist ownership. Surgical clinics that had already been issued a license would not have that license renewed. Although state law would appear to give CDPH/L&C the authority to issue licenses to physicians and dentists who voluntarily seek licensure, the department has concluded that the court decision removes any authority to issue such licenses. Previously licensed surgical clinics that were also certified as nonaccredited ASCs continued to be under the oversight of CDPH/L&C. However, approximately 400 previously licensed surgical clinics were no longer under the authority of CDPH.

After that date, physician- or dentist-owned outpatient surgery settings that did not seek Medicare/Medi-Cal reimbursement through certification as an ambulatory surgery center were operating solely under their individual owner/practitioner license, under the authority of their respective licensing board. A period of uncertainty resulted, as some practitioners who sought the option to be licensed as surgical clinics reported having their requests denied. Practitioners were also concerned about being out of compliance with state pharmacy rules that required licensure.[7]

As noted in a recent California HealthCare Foundation publication, these outpatient surgery settings that were previously licensed as surgical clinics no longer had to report patient encounter data or financial data to the Office of Statewide Health Planning and Development.[8] This resulted in a significant decrease in the information publicly available about patient outcomes, the types of procedures performed, payment for procedures, and other important utilization data. This information is essential to state decisionmakers and stakeholders for identifying the number and nature of care provided by this major segment of the health care delivery system in California.

**OPPORTUNITY 3.** Consideration should be given to amending state law to require ASCs (regulated by CDPH/L&C) and outpatient surgery

**Table 2. Accreditation Organizations (AOs) Operating in California, by Setting Category**

| | HOSPITAL-BASED OUTPATIENT SURGERY SERVICES* (CDPH/L&C) | SURGICAL CLINICS (CDPH/L&C) | ASCs (CDPH/L&C) | OUTPATIENT SURGERY SETTINGS† (MBC) | COMMENTS |
|---|---|---|---|---|---|
| **American Association for Ambulatory Health Care (AAAHC)** | Unknown | 8‡ | 187§ | 241 | |
| **American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF)** | Not applicable# | 0 | 68 | 255 | |
| **American Osteopathic Association/ Health Facilities Accreditation Program (AOA/HFAP)** | Unknown | 0 | 4 | 0 | At the time the data was provided, the AOA/HFAP was not an approved agency. AOA/HFAP has subsequently received MBC approval. |
| **Center for Improvement in Healthcare Quality (CIHQ)** | Unknown | Not applicable | Not applicable | Not applicable | CIHQ is an approved AO for hospitals and hospital-based services only. |
| **Det Norske Veritas Healthcare (DNV)** | Unknown | Not applicable | Not applicable | Not applicable | DNV is an approved AO for hospitals and critical access hospitals only and hospital-based services. |
| **California Medical Association (CMA)/ Institute for Medical Quality (IMQ)** | Not applicable | Not applicable | Not applicable | 123 | The CMA/IMQ is in the process of seeking CMS approval to become an approved accreditation organization for deemed status purposes for ASCs, now that they provide accreditation services in multiple states. |
| **Joint Commission (JC)** | Unknown | 5 | 81** | 87 | The Joint Commission is an approved AO for both ASCs and hospital-based servics |
| **Not Accredited/Deemed** | Unknown | 25 | 400†† | Not applicable | Outpatient surgery settings that are not certified as an ASC must be accredited by an accrediting agency approved by MBC. |
| **Totals** | **Unknown** | **12** | **740** | **706‡‡** | |

Note: Outpatient surgery services of correctional treatment centers are not included in this table.

*The entire hospital would be accredited. CDPH cannot easily identify hospitals with approved outpatient surgery services. Therefore, data that links the AO to hospitals with outpatient surgery services is not included.

†Data received from MBC in December 2013. The total number of OSSs under the authority of the board has increased to 938 settings according to data received from the board in September 2014. However, the more recent data does not include information on the accrediting agency because it was obtained for another purpose.

‡Four of the eight surgical clinics accredited by the AAAHC are also certified as ASCs.

§Four of the 187 ASCs accredited by the AAAHC are also licensed surgical clinics.

#"Not applicable" means that the AO has not been approved, or does not conduct accreditation for, a specific category/setting.

**Five of the 81 ASCs accredited by the Joint Commission are also licensed surgical clinics.

††Twenty-one of the 400 ASCs that are not accredited are also licensed surgical clinics.

‡‡The total number of OSSs regulated by the Medical Board of California has increased to 938 settings based on data received September 2014. The more recent data did not identify the accreditation agency for each setting, because the data was requested for another purpose.

settings regulated by MBC, to submit annual utilization reports to the Office of Statewide Health Planning and Development.

In 2011, legislation was introduced to address concerns about the lack of effective regulation of outpatient surgery settings that were not regulated by CDPH. Effective January 1, 2012, a new law took effect that clarified and enhanced the Medical Board of California's authority to regulate outpatient settings.[9]

Except for the pharmacies and related entities licensed by the California State Board of Pharmacy, the Medical Board of California is the only health care practitioner licensing board that is responsible for the accreditation of settings, in addition to their core responsibilities related to individual professional licensure.

Outpatient settings regulated by MBC may be owned/operated by nonphysician practitioners (such as podiatrists or dentists), or any other entity that meets accreditation standards. Although 12 other state medical boards regulate outpatient surgery settings, California is the only state where the medical board also regulates settings owned by nonphysicians.

This fragmentation of oversight responsibilities continues to give rise to stakeholder questions about the extent to which the regulation of any outpatient settings should continue under authority of the Medical Board of California. All other outpatient settings are regulated by CDPH/L&C.

**OPPORTUNITY 4.** A re-evaluation of the decision to place oversight of outpatient settings under MBC may be in order, with consideration given to consolidating the oversight authority for all settings under CDPH/L&C.

Having different agencies with responsibility for settings of care performing similar kinds of services creates a potential communications disconnect. While the majority of regulatory responsibilities for outpatient surgery settings rest with the California Department of Public Health, the Medical Board of California has responsibility for one sizeable category of outpatient setting. Regulation of other individual practitioners rests with each licensing board. During the course of their respective investigations or surveys, the boards or CDPH may encounter deficient practices that affect the health and safety of patients.

Although there may be informal mechanisms for referring information to the appropriate licensing board or state department, there are no formal interagency agreements in place that outline the circumstances under which investigative findings should be shared, or for tracking such referrals. Investigative facts that intersect both the settings and the practitioners should be shared to promote full accountability.

**OPPORTUNITY 5.** Consideration should be given to establishing formal interagency agreements or memoranda of understanding between CDPH/L&C and the various licensing boards and bureaus, outlining the circumstances under which investigation findings should be shared between state agencies. Criteria for referral should be developed, and clear statutory authority to share this information should be granted, if needed.

## Timeliness of ASC Complaint Investigations

Effective oversight depends on the CDPH's ability to respond to complaints and/or facility-reported events in a timely fashion. Failure to do so significantly increases the opportunity for substandard settings to continue performing surgeries, and jeopardizes patient health and safety.

CDPH/L&C has struggled for years to have sufficient seasoned staff to complete the workload required under state law, plus the terms and conditions of the federal grant from CMS. Survey competency in specialty surveys can take two to three years. The extent to which having insufficient seasoned staff has affected the timeliness of investigations of complaints or facility-reported events is outside the purview of this report. In addition, CDPH is competing with the private sector when hiring nurse surveyors and other specialty clinical consultants (physicians, registered dieticians, pharmacists, medical records technicians). Having a seasoned, stable workforce is essential to conducting adequate oversight of health care settings.

Table 3 illustrates the average lag time between the receipt of a complaint or facility-reported event

**Table 3. Average Lag Time for Completion of Investigations**

| YEAR OF INTAKE RECEIPT | AVERAGE LAG TIME BETWEEN RECEIPT OF COMPLAINT AND INVESTIGATION... START DATE (IN DAYS) | CLOSE DATE (IN DAYS) |
|---|---|---|
| 2009 | 97.0 | 379.8 |
| 2010 | 122.7 | 323.7 |
| 2011 | 45.1 | 244.4 |
| 2012 | 55.4 | 146.4 |
| 2013 | 34.5 | 78.8 |
| Average for All Years | 71.3 | 237.6 |

Note: These data do not include complaints or facility-reported events that had a zero value in the fields.

and the date that the investigation is closed in the information system, regardless of the priority of the event. CDPH/L&C has a policy of prioritizing investigations based on the nature of the allegations. The overall lag time between receipt of an allegation and the start date of the investigation has clearly improved over recent years. Some of the lapsed time for closing out the allegations may be due to delays in data entry.

## Changes in the Federal Medicare Rules for Ambulatory Surgery Centers

In 2008, an outbreak of hepatitis C in Nevada was traced to poor infection control practices in two ASCs. The State of Nevada and federal epidemiologists identified a cluster of hepatitis C virus (HCV) infections where the infected individuals all had procedures in the same ASC. Subsequent surveys of that ASC identified unsafe injection practices related to the reuse of syringes and multiple reuse, among multiple patients, of single-use anesthesia medication vials.[10] Over 50,000 former patients had to be notified of potential exposure to hepatitis C and other infectious diseases, and reportedly over 100 people developed hepatitis C as a result of their exposure in the ASCs. Subsequent inspections of 28 Nevada ASCs for compliance with Medicare standards revealed that 64% had serious problems, primarily in infection control.

Noting the jeopardy to patient health and safety evidenced by the Nevada ASC and other prior years' problems with infection control practices in various other states, CMS responded with a three-fold strategy. CMS dramatically revised the Medicare Conditions of Participation/Coverage, provided additional guidance on interpretation of federal requirements,[11] and tested a new survey protocol to better focus surveyor scrutiny on ASC systems of care.

In response to these incidents, CMS implemented a pilot project in three states[12] to test a new survey protocol and tracer methodology (where surveyors follow a patient through the entire course of their ASC procedures) to improve the oversight of infection control practices in ASCs. The pilot project consisted of sample surveys of the three states' 68 ASCs. Nineteen percent of the sampled ASCs had condition levels not met, and 85% had standard level deficiencies, mostly related to infection control practices. Among the common deficient practices in the pilot were ASC use of single-dose vials of medication for multiple patients, improper sterilization practices (such as routine use of flash sterilization), general disinfection and sanitation problems, and failure to have any system for reporting notifiable diseases to their respective state health agency.[13]

As a result of the pilot project, the workload priority and frequency of state survey agency periodic surveys of ASCs without deemed status was increased. States had the option of using the new survey protocol in 2009 (and be eligible for immediate enhanced federal funding) but were required to implement the new survey protocol by no later than 2010.

In addition, accreditation organizations (approved by CMS) modified their ASC standards, and provided updated training to their surveyors, to reflect these changes in federal requirements.

# Quality of Care in Outpatient Surgery Settings

THE IDEAL WAY TO ENSURE QUALITY OF care is to have internal quality assurance processes within each individual setting, and to have some external way of measuring quality of care across settings, for similar procedures. If each provider is vigilant in benchmarking/tracking quality indicators and is engaged in continuous efforts to improve patient outcomes, patient health and safety will be better protected. State licensing, federal certification, and accreditation standards all require some level of internal quality assurance.

However, from an external perspective, quality of care is most often measured through determining compliance with minimum state, federal, or accreditation standards. Compliance is determined through periodic surveys or complaint investigations. Data on compliance trends is collected by the state and federal government and accreditation organizations, but there is very little data or analysis that is routinely made available to the public about the quality of care in outpatient surgery settings. Further, the data collected by external entities varies greatly, and quality comparisons across all setting categories for the same procedures are not possible at the current time.

Other mechanisms for measuring quality may include research studies or quality indicators. However, there have been very few published studies, articles, or analysis about the quality of care in outpatient surgery settings readily available to the public. One area of agreement in the limited published studies is that increased volumes of specific procedures can minimize negative patient outcomes. In other words, the more a particular outpatient setting performs a procedure, the more proficient in performing the procedure the practitioners become. This is consistent with other studies and practices for other types of surgical procedures (even those performed in inpatient settings). Indeed, some state and federal standards require minimum numbers of procedure as a condition of qualifying to perform those procedures.

While each of these methods of measuring quality of care has benefits, they are often under the oversight authority of different agencies or organizations (both public and private). The available information maintained or collected by these agencies differs greatly. Therefore, it is difficult to reach overall conclusions about the relative quality of care provided across all categories of outpatient surgical settings, in general or for specific procedures.

## What Does Published Research Contribute to Our Understanding About Quality of Care?

### Professional Associations and Journals

Outpatient surgery settings often specialize in the types of surgical or other treatments provided. Professional associations for those specialties have published articles about patient outcomes in outpatient surgery settings. These may identify the most common types of negative patient outcomes (mortality, morbidity, etc.) for those specialty procedures.

For example, one study conducted using data from office-based outpatient surgery centers (not ambulatory surgery centers) that were accredited by, and reporting data through, the American Association for Accredition of Ambulatory Surgery Facilities (AAAASF) reached several conclusions.[14] These included that out of a total of 411,670 procedures analyzed during a two-year period (2001-2002), there were 2,597 sequelae reported during that time (1,378 of which were significant); infection occurred in 388 cases; significant complications were infrequent; there was one unanticipated sequela per 299 procedures (incidence of 0.33%); seven deaths were reported (one in every 58,810 procedures); and the overall risk of death was comparable whether the procedure was performed in an AAAASF-accredited office surgery facility or in a hospital surgery facility.

A subsequent report based on AAAASF data collected from January 2001 to June 2006 was issued in 2008.[15] This article reported that, out of 1,141,418 procedures performed during that timeframe, there were 23 deaths. The leading cause of those deaths (13 of the 23) was pulmonary embolism. One death occurred as a result of an intraoperative adverse event. Three of the deaths were related to pain medication overdose in the first few days after surgery. The most common procedure that resulted in the pulmonary embolism was associated with abdominoplasty (commonly referred to as a "tummy tuck"). The article concluded that the frequency of pulmonary embolism warrants further study to determine predisposing factors, understanding its cause, and introducing guidelines to prevent its occurrence. The next most common procedure resulting in a pulmonary embolism was a facelift. The article noted that 9 of the 12 deaths associated with an abdominoplasty involved one or more additional procedures. Four of the abdominoplasty patients who died had liposuction as one of the other procedures. The article noted that a pulmonary embolism may occur following any procedure, whether performed in a hospital, an ambulatory surgery center, or a physician's office-based surgery facility. The article noted that "safe surgical practice in the outpatient setting has been difficult to evaluate because of the variable methods of collecting data." Also noted was that death rates for procedures performed on Medicare-age patients have been reported to be as high as 23 per 100,000 when reviewing procedures performed in outpatient settings in hospitals, ambulatory surgery centers, and office-based facilities.

Other articles:

- Compared hospital-based outpatient surgery with surgery performed in ambulatory surgery centers. These concluded that neither performed better overall, but that there was some difference by procedure that varied based on the risk-adjusted approach.[16]
- Examined the extent to which physician and patient volumes of ambulatory procedures was linked to improved patient outcomes. This article[17] concluded that patients treated by high-volume physicians or facilities had lower adjusted odds ratios for subsequent hospitalizations and mortality.
- Compared the quality of care in accredited and nonaccredited ambulatory surgical centers. This article[18] analyzed patient discharge data from Florida for 2004. It looked at the most common ambulatory surgical procedures: colonoscopy, cataract removal, upper gastroendoscopy, arthroscopy, and prostate biopsy. The study concluded that patients at Joint Commission-accredited facilities were significantly less likely to be hospitalized after colonoscopy (10.9% less likely to be hospitalized within 7 days of the procedure and 9.4% less likely to be hospitalized within 30 days after the procedure). No other difference in unexpected hospitalization rates were detected in the other procedures examined.
- Examined the potential associations among ASCs' organizational strategy, structure, and quality performance using several large-scale, all-payer claims datasets for 1997 to 2004. The findings[19] suggest that higher levels of specialization and the volume of procedures may be associated with a decrease in unplanned hospitalizations at ASCs.

## How Do Private Entities Promote Quality of Care?

Many private associations or accreditation organizations promote quality of care in outpatient surgery settings, in a variety of ways. Private associations may promote quality guidelines for facility-level quality measurement to their membership. Associations may also have professional journals through which articles or studies related to quality of care and best practices are shared. Accreditation organizations all track individual and aggregate patterns of compliance for those outpatient settings, as a result of periodic accreditation surveys, investigation of complaints/sentinel events, and (in one case) mandatory reporting of unanticipated patient outcomes.

### Professional Associations

There are many professional associations, at both national and statewide levels. Many of the association memberships are based on the type of specialty services provided (cosmetic surgery, plastic/reconstructive surgery, etc.). Each of these organizations shares research, guidelines, and best practices in promoting quality of care.

At the national level, a cooperative effort of organizations and companies was formed in early 2006: the ASC Quality Collaboration (ASC QC). This collaborative effort initiated a process to develop standardized ASC quality measures. The ASC QC surveyed measures and standards for several organizations, and publishes the *ASC Quality Measures: Implementation Guide* to help ASCs implement and collect data for six National Quality Forum-endorsed facility-level quality measures it has developed.

One California-based association, the California Ambulatory Surgery Association (CASA), shared examples of member quality assessment and performance improvement benchmarking to illustrate best practices in individual facility, internal quality assurance processes.

### Accreditation Organizations

While all accreditation organizations track individual and aggregate patterns of deficient practices as a result of periodic accreditation surveys or complaint/sentinel event investigations, only the American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF) has developed an Internet-based quality improvement and peer review program to analyze outcomes for surgery centers (whether office-based surgery facilities or ambulatory surgery centers). Reporting is mandatory for all surgeons operating in AAAASF-accredited facilities. All surgeons must report all unanticipated sequelae and at least six random cases reviewed by an accepted peer review group biannually.

## What Can Compliance with Minimum Standards Tell Us About Quality of Care?

California state laws and regulations set forth minimum standards for becoming licensed or certified (hospital-based surgery centers and some clinics), and federal laws and regulations set forth minimum standards for becoming certified for Medicare and/or Medicaid reimbursement (ASCs or hospital-based).

Compliance with these minimum standards is measured upon initial licensure or certification, and periodically thereafter. Periodic surveys of nonaccredited ASCs are conducted once every four years, and surveys of ASCs with deemed status and outpatient settings regulated by MBC are conducted once every three years. Any violations of these standards resulted in the regulatory entity issuing a deficiency and requiring the setting to submit a plan of correction that details how they will come back into compliance and prevent future violations from occurring.

State, federal, and accreditation standards all require some form of internal quality assurance process. For instance:

- Ambulatory surgery centers (ASC) have an ongoing quality assessment and performance improvement (QAPI) program in place to get at the core of quality of care. Failure to comply with this condition of participation can lead to loss of deemed status, or termination of certification, if the violation is not corrected.
- The QAPI program can track issues such as infection rates, length of stay, readmission rates, risk-adjusted mortality rates, complication rate, transfers to hospitals, and other important performance measures that have a direct impact on patient health and safety. Since licensed surgical clinics must meet ASC standards, surgical clinics are also required to have QAPI programs.

This requires the ASC to:

- Demonstrate improvement in patient health outcomes, and improve patient safety by using quality indicators or performance measures associated with improved health outcomes and by identifying and reducing medical errors.
- Measure, analyze, and track quality indicators, adverse patient events, infection control, and

other aspects of performance that include care and services furnished in the ASC.

- Set priorities for its performance improvement activities that focus on high-risk, high-volume, and problem-prone areas; consider the incidence, prevalence, and severity of problems in those areas; and affect health outcomes, patient safety, and quality of care.

All accreditation organizations require that a quality assurance process is in place, whether the accreditation is for an office-based setting or for accreditation of ASCs for deemed status. The American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF) is the only AO to require settings to report quality indicator data. This data must be submitted to AAAASF quarterly. This information is considered proprietary and is not available to the public.

California state licensing laws and federal Medicare requirements also require some quality assurance/performance improvement processes for hospitals (including outpatient surgery services).

## What Data Is Available on Compliance with Minimum Standards?

The following sections provide information on available data related to compliance with state, federal, and/or accreditation standards. These data includes the number and nature of complaints filed against entities and facility-reported events filed by entities, deficiencies resulting from complaint and facility-reported investigations, and from periodic surveys.

**Hospital-based outpatient surgery services.** Since deficiencies identified in hospital outpatient surgery services are not easily discernible from deficiencies issued to the hospital as a whole, this section does not include data on hospital-based outpatient surgery services. Licensing surveys and certification surveys for nonaccredited hospitals are public information. Copies of these surveys are not available online but are available through viewing the hospital file in the district office or by submitting a Public Records Act request. Copies of accreditation surveys of hospitals with deemed status are not public information.

**Surgical clinics.** Information and data on deficiencies issued to surgical clinics are integrated with the data for ambulatory surgery centers, unless otherwise noted. Copies of the survey reports are public information but are not available online.

**Ambulatory surgery centers.** Detail about compliance and quality of care is most available for ambulatory surgery centers without deemed status under the oversight of CDPH/L&C. No information is publicly available about deficiency patterns identified by accreditation organizations for accredited ASCs with deemed status. However, to the extent that ASCs with deemed status have been surveyed by CDPH/L&C as a result of a complaint investigation or sample validation survey, those deficiencies are included in this report, unless otherwise noted. Information was obtained from both CMS Region IX and CDPH. Survey reports on nonaccredited ASCs are public information but not available online. Survey reports prepared by accreditation organizations for ASCs with deemed status are not public information.

**Medical Board of California-regulated outpatient settings.** Although the survey reports issued by the accrediting agencies are available online for each setting, there is no data readily available to identify deficient practice trends identified in these settings. Accrediting agencies track deficiencies issued as a result of violation of accreditation standards, but an analysis of deficiencies identified is not available. However, MBC has provided information on the numbers of settings that have had their accreditation certification revoked, suspended, or placed on probation. Survey reports prepared by accreditation agencies are public information and are posted at each setting and online (by specific settings). In addition, if the accreditation status of a particular setting is revoked or suspended, this information will also be posted online.

**Dental Board of California-regulated outpatient settings.** As previously discussed, DBC does not regulate outpatient surgery settings. DBC does have the authority to conduct onsite inspections of dental office-based sites in which dentists perform surgery, as a part of verifying compliance with requirements to hold a permit.

These inspection reports are not available to the public, nor are any data about the types of findings resulting from these inspections.

**Board of Podiatric Medicine.** Not applicable, as the board does not regulate settings or inspect the sites at which podiatrists practice podiatric surgery. Inspections/surveys of those sites at which podiatrists practice are under the authority of other state regulatory agencies.

## ASC/Surgical Clinic Complaints and Facility-Reported Events

From 2009 through 2013, there were 222 complaints and/or facility-reported events filed with CDPH/L&C.[20] The scope of these investigations focus on the allegations or issue involved with the facility-reported event, although the surveyors may also cite other deficient practices if identified during the course of the investigation. Of this number, 36 were ASCs that were also licensed as surgical clinics; the remainder were filed against or by certified-only ASCs.

**Table 4. Complaints/Facility-Reported Events Received**

| CALENDAR YEAR OF INTAKE RECEIPT | NUMBER OF COMPLAINTS |
|---|---|
| 2009 | 42 |
| 2010 | 44 |
| 2011 | 40 |
| 2012 | 42 |
| 2013 | 54 |

**Table 5. Intake Allegations/Facility-Reported Events**

| CATEGORY | 2009 | 2010 | 2011 | 2012 | 2013 | TOTAL |
|---|---|---|---|---|---|---|
| Quality of Care/ Treatment | 19 | 21 | 15 | 16 | 27 | **98** |
| Infection Control | 7 | 10 | 5 | 6 | 10 | **38** |
| Resident/Patient/ Client Rights | 4 | 3 | 6 | 9 | 2 | **24** |
| Physical Environment | 4 | 1 | 2 | 2 | 3 | **12** |
| Fraud/False Billing | 0 | 1 | 1 | 4 | 1 | **7** |
| Administration/ Personnel | 1 | 2 | 2 | 2 | 0 | **7** |
| State Monitoring | 0 | 1 | 0 | 1 | 4 | **6** |
| Physician Services | 1 | 0 | 2 | 1 | 0 | **4** |
| Nursing Services | 1 | 2 | 1 | 0 | 0 | **4** |
| Other | 0 | 0 | 1 | 0 | 2 | **3** |
| Resident/Patient/ Client Assessment | 0 | 0 | 2 | 0 | 1 | **3** |
| Unqualified Personnel | 3 | 0 | 0 | 0 | 0 | **3** |
| Admission, Transfer, and Discharge Rights | 0 | 0 | 1 | 0 | 1 | **2** |
| Other Services | 1 | 1 | 0 | 0 | 0 | **2** |
| Resident/Patient/ Client Abuse | 0 | 0 | 1 | 0 | 1 | **2** |
| Pharmaceutical Services | 0 | 1 | 0 | 0 | 1 | **2** |
| Death — General | 0 | 0 | 1 | 0 | 0 | **1** |
| Resident/Patient/ Client Neglect | 0 | 0 | 0 | 1 | 0 | **1** |
| Falsification of Records/Reports | 0 | 0 | 0 | 0 | 1 | **1** |
| Life Safety Code | 1 | 0 | 0 | 0 | 0 | **1** |
| State Licensure | 0 | 1 | 0 | 0 | 0 | **1** |
| Dental Services | 0 | 0 | 0 | 0 | 0 | **0** |

**Table 6. Allegations with Violation Substantiated**

| YEAR OF INTAKE RECEIPT | SUBSTANTIATED (UNSUBSTANTIATED) | BLANK |
|---|---|---|
| 2009 | 17 (15) | 10 |
| 2010 | 14 (17) | 13 |
| 2011 | 8 (15) | 17 |
| 2012 | 14 (17) | 11 |
| 2013 | 13 (19) | 22 |

Note: "Blank" means that there was no value entered in the data provided to identify whether an allegation resulted in a violation being substantiated or not.

As a result of these investigations, there were 261 deficiencies issued. (See Tables 7 and 8.)

**Table 7. Violations Identified as a Result of a Complaint**

| CATEGORY | 2009 | 2010 | 2011 | 2012 | 2013 | TOTAL |
|---|---|---|---|---|---|---|
| Sanitary Environment | 3 | 4 | 3 | 0 | 4 | **14** |
| Form and Content of Record | 3 | 5 | 1 | 1 | 3 | **13** |
| Administration of Drugs | 4 | 2 | 2 | 1 | 3 | **12** |
| Governing Body and Management | 2 | 4 | 3 | 0 | 0 | **9** |
| Organization and Staffing | 2 | 2 | 1 | 2 | 2 | **9** |
| Anesthetic Risk and Evaluation | 3 | 2 | 1 | 2 | 0 | **8** |
| Physical Environment | 2 | 4 | 1 | 0 | 1 | **8** |
| Admission Assessment | 1 | 3 | 1 | 1 | 2 | **8** |
| Infection Control Program | 1 | 3 | 1 | 0 | 2 | **7** |
| Pre-Surgical Assessment | 1 | 3 | 3 | 0 | 0 | **7** |

| CATEGORY | 2009 | 2010 | 2011 | 2012 | 2013 | TOTAL |
|---|---|---|---|---|---|---|
| Environment | 2 | 2 | 1 | 0 | 0 | **5** |
| Membership and Clinical Privileges | 3 | 1 | 1 | 0 | 0 | **5** |
| Infection Control | 1 | 1 | 2 | 0 | 1 | **5** |
| Surgical Services | 1 | 2 | 1 | 0 | 0 | **4** |
| Governing Body Responsibilities | 1 | 1 | 1 | 0 | 1 | **4** |
| Notice – Posting | 0 | 2 | 1 | 0 | 1 | **4** |
| Advance Directives | 0 | 2 | 1 | 0 | 1 | **4** |
| Post-Surgical Assessment | 0 | 2 | 1 | 0 | 1 | **4** |
| Discharge – Order | 1 | 2 | 1 | 0 | 0 | **4** |
| Physical Environment | 3 | 0 | 0 | 0 | 0 | **3** |
| Reappraisals | 2 | 0 | 1 | 0 | 0 | **3** |
| Disaster Preparedness Plan | 0 | 1 | 2 | 0 | 0 | **3** |
| Anesthetic – Discharge | 1 | 0 | 2 | 0 | 0 | **3** |
| Quality Assessment and Performance Improvement | 1 | 1 | 1 | 0 | 0 | **3** |
| Program Data, Program Activities | 1 | 1 | 0 | 0 | 1 | **3** |
| Nursing Services | 1 | 0 | 2 | 0 | 0 | **3** |
| Medical Records | 1 | 0 | 0 | 1 | 1 | **3** |
| Organization | 1 | 0 | 1 | 0 | 1 | **3** |
| Pharmaceutical Services | 1 | 1 | 1 | 0 | 0 | **3** |
| Notice of Rights | 0 | 2 | 0 | 0 | 1 | **3** |
| Infection Control Program – Responsibilities | 1 | 0 | 2 | 0 | 0 | **3** |

| CATEGORY | 2009 | 2010 | 2011 | 2012 | 2013 | TOTAL |
|---|---|---|---|---|---|---|
| Patient Admission, Assessment, and Discharge | 0 | 2 | 0 | 0 | 1 | **3** |
| Admission Assessment – Record | 0 | 2 | 0 | 0 | 1 | **3** |
| Other Practitioners | 2 | 0 | 0 | 0 | 0 | **2** |
| Laboratory and Radiologic Services | 2 | 0 | 0 | 0 | 0 | **2** |
| Contract Services | 0 | 1 | 1 | 0 | 0 | **2** |
| Administration of Anesthesia | 0 | 2 | 0 | 0 | 0 | **2** |
| Program Scope, Program Activities | 0 | 0 | 1 | 0 | 1 | **2** |
| Identification, Prevention, and Maintenance | 1 | 1 | 0 | 0 | 0 | **2** |
| Verbal Orders | 1 | 0 | 0 | 0 | 1 | **2** |
| Laboratory Services | 1 | 0 | 1 | 0 | 0 | **2** |
| Radiologic Services | 2 | 0 | 0 | 0 | 0 | **2** |
| Submission and Investigation of Grievances | 0 | 1 | 0 | 0 | 1 | **2** |
| Safety – Abuse/ Harassment | 0 | 0 | 1 | 1 | 0 | **2** |
| Infection Control Program – Direction | 1 | 0 | 1 | 0 | 0 | **2** |
| Infection Control Program – QAPI | 1 | 0 | 1 | 0 | 0 | **2** |
| Life Safety Code Standard | 2 | 0 | 0 | 0 | 0 | **2** |
| Health and Safety Code 1280 | 0 | 0 | 0 | 0 | 1 | **1** |
| Evaluation of Quality | 1 | 0 | 0 | 0 | 0 | **1** |
| Safety from Fire | 1 | 0 | 0 | 0 | 0 | **1** |

| CATEGORY | 2009 | 2010 | 2011 | 2012 | 2013 | TOTAL |
|---|---|---|---|---|---|---|
| Definitions | 0 | 1 | 0 | 0 | 0 | **1** |
| Hospitalization | 1 | 0 | 0 | 0 | 0 | **1** |
| Performance Improvement Projects | 0 | 1 | 0 | 0 | 0 | **1** |
| Emergency Personnel | 0 | 1 | 0 | 0 | 0 | **1** |
| Medical Staff | 1 | 0 | 0 | 0 | 0 | **1** |
| Patient Rights | 0 | 0 | 1 | 0 | 0 | **1** |
| Notice – Physician Ownership | 0 | 0 | 1 | 0 | 0 | **1** |
| Grievances – Mistreatment, Abuse, Neglect | 0 | 0 | 1 | 0 | 0 | **1** |
| Exercise of Rights – Grievances | 0 | 0 | 0 | 1 | 0 | **1** |
| Exercise of Rights – Informed Consent | 0 | 0 | 0 | 0 | 1 | **1** |
| Confidentiality of Clinical Records | 0 | 1 | 0 | 0 | 0 | **1** |
| Discharge with Responsible Adult | 0 | 1 | 0 | 0 | 0 | **1** |
| Quality Assessment and Performance | 0 | 0 | 0 | 0 | 1 | **1** |
| Grievances – Mistreatment, Abuse | 0 | 0 | 0 | 0 | 1 | **1** |
| Emergency Equipment | 0 | 0 | 0 | 0 | 0 | **0** |
| Safety | 0 | 0 | 0 | 0 | 0 | **0** |

**Table 8. Violations Identified as a Result of a Facility-Reported Event**

| CATEGORY | 2009 | 2010 | 2011 | 2012 | 2013 | TOTAL |
|---|---|---|---|---|---|---|
| Surgical Services | 0 | 0 | 1 | 1 | 1 | **3** |
| Form and Content of Record | 0 | 0 | 0 | 1 | 1 | **2** |
| Organization and Staffing | 0 | 0 | 1 | 0 | 1 | **2** |
| Anesthetic Risk and Evaluation | 0 | 0 | 1 | 0 | 1 | **2** |
| Admission Assessment | 0 | 0 | 1 | 0 | 1 | **2** |
| Infection Control | 0 | 0 | 0 | 1 | 1 | **2** |
| Governing Body Responsibilities | 0 | 0 | 1 | 1 | 0 | **2** |
| Reappraisals | 0 | 0 | 1 | 0 | 1 | **2** |
| Infection Control Program – QAPI | 0 | 0 | 1 | 1 | 0 | **2** |
| Health and Safety Code 1280 | 1 | 0 | 0 | 0 | 1 | **2** |
| Sanitary Environment | 0 | 0 | 0 | 1 | 0 | **1** |
| Administration of Drugs | 0 | 0 | 1 | 0 | 0 | **1** |
| Governing Body and Management | 0 | 0 | 0 | 0 | 1 | **1** |
| Pre-Surgical Assessment | 0 | 0 | 1 | 0 | 0 | **1** |
| Post-Surgical Assessment | 0 | 0 | 1 | 0 | 0 | **1** |
| Discharge – Order | 0 | 0 | 0 | 0 | 1 | **1** |
| Quality Assessment and Performance Improvement | 0 | 0 | 1 | 0 | 0 | **1** |
| Program Data, Program Activities | 0 | 0 | 0 | 1 | 0 | **1** |
| Nursing Services | 0 | 0 | 0 | 0 | 1 | **1** |
| Infection Control Program – Responsibilities | 0 | 0 | 0 | 1 | 0 | **1** |
| Patient Admission, Assessment, and Discharge | 0 | 0 | 1 | 0 | 0 | **1** |
| Contract Services | 0 | 0 | 0 | 0 | 1 | **1** |
| Life Safety Code Standard | 0 | 0 | 0 | 0 | 1 | **1** |
| Emergency Personnel | 0 | 0 | 1 | 0 | 0 | **1** |
| Medical Staff | 0 | 0 | 1 | 0 | 0 | **1** |
| Patient Rights | 0 | 0 | 0 | 1 | 0 | **1** |
| Notice – Physician Ownership | 0 | 0 | 1 | 0 | 0 | **1** |
| Emergency Equipment | 0 | 0 | 1 | 0 | 0 | **1** |
| Safety | 0 | 0 | 0 | 1 | 0 | **1** |
| Physical Environment | 0 | 0 | 0 | 0 | 0 | **0** |
| Infection Control Program | 0 | 0 | 0 | 0 | 0 | **0** |
| Environment | 0 | 0 | 0 | 0 | 0 | **0** |
| Membership And Clinical Privileges | 0 | 0 | 0 | 0 | 0 | **0** |
| Notice – Posting | 0 | 0 | 0 | 0 | 0 | **0** |
| Advance Directives | 0 | 0 | 0 | 0 | 0 | **0** |
| Physical Environment | 0 | 0 | 0 | 0 | 0 | **0** |
| Disaster Preparedness Plan | 0 | 0 | 0 | 0 | 0 | **0** |
| Anesthetic – Discharge | 0 | 0 | 0 | 0 | 0 | **0** |
| Medical Records | 0 | 0 | 0 | 0 | 0 | **0** |
| Organization | 0 | 0 | 0 | 0 | 0 | **0** |
| Pharmaceutical Services | 0 | 0 | 0 | 0 | 0 | **0** |
| Notice of Rights | 0 | 0 | 0 | 0 | 0 | **0** |
| Admission Assessment – Record | 0 | 0 | 0 | 0 | 0 | **0** |
| Other Practitioners | 0 | 0 | 0 | 0 | 0 | **0** |
| Laboratory and Radiologic Services | 0 | 0 | 0 | 0 | 0 | **0** |
| Administration of Anesthesia | 0 | 0 | 0 | 0 | 0 | **0** |
| Program Scope, Program Activities | 0 | 0 | 0 | 0 | 0 | **0** |
| Identification, Prevention, and Maintenance | 0 | 0 | 0 | 0 | 0 | **0** |
| Verbal Orders | 0 | 0 | 0 | 0 | 0 | **0** |
| Laboratory Services | 0 | 0 | 0 | 0 | 0 | **0** |
| Radiologic Services | 0 | 0 | 0 | 0 | 0 | **0** |
| Submission and Investigation of Grievances | 0 | 0 | 0 | 0 | 0 | **0** |
| Safety – Abuse/ Harassment | 0 | 0 | 0 | 0 | 0 | **0** |
| Infection Control Program – Direction | 0 | 0 | 0 | 0 | 0 | **0** |
| Evaluation of Quality | 0 | 0 | 0 | 0 | 0 | **0** |
| Safety from Fire | 0 | 0 | 0 | 0 | 0 | **0** |
| Definitions | 0 | 0 | 0 | 0 | 0 | **0** |
| Hospitalization | 0 | 0 | 0 | 0 | 0 | **0** |
| Performance Improvement Projects | 0 | 0 | 0 | 0 | 0 | **0** |
| Grievances – Mistreatment, Abuse, Neglect | 0 | 0 | 0 | 0 | 0 | **0** |

| CATEGORY | 2009 | 2010 | 2011 | 2012 | 2013 | TOTAL |
|---|---|---|---|---|---|---|
| Exercise of Rights – Grievances | 0 | 0 | 0 | 0 | 0 | **0** |
| Exercise of Rights – Informed Consent | 0 | 0 | 0 | 0 | 0 | **0** |
| Confidentiality of Clinical Records | 0 | 0 | 0 | 0 | 0 | **0** |
| Discharge with Responsible Adult | 0 | 0 | 0 | 0 | 0 | **0** |
| Quality Assessment and Performance | 0 | 0 | 0 | 0 | 0 | **0** |
| Grievances – Mistreatment, Abuse | 0 | 0 | 0 | 0 | 0 | **0** |

## On Average, How Many Deficiencies Were Cited Against Ambulatory Surgical Centers During Investigations and Surveys?

The following data reflects the findings of CDPH/L&C as a result of surveys and complaint investigations conducted in California's 740 ASCs.[21] The majority of the ASCs included in these figures are non-deemed. Out of the 740 ASCs, there were a total of 1,290 standard, complaint, and/or facility-reported event-related surveys conducted between 2009 and 2013. Only 79 (6%) out of the 1,290 surveys/investigations had no deficiencies identified. It should be noted that when CDPH/L&C conducts sample validation surveys of ASCs with deemed status, 80% of the ASCs have deficiencies identified. Although the standards are different and cannot be easily compared, it is interesting to note that outpatient settings regulated by MBC, and surveyed by accreditation agencies, reported that 66% of periodic surveys had no deficiencies.

On average, CDPH/L&C is also citing significantly more deficiencies than the rest of the nation (see Table 9). California is one of the few states to use specialized surveyors such as physicians, pharmacists, and infection control specialists. It is difficult to derive conclusions about the quality of care from this data alone. Some might suggest that California surveyors are more aggressive in citing deficiencies than other states, while others might assert that this reflects proportionately more compliance problems in California ASCs.

**Table 9. Deficiencies Issued on Standard and Complaint Surveys**

| FEDERAL FISCAL YEAR | TOTAL NUMBER OF DEFICIENCIES CITED | | AVERAGE NUMBER OF DEFICIENCIES CITED PER SURVEY | |
|---|---|---|---|---|
| | NATION | CA | NATION | CA |
| 2011 | 1,703 | 208 | 5.3 | 8.4 |
| 2012 | 1,434 | 194 | 5.2 | 9.5 |
| 2013 | 1,456 | 211 | 5.2 | 7.5 |

Using data received from CDPH/L&C, Table 10 provides more data on the number of deficiencies issued. These data include deficiencies issued to ASCs and surgical clinics for all categories of surveys and investigations, so the data is not directly comparable to the previous table.

**Table 10. Deficiencies Issued, All Surveys**

| CALENDAR YEAR | TOTAL NUMBER OF FEDERAL DEFICIENCIES |
|---|---|
| 2009 | 1,052 |
| 2010 | 3,350 |
| 2011 | 2,155 |
| 2012 | 2,453 |
| 2013 | 2,209 |

## What Are the Most Commonly Cited Categories of Deficiencies in ASCs/ Surgical Clinics?

Table 11 provides a high-level summary of the top 20 categories of deficiencies identified in ASCs/ surgical clinics. (See page 27.) A table with the complete chart of the numbers of deficiencies issued, by category, is included in Appendix E. Appendix F contains a detailed list of the number of deficiencies issued by specific regulatory citation.

**Table 11. Top Deficiencies Issued, All Surveys**

| CATEGORY | 2009 | 2010 | 2011 | 2012 | 2013 | TOTAL |
|---|---|---|---|---|---|---|
| Life Safety Code Standard | 266 | 843 | 496 | 596 | 515 | **2,716** |
| Drug Administration | 49 | 125 | 75 | 96 | 87 | **432** |
| Infection Control Program | 27 | 99 | 78 | 85 | 84 | **373** |
| Sanitary Environment | 25 | 97 | 68 | 78 | 89 | **357** |
| Organization and Staffing | 29 | 86 | 66 | 79 | 66 | **326** |
| Miscellaneous | 24 | 90 | 65 | 65 | 62 | **306** |
| Record Form/Content | 26 | 77 | 55 | 73 | 57 | **288** |
| Governing Body and Management | 30 | 88 | 54 | 55 | 56 | **283** |
| Physical Environment | 17 | 82 | 47 | 68 | 65 | **279** |
| Membership and Clinical Privileges | 31 | 80 | 48 | 48 | 46 | **253** |
| Infection Control | 20 | 67 | 46 | 53 | 60 | **246** |
| Reappraisals | 27 | 82 | 46 | 48 | 41 | **244** |
| Admission Assessment | 14 | 68 | 52 | 60 | 44 | **238** |
| Disaster Preparedness Plan | 17 | 67 | 49 | 50 | 46 | **229** |
| Program Scope, Program Activities | 18 | 58 | 37 | 46 | 36 | **195** |
| Governing Body Responsibilities | 17 | 61 | 35 | 41 | 39 | **193** |
| Advance Directives | 12 | 60 | 35 | 46 | 38 | **191** |
| Medical Staff | 20 | 66 | 33 | 39 | 21 | **179** |
| Quality Assessment and Performance Improvement | 23 | 54 | 32 | 39 | 22 | **170** |
| Program Data, Program Activities | 17 | 44 | 27 | 42 | 39 | **169** |

## How Many Ambulatory Surgery Centers Had Federal Medicare Conditions of Participation Not Met?

As previously discussed, if the deficiencies are serious enough, a Medicare condition of participation may be not met. The provider is notified that the ASC is in jeopardy of having its Medicare/Medi-Cal certification terminated if it fails to correct these serious problems. There can be multiple COPs not met on a single survey for a single facility. The following tables summarize the numbers and nature of COPs not met.

**Table 12. Facilities with Conditions of Participation Not Met**

| FEDERAL FISCAL YEAR | NUMBER OF FACILITIES |
|---|---|
| 2011 | 62 |
| 2012 | 72 |
| 2013 | 76 |

Note: Based on data provided by CMS Region IX.

**Table 13. Conditions of Participation Not Met**
(2009 to 2013)

| CPO CATEGORY (n=744 SURGICAL CLINICS/ASCs) | NUMBER NOT MET |
|---|---|
| Governing Body and Management | 293 |
| Infection Control | 253 |
| Medical Staff | 181 |
| Quality Assessment and Performance Improvement | 174 |
| Nursing Services | 137 |
| Environment | 122 |
| Surgical Services | 121 |
| Pharmaceutical Services | 118 |
| Patient Admission, Assessment, and Discharge | 70 |
| Laboratory and Radiologic Services | 66 |
| Medical Records | 62 |
| Patient Rights | 57 |
| Quality Assessment and Performance | 14 |
| Compliance with State Licensure Law | 2 |

Notes: Based on data provided by CDPH/L&C, current as of August 2014. Multiple COPs may be not met for a single facility survey.

## How Many Ambulatory Surgery Centers Have Had Their Medicare Certification Terminated?

Terminating Medicare certification can be done on a voluntary basis or on an involuntary basis. Voluntary termination may occur for many reasons: the ASC closes, the ASC merges with another ASC owner and relinquishes its Medicare provider number, or other operational decisions such as bankruptcy or change of ownership. Some

### What Constitutes a Deficiency Serious Enough to Have Medicare Conditions of Participation Not Met?

*Violations of federal requirements that result in a "condition of participation not met" identify serious problems that have or could jeopardize the health and safety of patients. Here are excerpts from a few survey reports to illustrate the seriousness of these violations:*

"The ASC failed to ensure that, prior to being granted surgical privileges, all physicians were properly credentialed to ensure that they were fully trained and found to have the necessary clinical and surgical competency to safely perform surgical procedures on patients in the ASC."

"The ASC failed to ensure that a pre-anesthesia assessment was complete for one patient, creating the risk of poor surgical outcomes to this patient" [with sleep apnea and scheduled to receive general anesthesia].

"Drugs and biologicals were not prepared and administered in accordance to established policies and procedures and standards of practice when: 1) IV solutions were stored in a warmer unit. 2) Numerous large plastic containers were not labeled when opened; brown substance used in surgery was not labeled or dated when placed in another container for use. 3) Test strips found in patient care areas should have been stored in the medication room."

"Wasting narcotic medications were not witnessed and signed by two licensed staff [in three months of 2013] . . . single use vial medications were used on multiple patients during their surgical procedures. . . . [Yet] the monthly pharmacy/drug audit completed in 2013 showed documentation of 100% compliance with wasting narcotic medications that were witnessed and signed by two licensed staff. In addition, use of single-use vial medications for multiple patients was not identified during the monthly pharmacy audits in 2013. The consulting pharmacist's report dated 7/11/13 showed documentation that narcotic inspection was conducted and showed no discrepancies or irregularities."

"The ASC failed to ensure the medications and IV fluids were ordered by the physician for 2 of 20 sampled patients. . . . The ASC failed to ensure the physician's orders for multiple pain medications provided specific instructions as to when to administer each pain medications for 4 of 20 sampled patients."

[On a survey conducted on 1/23/14]

"The maintenance record for the anesthesia machines was reviewed and showed the Penlon anesthesia machine was last maintained on 5/15/13, and previously on 1/17/11. The Ohmeda anesthesia machine in OR 3 anesthesia machine was last maintained on 4/22/13. The manufacturer's recommendations for maintenance of anesthesia machines showed preventive maintenance shall be done at least twice annually."

voluntary terminations may be initiated by the provider if it looks like it is at risk for involuntary termination.

Involuntary termination is most often the result of the ASC's failure to meet the Medicare health and safety requirements and is initiated by CMS based on survey findings. Involuntary termination occurs if the ASC has been unable to correct very serious, previously identified, condition-level deficiencies. Although 62 ASCs had their certification terminated, only 16[22] were terminated for serious violations of health and safety or other federal requirements, during the three years for which data was made available. (See Table 15 on the following page.)

**Table 14. Total Number of Terminations, All Reasons**

| FEDERAL FISCAL YEAR | NATIONAL | CALIFORNIA |
|---|---|---|
| 2011 | 154 | 22 |
| 2012 | 127 | 23 |
| 2013 | 106 | 17 |
| 2014* | 21 | 4 |

*Partial year: October 1, 2013 through April 7, 2014.

Notes: CMS Region IX provided data from 2011 through April 10, 2014. The federal fiscal year begins on October 1.

**Table 15. Reasons for Terminations**

| FEDERAL FISCAL YEAR | VOLUNTARY | | | INVOLUNTARY | | TOTAL |
|---|---|---|---|---|---|---|
| | MERGER/ CLOSURE | RISK OF INVOLUNTARY TERMINATION | OTHER | HEALTH AND SAFETY VIOLATIONS | FAILURE TO MEET AGREEMENT | |
| 2011 | 10 | 0 | 3 | 9 | 0 | **22** |
| 2012 | 15 | 1 | 2 | 3 | 2 | **23** |
| 2013 | 13 | 0 | 3 | 1 | 0 | **17** |

Notes: CMS Region IX provided data from 2011 through April 10, 2014. The federal fiscal year begins on October 1.

### What Constitutes a Deficiency Serious Enough to Terminate Medicare Certification?

*Violations of federal requirements that result in a "termination of Medicare certification" identify serious problems that have or could jeopardize the health and safety of patients, and which the provider has been unable or unwilling to correct. Here are excerpts from a few survey reports to illustrate the seriousness of these violations:*

"Immediate jeopardy was determined to be present concerning the lack of initial or current skills competency evaluations of all the clinical staff in the ambulatory surgery center (ASC), as well as the lack of credentialing of a surgeon scheduled to perform surgery the next day."

". . . The administrator acknowledged that the ASC has not conducted fire or disaster drills. . . acknowledged that there is no radiation safety program. . . The medical director stated that there was no QAPI program. . . acknowledged that two MDs do not have surgical privileges granted by the governing body and that there is no nursing leadership to ensure competency of nursing and surgical staff and no infection control program that is coordinated by a licensing health care practitioner. The cumulative effect of these systemic problems resulted in the facility's failure to deliver care in compliance. . . and failure to provide care to their patients in a safe environment."

". . . The clinic staff assisted and/or performed services for the ASC (laser surgeries) patients. There was no registered nurse in attendance for all surgical patients. . . no medical records were found for 6 of 20 patients. . . no personnel files were created for ASC staff to ensure qualifications and training pertinent to this location and the services was evaluated. . . . The Ambulatory Surgery Center (ASC) filed to ensure that contracted services were properly arranged, monitored, and periodically evaluated in order to ensure the services were safe and effective for 10 of 10 services (janitorial, laundry, ventilation, medical wasted disposal, laboratory, x-ray, surgical equipment, medical gas, bioengineering, and communications call center vendors). . . the ASC had one operating room (OR) which was not used or maintained. The ASC performed laser surgical procedures in a room designated as a preoperative/postoperative unit. . . there was no restricted or semi-restricted areas in the ASC. The perioperative areas in the ASC were accessible without any restriction to ASC staff, clinic staff and to other patients and/or visitors."

## Outpatient Surgical Settings Regulated by the Medical Board of California

The Medical Board of California receives quarterly reports from the accrediting agencies on outpatient surgery settings that have a change in their accreditation status. Table 16 summarizes those changes.

**Table 16. Changes in Accreditation Status**

| STATUS | NUMBER |
|---|---|
| Initial Accreditation | 14 |
| Accreditation Renewed | 504 |
| Accreditation Lapsed | 56 |
| Accreditation Revoked | 195 |
| Accreditation Canceled | 32 |
| Accreditation Denied | 3 |
| Accreditation Suspended | 16 |

Notes: Data are current as of September 2014 and includes changes in accreditation status since the MBC began collecting this information (in 2010).

Out of the 938 settings, 618 (66%) had zero deficiencies identified as a result of the accreditation survey, and 320 settings (34%) had deficiencies identified.

Although settings are required to post any deficiency reports and plans of correction in the facility, and the board posts this information online for each setting, there is no data or analysis available on deficiency trends/findings for accredited settings under the authority of the board. The accrediting agencies do analyze deficiency patterns internally, but data is not easily

available for deficiencies identified by accrediting agencies; the data would have to be extracted from each individual survey report.

**OPPORTUNITY 6.** Consideration should be given to providing the Medical Board of California with the authority to require accrediting agencies to report data on the number and nature of deficient practices identified in outpatient surgery settings (individual and aggregate), from periodic accreditation surveys and complaint investigations, and that this information be provided to the public online.

## What Enforcement Tools Does the State Have?

State regulatory agencies are given specific authority to enforce compliance with minimum requirements, and to hold entities accountable for failure to meet those requirements. The enforcement tools given to state agencies vary depending on the category of setting. Outpatient settings are required to report adverse events, and are subject to penalties for failure to report. Outpatient settings (except those operated by a hospital) are not subject to monetary fines or penalties for serious violations that affect patient health and safety.

### California Department of Public Health

Of the multiple categories of settings regulated by CDPH, the following are the enforcement tools available:

- Issuing a deficiency and requiring a plan of correction for all categories of settings
- Conducting a revisit to determine correction of serious deficiencies
- Revoking the license of a surgical clinic, correctional treatment center, or hospital
- Issuing a temporary suspension order (TSO), which requires the setting to immediately cease operations

Ambulatory surgery centers are a federal category and are, therefore, subject only to federal enforcement remedies, including:

- Issuing a deficiency and requiring a plan of correction
- Conducting a revisit to determine correction of serious deficiencies
- For Conditions of Participation found not met, removing deemed status
- Terminating Medicare certification

### Medical Board of California

Outpatient settings regulated by MBC are required to maintain their certification from an accrediting agency. The enforcement remedies include:

- Issuing a deficiency and requiring a plan of correction
- Conducting a revisit to determine correction of serious deficiencies, if determined appropriate by accrediting agency
- Changing the accreditation status of the outpatient setting, including denial, revocation, or suspension
- Seeking an injunction through the State Attorney General or Local District Attorney after the setting has had an opportunity to correct
- In addition, MBC may take disciplinary action against a physician's license, if warranted by the facts related to the violation

## Federal- and State-Mandated Reporting Requirements for Outpatient Surgery Settings Related to the Quality of Patient Care

The information in this section was obtained from state and federal websites, statutes, regulations, Public Records Act requests, and other sources. Thus, the information reflects states with reporting requirements easily identifiable through online research. Many states require reports of adverse events, health care-acquired infections, or other data from incidents or patient encounters that occur in outpatient surgery settings. As a condition of professional licensure, there are other mandated reports related to impaired practice, litigation,

and so on, but these are related to the individual practitioners and are not counted in these tables.

Outpatient surgery settings have some similar and often duplicative reporting requirements to the federal and state government (or to accreditation organizations). Using California as an example, Table 17 illustrates the multiple reporting requirements for various outpatient surgery settings.

## California Adverse Event Reporting

California's adverse event reporting law is based on the National Quality Forum's list of serious reportable events, defined as "serious, largely preventable, and harmful clinical events, designed to help the health care field assess, measure, and report performance in providing safe care."[23] California law originally required only general acute care hospitals, acute psychiatric hospitals, and special hospitals to report adverse events.[24]

Currently, California law requires adverse event reporting by:

- All clinics that meet the definition of outpatient setting (including surgical clinics) and are regulated by the MBC
- Ambulatory surgery centers that are also regulated by the MBC
- General acute care hospitals (including outpatient surgery-related incidents)
- Acute psychiatric hospitals
- Special hospitals
- Outpatient settings regulated by the Medical Board of California

ASCs and clinics that are not also accredited as outpatient settings by the MBC are not required to report adverse events to CDPH/L&C.

In California, the same criteria for reporting adverse events are applied equally to hospitals (including outpatient surgical services), and outpatient settings regulated by the MBC.

Initially, adverse events were only required to be reported by general acute care hospitals, acute psychiatric hospitals, and special hospitals (effective July 1, 2007). From 2012 to 2013, CDPH continued to receive adverse event reports for outpatient settings that were under the authority of the Medical Board of California, but they were unable to investigate these settings, for which they had no authority. Legislation was enacted requiring the reports to be filed with MBC.[25] This new law went into effect on January 1, 2014. Unlike the statutes related to adverse event reports filed with CDPH/L&C, the statutes did not require MBC to treat these reports as entity-reported incidents to be investigated within a specific timeframe. However, MBC's practice is that these reports are handled like complaints, the accreditation agency investigates reports that concern the setting's operations, and MBC investigates reports

**Table 17. Types of Quality-of-Care Reporting Requirements for Outpatient Surgery Settings**

| REQUIRED REPORTS | LICENSED-ONLY SURGICAL CLINICS (CDPH) | AMBULATORY SURGERY CENTERS* (CDPH) | HOSPITAL-BASED OUTPATIENT SURGERY (CDPH) | OUTPATIENT SETTINGS (MBC) |
|---|---|---|---|---|
| Adverse Event Reports (to CDPH) | ✔ | | ✔† | |
| Adverse Event Reports (to MBC, same criteria as above) | | | | ✔ |
| Unusual Occurrence Report (to CDPH) | | | ✔ | |
| Quality Reports for ASCs (to CMS for Medicare reimbursement only) | | ✔ | | |
| Quality Reports for Hospitals (to CMS for Medicare reimbursement and quality comparison) | | | ✔ | |
| Health Care-Acquired Infections (to CDPH through national portal) | | | ✔ | |
| Provider-Preventable Conditions (to DHCS) | | ✔ | ✔ | ✔ |

*In addition to these requirements, accredited health care settings are usually required to report specific "sentinel events" to the accreditation organization.
†Adverse events occurring in all parts of the hospital (which include outpatient surgery services) are required to be reported. Reports filed for outpatient surgical services vs. inpatient services cannot be easily identified.

that indicate some question about an individual licensee's standard of practice.

Even though the vast majority of state dental boards do not regulate the settings in which outpatient dental surgery is performed, 38 state dental boards require dentists who hold anesthesia/sedation permits to report specific adverse events to their state licensing boards. These events include (at minimum) injuries, illness, deaths, or unanticipated emergency transfers to a hospital from the outpatient setting. Like most other states, the Dental Board of California does not regulate outpatient settings, but unlike most other states, current California law does not require anesthesia/sedation permit holders to report adverse events that arise as a result of outpatient dental surgery.

One reporting criterion not required in California of outpatient surgery settings, and common in many states, involves emergency transfers from the outpatient setting to a hospital. This may be because the adverse event criteria were initially developed with hospitals in mind, rather than outpatient surgery settings outside of a hospital setting, and have not been updated.

The number of adverse events reported to CDPH/L&C raises questions about whether facilities are submitting reports as required by law. Failure to report adverse events carries an administrative penalty of $100 per day for every day past the required reporting timeframe. In 2011, the department identified those hospitals that had not filed an adverse event report. These hospitals were asked to attest that they had not had any adverse events to report. While this initiative was a one-time effort to identify the extent to which hospitals were not reporting, the department may also identify unreported adverse events through receipt of a complaint or during the course of a survey of the facility.

The California Department of Public Health is required by law to investigate adverse event reports. The fact that an adverse event report was submitted does not mean that the event involved a violation of state or federal standards. Of the 30 adverse event reports that were submitted to the department from 2009 through 2013, violations were substantiated for 14 reports, unsubstantiated for 5 reports, and 11 reports had no disposition at the time the data was provided. (See Table 19.)

**Table 19. Adverse Event Reports Submitted by ASCs/Surgical Clinics**
(January 1, 2009 to December 1, 2013)

| TYPE OF EVENT | NO. |
|---|---|
| Surgery Performed on Wrong Body Part | 11 |
| Wrong Surgical Procedures Performed on Patient | 6 |
| Retention of Foreign Object in Patient | 5 |
| Death During or up to 24 Hours After Surgery | 3 |
| Death or Serious Disability Associated with the Use of a Device Other Than as Intended | 1 |
| Adverse Event or Series of Adverse Events | 4 |

**OPPORTUNITY 7.** Consideration should be given to amending state statutes to declare adverse event reports submitted to the Medical Board of California to be public information. The Medical Board of California should consider posting information about adverse events online. Further,

**Table 18. Adverse Events Reported to State Agencies by California Outpatient Surgery Settings**

| CALENDAR YEAR | LICENSED-ONLY SURGICAL CLINICS AND AMBULATORY SURGERY CENTERS* (CDPH) | HOSPITAL-BASED OUTPATIENT SURGERY SERVICES† (CDPH) | OUTPATIENT SETTINGS‡ (MBC) |
|---|---|---|---|
| 2009 | 1 | Unknown | N/A |
| 2010 | 3 | Unknown | N/A |
| 2011 | 0 | Unknown | N/A |
| 2012 | 4 | Unknown | N/A |
| 2013 | 22 | Unknown | N/A |
| 2014§ | Unknown | Unknown | 75 |

*Also accredited through MBC. Data based on data received from CDPH/L&C in August 2014.
†Adverse event reports filed by hospitals for events that occurred in outpatient surgical settings are not easily identifiable from events that occurred in inpatient settings.
‡Adverse event reporting requirements to MBC were effective on January 1, 2014.
§Partial year: January 1, 2014 to September 15, 2014.

specific authority should be given for the board (or its agents) to investigate adverse events.

**OPPORTUNITY 8.** It is recommended that correctional treatment centers that may be approved for outpatient surgery services be required to report adverse events, with associated penalties for failure to report.

**OPPORTUNITY 9.** Consideration should be given to providing the Dental Board of California with the authority to require dentists who have anesthesia/sedation permits to report adverse events, with associated penalties for failure to report.

**OPPORTUNITY 10.** Consideration should be given to the development of additional, specific criteria for nonhospital-based outpatient settings (surgical clinics, ASCs, dental board permit holders, other clinics, correctional treatment centers with outpatient surgery services, and outpatient settings regulated by MBC). These should include any incident which requires the transfer of a patient to a hospital from the outpatient setting, for observation or treatment. There may be other adverse events unique to outpatient settings that should be considered after discussions with key stakeholders.

**OPPORTUNITY 11.** Additional analysis is needed to determine the extent to which data that can help assess quality of care (whether compliance with minimum standards, or quality indicator data) can be standardized or otherwise made comparable across all categories of settings.

## Mandated Reporting of Quality Indicators for Reimbursement

### Provider-Preventable Conditions

(providers serving Medi-Cal beneficiaries — DHCS)

Effective July 1, 2012, all states must implement nonpayment programs for services provided to Medi-Cal beneficiaries that involve provider-preventable conditions and health care-acquired conditions, as defined in federal law. Medi-Cal providers are required to report these PPCs/HCACs to the state Medicaid agency. The state Medicaid agency must then determine the amount of nonpayment to apply to the event. Health care-acquired conditions relate only to inpatient hospitalizations. PPCs are for all Medi-Cal provider settings (including outpatient surgery settings) and include:

- Wrong surgical or other invasive procedure performed on a patient
- Surgical or other invasive procedure performed on the wrong body part
- Surgical or other invasive procedure performed on the wrong patient

These mirror some criteria for reporting adverse events (reported to CDPH/L&C and MBC). The Department of Health Care Services has been working with CDPH to identify opportunities for a web-based, common provider reporting process that meets the needs of both departments.

### ASC Quality Reporting Program

The Ambulatory Surgical Center Quality Reporting (ASCQR) Program is a federal pay-for-reporting, quality data program required by the Centers for Medicare & Medicaid Services (CMS).[26] Under this program, ASCs report quality-of-care data for standardized measures to receive the full annual update to their ASC annual payment rate, beginning with Calendar Year 2014 payments. In addition to the primary goal of providing reimbursement incentives for quality of care, CMS intends to align ASC quality measure requirements with those of other reporting programs, including the Hospital Outpatient Quality Reporting Program, the Hospital Inpatient Quality Reporting Program, and the Physician Quality Reporting System, with the intent that the burden of reporting will be reduced.

These reporting requirements are in addition to state reporting requirements for adverse event reporting, provider-preventable conditions, and health care-acquired infection reports. The quality reports submitted by ASCs for reimbursement are not shared with the CMS Survey and Certification Program, nor with the state survey agency responsible for surveying nonaccredited ASCs (CDPH).

A summary of the quality-of-care measures currently required to be reported, as well as future measures, can be found in Appendix I.

# **Appendix A.** How Does California's Oversight Compare to Other States' Oversight?

A 50-state environmental scan was conducted based on state statutory or regulatory requirements, or other information that is readily available on state websites. For purposes of this report, "dental board regulated" means settings under the authority of the state dental board, "freestanding facility" means an outpatient surgery setting that is not a part of a hospital and is most often under the authority of the state health facility survey agency, "medical board regulated" means settings under the authority of the state medical board, and "podiatry board regulated" means settings under the authority of the state podiatry board. Hospital-based outpatient surgery settings are not included in this comparison. In some states, the podiatry board is a part of the medical board.

## How Many States Regulate Outpatient Surgery Settings by Requiring a License, Certificate, Permit, or Registration for the Outpatient Surgical Setting Location?

Freestanding outpatient surgery setting locations are significantly more likely to be required to obtain a license, certificate, permit, or registration for the location than are settings owned by dentists, physicians, or podiatrists. Most physician-owned settings that are regulated (13 out of 50) are required to have approval from an accreditation organization. Some states require the individual practitioners to register with or obtain permits from the board if they perform office-based surgery, but there may not be regulatory requirements for oversight of the outpatient surgery setting itself.

In some states, physician-, dentist-, or podiatrist-owned outpatient surgery settings are not regulated by their respective practitioner licensing boards but are required to be licensed by the state agency responsible for health facility licensure. California, New York, and Rhode Island are the three states with this regulatory approach.

**Table 20. Settings That Require a State License, Certificate, Permit, or Registration**

| SETTING TYPE | NO | YES | TOTAL |
|---|---|---|---|
| Dentist Board Regulated | 45 | 5* | 50 |
| Freestanding Facility | 3† | 48 | 51‡ |
| Medical Board Regulated | 37 | 13§ | 50 |
| Podiatry Board Regulated | 48 | 2# | 50 |

*Forty-eight state dental boards require the individual dentists to obtain a permit, depending on the level of anesthesia/sedation. Forty states provide the authority to conduct onsite inspections, but only five require a permit for the setting itself — Kentucky, Massachusetts, Missouri, Nebraska, and New Jersey.

†Vermont, West Virginia, and Wisconsin do not have state requirements for freestanding facilities, but a facility may voluntarily seek federal certification as an ASC to provide services to Medicare/Medicaid beneficiaries.

‡Connecticut has two categories of freestanding outpatient surgery settings.

§California, Connecticut, Florida, Indiana, Nevada, New Jersey, New York, Ohio, Oregon, Rhode Island, South Carolina, Tennessee, and Washington.

#Ohio and Washington (note: the podiatry board is a part of the medical board in Ohio).

## How Many States Require, or Have the Discretion to Conduct, an Onsite Inspection of the Outpatient Surgery Setting Location?

Freestanding outpatient surgery setting locations are significantly more likely to be required to have an onsite inspection of the facility than are settings that come under the authority of state medical, dental, or podiatry boards. Interestingly, although dental boards do not usually regulate the settings in which dental surgeries take place, 48 of the 50 dental boards have either the discretion or the mandate to also conduct onsite inspections of settings, as a part of the qualifications process for issuing anesthesia/sedation permits to individual dentists.

The Dental Board of California conducts inspections of the settings in which the dental permit holders practice, as a part of determining the qualifications of the permit holder, but not all locations used by a specific permit holder are inspected. The Dental Board of California does not have the authority over registration, or anything else related to outpatient settings, for oral and maxillofacial surgeons, and therefore does not conduct routine inspections of these settings.

All 13 states that regulate physician-owned office-based surgery settings (including California) require an onsite inspection, either by a state agency or by an accreditation organization. In California, outpatient settings can be owned and operated by any entity if the setting is accredited by an accrediting agency approved by MBC, and is not otherwise required to be licensed as another category of facility.

**Table 21. Onsite Inspection Required/Permitted**

| SETTING TYPE | NO | YES |
|---|---|---|
| Dental Board Regulated (out of 48) | 8 | 40* |
| Freestanding Facility (out of 48) | 0 | 48 |
| Medical Board Regulated (out of 13) | 0 | 13 |
| Podiatry Board Regulated (out of 2) | 0 | 2 |

*Even though the state dental board regulates the individual practitioner, rather than the setting, the board still has the authority to conduct onsite inspections.

## What Is the Frequently of Onsite Inspections?

There is a wide variation of onsite inspections conducted under states' laws. However, any of these settings that may be certified as an ASC receive an onsite survey once every three years from an accreditation organization, or once every four years from the state survey agency for those ASCs that do not have deemed status.[27] (See Table 22.)

## How Many States Provide an Online Listing of Outpatient Settings?

While most patients receive care in outpatient surgery settings that are affiliated with, or recommended by, their physician, it is helpful to know about available outpatient surgery options in their communities. All states, except California, have an online listing of their state freestanding outpatient surgery settings (surgical clinics in California), and/or the federally certified ambulatory surgical centers operating in their state.

The Medical Board of California provides an online searchable database by the name of the outpatient surgery setting or by physician for settings under their authority. MBC is also planning to add the capability to search by city and/or county. The Dental Board of California has an online listing of dentists who are issued elective facial cosmetic surgery permits, and a searchable database by the type of permit issued, if the name of the dentist is known. However, the list does not include the locations of the settings in which permit holders perform surgeries.

Many state professional licensing boards have a listing or an ability to search the currency of a licensee, but these lists are not necessarily associated with the

locations of the outpatient surgery settings, unless indicated in the chart below.

**Table 23. Online Availability of Settings List**

| SETTING TYPE | NO | YES |
|---|---|---|
| Dental Board Regulated (out of 5) | 47 | 1* |
| Freestanding Facility (out of 48 with state designations, and 3 states without designations) | 1† | 50‡ |
| Medical Board Regulated (out of 13) | 8 | 5§ |
| Podiatry Board Regulated (out of 2) | 2 | 0 |

*Missouri is the only state that requires a permit/registration for the setting and posts a list of those settings online.

†California is the only state where no online listing of freestanding facilities (or ASCs) is made available.

‡Even though three states (Vermont, West Virginia, and Wisconsin) do not have state requirements for outpatient surgery settings, these states do provide a list of federally certified ambulatory surgery centers on their website.

§California, Nevada, New York, Rhode Island, and Tennessee.

**OPPORTUNITY 12**. CDPH/L&C should provide an online, searchable listing of all outpatient surgery settings. CDPH/L&C should be encouraged and fully supported to meet its goal of posting these hospital compliance reports on the Health Facility Consumer Information System (HFCIS) as soon as possible. Further, CDPH/L&C should expand HFCIS to include an online searchable database of ambulatory surgery centers and surgical clinics.

## What Online Information Is Available About Complaints?

Easy access to online information about the number or nature of complaints filed against outpatient surgery settings can help to inform consumers about the quality of care provided by them.

Most professional licensing boards (physician, dental, and podiatrist) do not consider information about the number, nature, outcome, or copies of the reports related to complaints to be public. If, as a result of a complaint investigation against a licensee, there are found to be grounds for disciplinary or enforcement actions against the individual licensee, the final board actions are often posted on the state website and are considered public information.

In California, information about the number of complaints filed, whether complaints were substantiated, and copies of the complaint investigation reports filed against hospitals, surgical clinics, and ambulatory surgery centers are considered public information but are not available online. This information is available only through visiting CDPH/L&C district offices or by submitting a Public Records Act (PRA) request.

**OPPORTUNITY 13**. CDPH/L&C should post online information about complaints filed against outpatient settings, whether those complaints were substantiated, and copies of the substantiated complaint reports.

Complaints filed against outpatient settings regulated by the Medical Board of California are first investigated by the accrediting agency. If the accrediting agency substantiates the complaint, it may jeopardize the setting's accreditation. Current law does not require the outpatient setting to post complaint investigation reports, nor for MBC to post the investigation reports online, whether or not the complaint is substantiated. MBC reviews all survey and complaint investigation reports submitted by the AO. If there is evidence of violations of individual standards of practice, MBC will investigate the facts of the case and take enforcement action against the individual, if warranted.

**Table 24. Online Availability of Information About Complaints**

| SETTING TYPE | NO | YES |
|---|---|---|
| Dental Board Regulated (out of 5) | 5 | 0* |
| Freestanding Facility (out of 48) | 43 | 5† |
| Medical Board Regulated (out of 13) | 13 | 0 |
| Podiatry Board Regulated (out of 2) | 2 | 0 |

*Hawaii and New Mexico post information on all dental complaints (but do not separate those pertaining to outpatient surgery settings).

†Arizona, Idaho, Indiana, New Hampshire, and Tennessee.

The Medical Board of California has no authority to post information about the number and nature of complaints filed against each setting, the extent to which those allegations were substantiated, and copies of the final investigation reports. While complaints filed against individual practitioners are not considered public information unless the investigation leads to disciplinary action, complaints investigations filed against care provided in outpatient settings should be considered public information.

**OPPORTUNITY 14**. Consideration should be given to providing authority to the Medical Board of California to post information online about complaints received against outpatient surgery settings, the number and nature of the complaint, whether the allegations were substantiated, and copies of any reports that might result from a complaint investigation.

## Are Copies or Information on State Onsite Inspection Reports Available Online?

Like all but nine states, California does not have copies or information about state licensing surveys of surgery clinics (or federal surveys of ambulatory surgery centers) on the state website. However, copies of state surveys of freestanding surgery clinics are considered public information and are available through visiting the CDPH/L&C district office or by submitting a PRA. Inspection reports for hospitals (which would include outpatient surgical services) are not available online at the time of this report. However, according to the CDPH/L&C website, those reports, with the plans of correction, are scheduled to be available online by January 2015.

**Table 25. Online Availability of State and/or Federal Inspection Reports**

| SETTING TYPE | NO | YES |
|---|---|---|
| Dental Board Regulated (out of 40 that provide the authority or require onsite inspections) | 39 | 1* |
| Freestanding Facility (out of 48) | 39 | 9† |
| Medical Board Regulated (out of 13) | 13 | 0‡ |
| Podiatry Board Regulated (out of 2) | 2 | 0 |

*New Mexico.

†Alabama, Arizona, Colorado, Connecticut, Indiana, Nevada, New Hampshire, Pennsylvania, and Wyoming.

‡MBC makes the inspection reports from the accrediting agencies available online (see Table 11).

As previously discussed, while CDPH/L&C regulates many[28] outpatient settings, there is no list of these settings available to the public. Further, there is no online information about survey findings, complaint investigations, or enforcement actions taken. CDPH/L&C has stated the intent of posting hospital reports online. Settings regulated by the Medical Board of California have the survey reports and accreditation status posted online.

**OPPORTUNITY 15**. CDPH/L&C should post copies of periodic state and federal survey reports online for all outpatient surgery settings under their authority.

## Are Copies of, or Information Contained in, Accreditation Organization Reports Available Online?

Some state agencies accept or require accreditation by an approved accreditation organization (AO) as meeting state licensing requirements. The Centers for Medicare & Medicaid Services (CMS) permits ambulatory surgery centers to become certified through an approved AO, in lieu of seeking certification through a survey from the state survey agency. Providers pay the AO a fee for the accreditation process. Accreditation reports (even for federal certification purposes) are not usually considered public information unless otherwise required by state law.

Alaska, Nevada, and Oregon require that a copy of the accreditation report for freestanding outpatient surgery settings be provided to the state survey agency. There were no readily accessible data to indicate that other states also required a copy of the accreditation report to the filed with the state survey agency.

Some professional boards require outpatient surgery settings to be accredited, but there was no evidence that the outcome of those accreditation surveys were considered public information, except for settings regulated by MBC.

In California, accreditation inspection reports for outpatient surgery settings that are regulated by MBC are considered public information. Copies of the reports (and the plan of correction) are required to be posted at the facility in a location that is accessible to the public. In addition MBC posts a copy of the deficiency report, plan of correction, and final report online. California is the only state to have these accreditation reports posted online.

**Table 26. Online Availability of Accreditation Organization Reports**

| SETTING TYPE | N/A | NO | YES |
|---|---|---|---|
| Dental Board Regulated (40) | 30 | 10 | 0 |
| Freestanding Facility (48) | 30 | 18* | 0 |
| Medical Board Regulated (13) | 2 | 10 | 1† |
| Podiatry Board Regulated (2) | 0 | 2 | 0 |

*These are states that recognize accreditation as meeting state requirements but do not have information about the accreditation surveys on their website.

†California.

While state law requires that accreditation reports for outpatient settings regulated by the Medical Board of California be made available to the public, the law does not currently require accreditation reports for ambulatory surgery centers and hospitals (which includes outpatient surgery services) to be made available to the public. All ambulatory surgical centers and hospitals receive public funds for the provision of patient care. This lack of transparency means that the public does not have any access to findings of deficiencies for the vast majority of outpatient settings regulated by CDPH/L&C.

**OPPORTUNITY 16**. Consideration should be given to amend state law to require all accreditation reports for hospitals, and ambulatory surgery centers where deemed status is granted, to be public information and posted online. This would not include accreditation reports for any provider who voluntarily selects accreditation and does not use accreditation for deemed status purposes.

## Is Information About Enforcement Actions Taken Against Outpatient Settings Available Online?

Most professional licensing boards (in this case, physician, dental, and podiatric) consider final disciplinary or enforcement actions taken against a licensee to be public information, and some will post this information online. However, these board actions may not be directly related to problems that occur in an outpatient surgery setting, but rather with the individual practitioner.

MBC posts online information on enforcement actions taken by the accrediting agency to terminate, suspend, or place on probation individual outpatient surgery settings. California is the only state to make this information available online to the public. California does not currently provide online information on enforcement actions related to surgical clinics, ASCs, or CTC-based outpatient surgery services.

Table 27 illustrates those states that regulate outpatient surgery settings and post enforcement actions online. This does not include online posting of enforcement actions taken against individual practitioners.

**Table 27. Online Availability of State, Federal, or Accreditation Enforcement**

| SETTING TYPE | NO | YES |
|---|---|---|
| Dental Board Regulated (out of 48) | 48 | 0 |
| Freestanding Facility (out of 48) | 42 | 6* |
| Medical Board Regulated (out of 13) | 12 | 1† |
| Podiatry Board Regulated (out of 2) | 2 | 0 |

*Arizona, Colorado, Connecticut, Nevada, New Hampshire, and Texas.

†California posts information on the accreditation status of outpatient settings, including suspension, termination, or probation.

## California and Other States Requiring Adverse Event Reports

Not all adverse event criteria concern surgical procedures. Criteria for adverse events are not uniformly defined across states or within a state.[29] Some adverse event reporting requirements are quite detailed, while others require minimum reporting of deaths, injuries, or unplanned transfers to a hospital from the outpatient surgery setting. The timeline within which the incidents must be reported also varies. Some states have more-extensive reporting requirements that closely mirror the National Quality Forum's "serious reportable events."[30]

Hospital-based and freestanding facilities, including ambulatory surgery centers, tend to have more-extensive reporting requirements than other categories.

Some state professional licensure boards require licensees to report adverse events that occur in outpatient surgery settings, even if they do not require state licensing, certification, registration, or permits for those settings.

Nationwide, state dental boards more consistently require some level of adverse event reporting by individual dentists who have been issued anesthesia/sedation permits (as defined by each state), even if the dental boards do not regulate the settings in which these events occurred. However, the reporting criteria are usually more limited than for other outpatient surgery settings. Based on reporting requirements in most other states, these adverse events include, at minimum:

- Any mortality or morbidity which directly results from the administration of any level of sedation or anesthesia and which occurs in the facility or during the first 24 hours immediately following the patient's departure from the facility
- Any serious complication or any injury which may have resulted from the administration of general anesthesia/deep sedation, or conscious sedation/moderate sedation
- Other injuries which result in temporary or permanent physical injury requiring any period of hospitalization
- Any incident occurring in a dental office, clinic, or other dental facility which requires the transfer of a patient to a hospital for observation or treatment

**Table 28. State Adverse Event Reporting for Outpatient Surgery Settings**

| SETTING TYPE | NO | YES |
|---|---|---|
| Dental Board Regulated* (out of 48) | 10 | 38 |
| Freestanding Facility (out of 48) | 28 | 20 |
| Medical Board Regulated (out of 13) | 5 | 8† |
| Podiatry Board Regulated (out of 2) | 2 | 0 |

*Even though only five state dental boards regulated outpatient settings, 38 states require adverse event reporting to the board.

†California, Florida, Nevada, New Jersey, New York, Oregon, Rhode Island, and South Carolina.

### Health Care-Acquired Infections (CDPH)

State law requires hospitals to report data quarterly on selected quality indicators related to health care-acquired infection (HAI) rates. These data are submitted through the National Healthcare Safety Network (NHSN) portal. Information on hospital infection rates is posted on the CDPH website. The reporting requirements do not duplicate the requirements for hospital adverse event reporting. No other categories of provider, except hospitals, are required to report HAIs. Health care-acquired infections occurring in hospital-based outpatient surgery settings are not differentiated from those that occur in inpatient settings.

**Table 29. Health Care-Acquired Infection Reports**

| SETTING TYPE | NO | YES |
|---|---|---|
| Dental Board Regulated (out of 5) | 5 | 0 |
| Freestanding Facility (out of 48) | 40 | 8* |
| Medical Board Regulated (out of 13) | 12 | 1† |
| Podiatry Board Regulated (out of 2) | 2 | 0 |

*Arkansas, Colorado, Connecticut, Massachusetts, Missouri, New Hampshire, New Jersey, and New York.

†New York.

### Other Reports Requirements

(such as patient encounter data, financial data, or utilization of services data)

One outcome of Capen vs. Shewry was that physician-owned outpatient surgery settings were no longer required to report financial and patient encounter data to the Office of Statewide Health Planning and Development. This information was helpful to public health policy decisionmakers by promoting a better understanding the health care delivery system (who provides what services), payment and costs of care, nature of services and treatments, as well as patient outcomes.

Table 30 provides information on states that require some financial, cost, patient encounter, or other data. It reflects only those states where reporting requirements were readily apparent from online review of the oversight agency's website, and may not represent all states where such data is required.

**Table 30. Other Data Reporting**

| SETTING TYPE | NO | YES |
|---|---|---|
| Dental Board Regulated (out of 48) | 48 | 0 |
| Freestanding Facility (out of 48) | 32 | 16* |
| Medical Board Regulated (out of 13) | 12 | 1† |
| Podiatry Board Regulated (out of 2) | 1 | 1† |

*California, Connecticut (2 categories), Georgia, Illinois, Indiana, Minnesota, Montana, Nebraska, New York, Ohio, Pennsylvania, Rhode Island, Tennessee, Texas, Utah.

†Rhode Island requires that information on utilization, costs, charges, financial condition, and quality of care be submitted to the department of health.

## Selected State Oversight Approaches

While the previous tables provide a general overview of states' regulation of outpatient surgery settings, there are many nuances to oversight programs that do not easily translate into a chart. The following states have some unique features that could help inform California's public policies related to outpatient surgery setting oversight:

- Arizona requires all surgeries where physicians use general anesthesia to be performed in an outpatient surgical service or hospital, both under the same regulatory entity.
- Colorado consolidates oversight of settings that advertise themselves as surgery centers, regardless of ownership.
- Florida requires physician-owned surgery centers to register with the Department of Health (DOH) and provides the option of being accredited or being inspected by the DOH.
- Maryland consolidates freestanding and physician-owned settings oversight under one authority.
- New Jersey regulates settings according to the number of surgical suites (differentiating between small practice models vs. setting that are used by a medical group or physicians other than the owners of the setting).
- New York consolidates freestanding and physician-owned settings oversight under one authority (with physician-owned settings required to be accredited by agencies selected by the Department of Health).

# **Appendix B.** Outpatient Surgery Settings

Health and Safety Code §1248-1248.85 established the definition and regulation of outpatient surgery. In part:

**1248.** For purposes of this chapter, the following definitions shall apply:

(a) "Division" means the Medical Board of California. All references in this chapter to the division, the Division of Licensing of the Medical Board of California, or the Division of Medical Quality shall be deemed to refer to the Medical Board of California pursuant to Section 2002 of the Business and Professions Code.

(b) (1) "Outpatient setting" means any facility, clinic, unlicensed clinic, center, office, or other setting that is not part of a general acute care facility, as defined in 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.

(2) "Outpatient setting" also means facilities that offer in vitro fertilization, as defined in subdivision (b) of Section 1374.55.

(3) "Outpatient setting" does 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.

(c) "Accreditation agency" means a public or private organization that is approved to issue certificates of accreditation to outpatient settings by the board pursuant to Sections 1248.15 and 1248.4.

**1248.1.** No association, corporation, firm, partnership, or person shall operate, manage, conduct, or maintain an outpatient setting in this state, unless the setting is one of the following:

(a) An ambulatory surgical center that is certified to participate in the Medicare program under Title XVIII (42 USC Sec. 1395 et seq.) of the federal Social Security Act.

(b) Any clinic conducted, maintained, or operated by a federally recognized Indian tribe or tribal organization, as defined in Section 450 or 1601 of Title 25 of the United States Code, and located on land recognized as tribal land by the federal government.

(c) Any clinic directly conducted, maintained, or operated by the United States or by any of its departments, officers, or agencies.

(d) Any primary care clinic licensed under subdivision (a) and any surgical clinic licensed under subdivision (b) of Section 1204.

(e) Any health facility licensed as a general acute care hospital under Chapter 2 (commencing with Section 1250).

(f) Any outpatient setting to the extent that it is used by a dentist or physician and surgeon in compliance with Article 2.7 (commencing with Section 1646) or Article 2.8 (commencing with Section 1647) of Chapter 4 of Division 2 of the Business and Professions Code.

(g) An outpatient setting accredited by an accreditation agency approved by the division pursuant to this chapter.

(h) A setting, including, but not limited to, a mobile van, in which equipment is used to treat patients admitted to a facility described in subdivision (a), (d), or (e), and in which the procedures performed are staffed by the medical staff of, or other health care practitioners with clinical privileges at, the facility and are subject to the peer review process of the facility but which setting is not a part of a facility described in subdivision (a), (d), or (e).

Nothing in this section shall relieve an association, corporation, firm, partnership, or person from complying with all other provisions of law that are otherwise applicable.

## **Appendix C.** Business and Professional Code §2472 (Pertaining to the Practice of Podiatric Medicine)

**2472.** (a) The certificate to practice podiatric medicine authorizes the holder to practice podiatric medicine.

(b) As used in this chapter, "podiatric medicine" means the diagnosis, medical, surgical, mechanical, manipulative, and electrical treatment of the human foot, including the ankle and tendons that insert into the foot and the nonsurgical treatment of the muscles and tendons of the leg governing the functions of the foot.

(c) A doctor of podiatric medicine may not administer an anesthetic other than local. If an anesthetic other than local is required for any procedure, the anesthetic shall be administered by another licensed health care practitioner who is authorized to administer the required anesthetic within the scope of his or her practice.

(d) (1) A doctor of podiatric medicine who is ankle certified by the board on and after January 1, 1984, may do the following:

(A) Perform surgical treatment of the ankle and tendons at the level of the ankle pursuant to subdivision (e).

(B) Perform services under the direct supervision of a physician and surgeon, as an assistant at surgery, in surgical procedures that are otherwise beyond the scope of practice of a doctor of podiatric medicine.

(C) Perform a partial amputation of the foot no further proximal than the Chopart's joint.

(2) Nothing in this subdivision shall be construed to permit a doctor of podiatric medicine to function as a primary surgeon for any procedure beyond his or her scope of practice.

(e) A doctor of podiatric medicine may perform surgical treatment of the ankle and tendons at the level of the ankle only in the following locations:

(1) A licensed general acute care hospital, as defined in Section 1250 of the Health and Safety Code.

(2) A licensed surgical clinic, as defined in Section 1204 of the Health and Safety Code, if the doctor of podiatric medicine has surgical privileges, including the privilege to perform surgery on the ankle, in a general acute care hospital described in paragraph (1) and meets all the protocols of the surgical clinic.

(3) An ambulatory surgical center that is certified to participate in the Medicare program under Title XVIII (42 USC Sec. 1395 et seq.) of the federal Social Security Act, if the doctor of podiatric medicine has surgical privileges, including the privilege to perform surgery on the ankle, in a general acute care hospital described in paragraph (1) and meets all the protocols of the surgical center.

(4) A freestanding physical plant housing outpatient services of a licensed general acute care hospital, as defined in Section 1250 of the Health and Safety Code, if the doctor of podiatric medicine has surgical privileges, including the privilege to perform surgery on the ankle, in a general acute care hospital described in paragraph (1). For purposes of this section, a "freestanding physical plant" means any building that is not physically attached to a building where inpatient services are provided.

(5) An outpatient setting accredited pursuant to subdivision (g) of Section 1248.1 of the Health and Safety Code.

# **Appendix D.** Surgical Specialties Provided in Outpatient Settings Regulated by the Medical Board of California

| SPECIALTY | NUMBER OF SETTINGS* |
|---|---|
| Plastic Surgery | 330 |
| Cosmetic Surgery | 168 |
| Other | 146 |
| Pain Management | 127 |
| General Surgery | 115 |
| Gastroenterology | 113 |
| Urology | 108 |
| Anesthesiology | 97 |
| Surgery | 95 |
| Obstetrics and Gynecology | 92 |
| Ophthalmology | 90 |
| Podiatry | 82 |
| Endoscopy | 80 |
| Otolaryngology | 71 |
| Dermatology | 70 |
| Facial Plastic and Reconstructive Surgery | 61 |
| Orthopedic Surgery | 60 |
| Radiology | 58 |
| Diagnostic Radiology | 57 |
| Orthopedics | 55 |
| Internal Medicine | 52 |
| Oral/Maxillofacial Surgery | 43 |
| Vascular Surgery | 42 |
| Infertility | 34 |
| Women's Health | 30 |
| Neurology | 27 |

| SPECIALTY | NUMBER OF SETTINGS* |
|---|---|
| Endocrinology | 27 |
| Oncology | 27 |
| Radiation Oncology | 25 |
| Primary Care | 24 |
| Occupational Medicine | 23 |
| Pediatrics | 19 |
| Lithotripsy | 15 |
| Cardiology | 14 |
| Family Practice | 13 |
| Reproductive Medicine | 13 |
| Physical Medicine and Rehabilitation | 12 |
| Pain Medicine | 11 |
| Sports Medicine | 8 |
| Bariatrics | 8 |
| Dentistry | 6 |
| Neuro-Radiology | 4 |
| Pulmonology | 3 |
| Chiropractic | 3 |
| Psychiatry | 3 |
| Allergy and Immunology | 2 |
| Behavioral Health | 1 |
| Nephrology | 1 |
| Nuclear Medicine | 1 |
| Rheumatology | 1 |
| Neurological Surgery | 1 |

*Some setting locations have more than one specialty and are therefore counted more than once.

# **Appendix E.** Number of Deficiencies Issued to ASCs, by Deficiency Category, 2009 to 2013

| DEFICIENCY CATEGORY | 2009 | 2010 | 2011 | 2012 | 2013 | TOTAL |
|---|---|---|---|---|---|---|
| Life Safety Code Standard | 266 | 843 | 496 | 596 | 515 | **2,716** |
| Administration of Drugs | 49 | 125 | 75 | 96 | 87 | **432** |
| Infection Control Program | 27 | 99 | 78 | 85 | 84 | **373** |
| Sanitary Environment | 25 | 97 | 68 | 78 | 89 | **357** |
| Organization and Staffing | 29 | 86 | 66 | 79 | 66 | **326** |
| Miscellaneous | 24 | 90 | 65 | 65 | 62 | **306** |
| Form and Content of Record | 26 | 77 | 55 | 73 | 57 | **288** |
| Governing Body and Management | 30 | 88 | 54 | 55 | 56 | **283** |
| Physical Environment | 17 | 82 | 47 | 68 | 65 | **279** |
| Membership and Clinical Privileges | 31 | 80 | 48 | 48 | 46 | **253** |
| Infection Control | 20 | 67 | 46 | 53 | 60 | **246** |
| Reappraisals | 27 | 82 | 46 | 48 | 41 | **244** |
| Admission Assessment | 14 | 68 | 52 | 60 | 44 | **238** |
| Disaster Preparedness Plan | 17 | 67 | 49 | 50 | 46 | **229** |
| Program Scope, Program Activities | 18 | 58 | 37 | 46 | 36 | **195** |
| Governing Body Responsibilities | 17 | 61 | 35 | 41 | 39 | **193** |
| Advance Directives | 12 | 60 | 35 | 46 | 38 | **191** |
| Medical Staff | 20 | 66 | 33 | 39 | 21 | **179** |
| Quality Assessment and Performance Improvement | 23 | 54 | 32 | 39 | 22 | **170** |
| Program Data, Program Activities | 17 | 44 | 27 | 42 | 39 | **169** |
| Infection Control Program — Direction | 15 | 50 | 28 | 36 | 24 | **153** |
| Contract Services | 10 | 53 | 28 | 23 | 37 | **151** |
| Notice — Posting | 10 | 50 | 33 | 39 | 16 | **148** |
| Pre-Surgical Assessment | 7 | 38 | 33 | 31 | 34 | **143** |
| Discharge — Order | 3 | 35 | 36 | 31 | 34 | **139** |
| Emergency Equipment | 9 | 41 | 22 | 30 | 34 | **136** |

| DEFICIENCY CATEGORY | 2009 | 2010 | 2011 | 2012 | 2013 | TOTAL |
|---|---|---|---|---|---|---|
| Nursing Services | 16 | 41 | 24 | 27 | 25 | **133** |
| Infection Control Program — QAPI | 7 | 32 | 25 | 40 | 26 | **130** |
| Radiologic Services | 6 | 47 | 23 | 28 | 23 | **127** |
| Environment | 15 | 37 | 22 | 24 | 19 | **117** |
| Pharmaceutical Services | 22 | 39 | 14 | 22 | 18 | **115** |
| Performance Improvement Projects | 7 | 37 | 18 | 25 | 28 | **115** |
| Surgical Services | 16 | 36 | 24 | 17 | 21 | **114** |
| Infection Control Program — Responsibilities | 6 | 29 | 17 | 37 | 15 | **104** |
| Anesthetic Risk and Evaluation | 13 | 16 | 22 | 26 | 22 | **99** |
| Other Practitioners | 11 | 30 | 21 | 18 | 12 | **92** |
| Submission and Investigation of Grievances | 5 | 24 | 16 | 26 | 17 | **88** |
| Anesthetic — Discharge | 15 | 29 | 22 | 15 | 6 | **87** |
| Notice of Rights | 5 | 24 | 18 | 17 | 22 | **86** |
| Notice — Physician Ownership | 2 | 22 | 17 | 18 | 17 | **76** |
| Identification, Prevention, and Maintenance | 14 | 26 | 15 | 12 | 7 | **74** |
| Laboratory Services | 10 | 18 | 18 | 12 | 11 | **69** |
| Definitions | 6 | 18 | 14 | 14 | 15 | **67** |
| Patient Admission, Assessment, and Discharge | 3 | 24 | 18 | 9 | 12 | **66** |
| Laboratory and Radiologic Services | 9 | 28 | 12 | 10 | 5 | **64** |
| Safety — Abuse/Harassment | 4 | 29 | 15 | 9 | 7 | **64** |
| Verbal Orders | 8 | 14 | 17 | 15 | 8 | **62** |
| Medical Records | 8 | 19 | 7 | 12 | 13 | **59** |
| Discharge with Responsible Adult | 2 | 12 | 13 | 14 | 18 | **59** |
| Organization | 9 | 18 | 16 | 10 | 5 | **58** |
| Patient Rights | 3 | 18 | 9 | 16 | 9 | **55** |
| Post-Surgical Assessment | 3 | 11 | 13 | 11 | 12 | **50** |

| DEFICIENCY CATEGORY | 2009 | 2010 | 2011 | 2012 | 2013 | TOTAL |
|---|---|---|---|---|---|---|
| Exercise of Rights — Informed Consent | 2 | 13 | 7 | 8 | 20 | **50** |
| Safety from Fire | 5 | 9 | 13 | 8 | 3 | **38** |
| Safety | 3 | 11 | 7 | 6 | 10 | **37** |
| Hospitalization | 3 | 11 | 8 | 4 | 9 | **35** |
| Admission Assessment — Record | 2 | 14 | 5 | 3 | 8 | **32** |
| Discharge — Supplies and Information | 0 | 7 | 2 | 8 | 12 | **29** |
| Administration of Anesthesia | 7 | 6 | 3 | 7 | 5 | **28** |
| Emergency Personnel | 4 | 7 | 4 | 5 | 7 | **27** |
| Grievances — Mistreatment, Abuse, Neglect | 2 | 7 | 5 | 8 | 4 | **26** |
| Confidentiality of Clinical Records | 1 | 9 | 6 | 3 | 4 | **23** |
| Privacy | 0 | 5 | 4 | 5 | 6 | **20** |
| Physical Environment | 19 | 0 | 0 | 0 | 0 | **19** |
| Quality Assessment and Performance | 0 | 0 | 0 | 0 | 13 | **13** |
| Advanced Directives | 0 | 0 | 0 | 0 | 13 | **13** |
| Basic Requirements | 2 | 1 | 4 | 3 | 2 | **12** |
| Separation | 2 | 2 | 2 | 1 | 4 | **11** |
| Exercise of Rights by Others | 3 | 2 | 6 | 0 | 0 | **11** |
| Respect — Property and Person | 2 | 4 | 2 | 0 | 0 | **8** |
| Evaluation of Quality | 6 | 0 | 0 | 0 | 0 | **6** |
| Exercise of Rights — Grievances | 0 | 0 | 1 | 2 | 1 | **4** |
| Compliance with State Licensure Law | 0 | 2 | 0 | 0 | 0 | **2** |
| Administration — Adverse Reactions | 0 | 0 | 1 | 1 | 0 | **2** |
| Safety — Abuse/Harassment | 0 | 0 | 0 | 0 | 2 | **2** |
| Radiologist Responsibilities | 0 | 1 | 0 | 0 | 0 | **1** |
| Blood and Blood Products | 1 | 0 | 0 | 0 | 0 | **1** |
| Grievances — Mistreatment, Abuse | 0 | 0 | 0 | 0 | 1 | **1** |
| Life Code | 0 | 0 | 1 | 0 | 0 | **1** |

# **Appendix F.** Number of Deficiencies Issued to ASCs, by Regulatory Citation, 2009 to 2013

| REGULATORY CITATION VIOLATED | 2009 | 2010 | 2011 | 2012 | 2013 | TOTAL |
|---|---|---|---|---|---|---|
| 416.44(b)(1) | 266 | 830 | 486 | 589 | 509 | **2,680** |
| 416.48(a) | 43 | 125 | 75 | 96 | 87 | **426** |
| 416.51(b) | 27 | 99 | 78 | 85 | 74 | **363** |
| 416.51(a) | 25 | 97 | 68 | 78 | 89 | **357** |
| 416.46(a) | 29 | 86 | 66 | 79 | 66 | **326** |
| 416.47(b) | 26 | 77 | 55 | 73 | 57 | **288** |
| 416.41 | 30 | 88 | 54 | 55 | 56 | **283** |
| 416.44(a)(1) | 19 | 82 | 47 | 68 | 65 | **281** |
| NFPA 101 | 24 | 86 | 57 | 56 | 51 | **274** |
| 416.45(a) | 31 | 80 | 48 | 48 | 46 | **253** |
| 416.51 | 20 | 67 | 46 | 53 | 60 | **246** |
| 416.45(b) | 27 | 82 | 46 | 48 | 41 | **244** |
| 416.52(a)(1) | 14 | 68 | 52 | 60 | 44 | **238** |
| 416.41(c) | 17 | 67 | 49 | 50 | 46 | **229** |
| 416.43(a), 416.43(c)(1) | 18 | 58 | 37 | 46 | 36 | **195** |
| 416.43(e) | 17 | 61 | 35 | 41 | 39 | **193** |
| 416.50(a)(2) | 12 | 60 | 35 | 46 | 38 | **191** |
| 416.43 | 29 | 54 | 32 | 39 | 35 | **189** |
| 416.45 | 20 | 66 | 33 | 39 | 21 | **179** |
| 416.43(b), 416.43(c)(2), 416.43(c)(3) | 17 | 44 | 27 | 42 | 39 | **169** |
| 416.51(b)(1) | 15 | 50 | 28 | 36 | 24 | **153** |
| 416.41(a) | 10 | 53 | 28 | 23 | 37 | **151** |
| 416.50(a)(1)(i) | 10 | 50 | 33 | 39 | 14 | **146** |
| 416.52(a)(2) | 7 | 38 | 33 | 31 | 34 | **143** |
| 416.52(c)(2) | 3 | 35 | 36 | 31 | 34 | **139** |
| 416.44(c) | 9 | 41 | 22 | 30 | 34 | **136** |
| 416.46 | 16 | 41 | 24 | 27 | 25 | **133** |

| REGULATORY CITATION VIOLATED | 2009 | 2010 | 2011 | 2012 | 2013 | TOTAL |
|---|---|---|---|---|---|---|
| 416.51(b)(2) | 7 | 32 | 25 | 40 | 26 | **130** |
| 416.49(b) | 6 | 46 | 23 | 28 | 23 | **126** |
| 416.44 | 15 | 37 | 22 | 24 | 19 | **117** |
| 416.48 | 22 | 39 | 14 | 22 | 18 | **115** |
| 416.43(d) | 7 | 37 | 18 | 25 | 28 | **115** |
| 416.42 | 16 | 36 | 24 | 17 | 21 | **114** |
| 416.51(b)(3) | 6 | 29 | 17 | 37 | 25 | **114** |
| 416.45(c) | 11 | 30 | 21 | 18 | 12 | **92** |
| 416.42(a)(1) | 6 | 16 | 22 | 26 | 22 | **92** |
| 416.42(a)(2) | 15 | 29 | 22 | 15 | 6 | **87** |
| 416.44(a)(3) | 22 | 26 | 15 | 12 | 7 | **82** |
| 416.50(a)(3)(i), (v), (vi), (vii) | 5 | 24 | 16 | 26 | 11 | **82** |
| 416.50(a)(1) | 5 | 24 | 18 | 17 | 13 | **77** |
| 416.50(a)(1)(ii) | 2 | 22 | 17 | 18 | 14 | **73** |
| 416.49(a) | 10 | 18 | 18 | 12 | 11 | **69** |
| MISSING CITATION | 0 | 17 | 19 | 16 | 17 | **69** |
| 416.2 | 6 | 18 | 14 | 14 | 15 | **67** |
| 416.48(a)(3) | 12 | 14 | 17 | 15 | 8 | **66** |
| 416.52 | 3 | 24 | 18 | 9 | 12 | **66** |
| 416.49 | 9 | 28 | 12 | 10 | 5 | **64** |
| 416.50(c)(3) | 4 | 29 | 15 | 9 | 7 | **64** |
| 416.47 | 8 | 19 | 7 | 12 | 13 | **59** |
| 416.52(c)(3) | 2 | 12 | 13 | 14 | 18 | **59** |
| 416.47(a) | 9 | 18 | 16 | 10 | 5 | **58** |
| 416.50 | 3 | 18 | 9 | 16 | 11 | **57** |
| 416.52(b) | 3 | 11 | 13 | 11 | 12 | **50** |
| 416.50(b)(1)(iii) | 2 | 13 | 7 | 8 | 14 | **44** |

| REGULATORY CITATION VIOLATED | 2009 | 2010 | 2011 | 2012 | 2013 | TOTAL |
|---|---|---|---|---|---|---|
| 416.44(b) | 5 | 9 | 13 | 8 | 3 | **38** |
| 416.50(c)(2) | 3 | 11 | 7 | 6 | 9 | **36** |
| 416.41(b) | 3 | 11 | 8 | 4 | 9 | **35** |
| 416.52(a)(3) | 2 | 14 | 5 | 3 | 8 | **32** |
| 416.52(c)(1) | 0 | 7 | 2 | 8 | 12 | **29** |
| 416.42(b), (c) | 7 | 6 | 3 | 7 | 5 | **28** |
| 416.44(d) | 4 | 7 | 4 | 5 | 7 | **27** |
| 416.50(a)(3)(ii), (iii), (iv) | 2 | 7 | 5 | 8 | 4 | **26** |
| 416.50(d) | 1 | 9 | 6 | 3 | 2 | **21** |
| 416.50(c)(1) | 0 | 5 | 4 | 5 | 5 | **19** |
| 416.44(a)(2) | 4 | 2 | 2 | 1 | 4 | **13** |
| 416.50(c)(1)(2)(3) | 0 | 0 | 0 | 0 | 13 | **13** |
| 416.25 | 2 | 1 | 4 | 3 | 2 | **12** |
| 416.50(b)(2), (3) | 3 | 2 | 6 | 0 | 0 | **11** |
| 416.50(a) | 0 | 0 | 0 | 0 | 9 | **9** |
| 416.50(b)(1)(i) | 2 | 4 | 2 | 0 | 0 | **8** |
| 416.42(a) | 7 | 0 | 0 | 0 | 0 | **7** |
| 416.44(a) | 7 | 0 | 0 | 0 | 0 | **7** |
| 416.50(d)(4), (5), (6) | 0 | 0 | 0 | 0 | 6 | **6** |
| 416.50(e)(1)(iii) | 0 | 0 | 0 | 0 | 6 | **6** |
| 416.50(b)(1)(ii) | 0 | 0 | 1 | 2 | 1 | **4** |
| 416.48(a)(1) | 1 | 0 | 1 | 1 | 0 | **3** |
| 416.50(b) | 0 | 0 | 0 | 0 | 3 | **3** |
| 416.48(a)(2) | 2 | 0 | 0 | 0 | 0 | **2** |
| 416.40 | 0 | 2 | 0 | 0 | 0 | **2** |
| 416.50(g) | 0 | 0 | 0 | 0 | 2 | **2** |
| 416.50(f)(3) | 0 | 0 | 0 | 0 | 2 | **2** |
| 482.26 | 0 | 1 | 0 | 0 | 0 | **1** |

| REGULATORY CITATION VIOLATED | 2009 | 2010 | 2011 | 2012 | 2013 | TOTAL |
|---|---|---|---|---|---|---|
| 482.26(c)(1) | 0 | 1 | 0 | 0 | 0 | **1** |
| 416.50(f)(1) | 0 | 0 | 0 | 0 | 1 | **1** |
| 416.50(f)(2) | 0 | 0 | 0 | 0 | 1 | **1** |
| 416.50(d)(1), (2), (3) | 0 | 0 | 0 | 0 | 1 | **1** |

## **Appendix G.** Number of Surveys Conducted by CDPH/L&C, by Survey Category, 2009 to 2013

| CATEGORY | DESCRIPTION | 2009 | 2010 | 2011 | 2012 | 2013 | TOTAL |
|---|---|---|---|---|---|---|---|
| I | Recertification | 135 | 339 | 231 | 258 | 262 | 1,225 |
| H | Life Safety Code | 69 | 173 | 115 | 132 | 135 | 624 |
| G | Validation | 4 | 6 | 8 | 22 | 34 | 74 |
| A | Complaint Investigation | 7 | 4 | 5 | 7 | 8 | 31 |
| E | Initial Certification | 9 | 7 | 2 | 7 | 2 | 27 |
| K | State Licensure | 5 | 7 | 7 | 3 | 0 | 22 |
| 1 | Initial Licensure | 3 | 3 | 3 | 3 | 0 | 12 |
| M | Other | 1 | 1 | 1 | 1 | 0 | 4 |
| 2 | Re-Licensure | 0 | 1 | 1 | 0 | 0 | 2 |
| 3 | Licensure Complaint | 0 | 0 | 0 | 1 | 0 | 1 |
| D | Follow-Up/Revisit | 0 | 0 | 0 | 1 | 0 | 1 |
| B | Dumping Investigation | 0 | 0 | 0 | 0 | 0 | 0 |
| C | Federal Monitoring | 0 | 0 | 0 | 0 | 0 | 0 |
| F | Inspection of Care | 0 | 0 | 0 | 0 | 0 | 0 |
| J | Sanctions/Hearing | 0 | 0 | 0 | 0 | 0 | 0 |
| L | Change of Owner | 0 | 0 | 0 | 0 | 0 | 0 |
| S | Add of Specialties | 0 | 0 | 0 | 0 | 0 | 0 |
| W | CW Project | 0 | 0 | 0 | 0 | 0 | 0 |

## **Appendix H.** Adverse Events

Per California Health and Safety Code, Section 1279.1(b), "adverse event" includes any of the following:

**(1) Surgical events, including the following:**

(A) Surgery performed on a wrong body part that is inconsistent with the documented informed consent for that patient. A reportable event under this subparagraph 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.

(B) Surgery performed on the wrong patient.

(C) 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. A reportable event under this subparagraph 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.

(D) 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.

(E) 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.

**(2) Product or device events, including the following:**

(A) 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.

(B) 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 is not limited to, a catheter, drain, or other specialized tube, infusion pump, or ventilator.

(C) 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.

**(3) Patient protection events, including the following:**

(A) An infant discharged to the wrong person.

(B) Patient death or serious disability associated with patient disappearance for more than four hours, excluding events involving adults who have competency or decisionmaking capacity.

(C) 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 admission to the health facility.

**(4) Care management events, including the following:**

(A) 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.

(B) A patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products.

(C) 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 post-delivery and excluding deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy, or cardiomyopathy.

(D) 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.

(E) 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 milligrams per deciliter.

(F) 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.

(G) A patient death or serious disability due to spinal manipulative therapy performed at the health facility.

**(5) Environmental events, including the following:**

(A) 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.

(B) 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.

(C) A patient death or serious disability associated with a burn incurred from any source while being cared for in a health facility.

(D) A patient death associated with a fall while being cared for in a health facility.

(E) A patient death or serious disability associated with the use of restraints or bedrails while being cared for in a health facility.

**(6) Criminal events, including the following:**

(A) Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider.

(B) The abduction of a patient of any age.

(C) The sexual assault on a patient within or on the grounds of a health facility.

(D) 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.

**(7) An adverse event or series of adverse events that cause the death or serious disability of a patient, personnel, or visitor.**

## **Appendix I.** ASC Quality Reporting Requirements for Medicare Reimbursement

**Measures for CY 2014 Payment Determination**

- ASC-1 Patient Burn
- ASC-2 Patient Fall
- ASC-3 Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant
- ASC-4 Hospital Transfer/Admission
- ASC-5 Prophylactic Intravenous (IV) Antibiotic Timing

**Measures for CY 2015 Payment Determination**

- ASC-1 Patient Burn
- ASC-2 Patient Fall
- ASC-3 Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant
- ASC-4 Hospital Transfer/Admission
- ASC-5 Prophylactic Intravenous (IV) Antibiotic Timing
- ASC-6 Safe Surgery Checklist Use
- ASC-7 ASC Facility Volume Data on Selected ASC Surgical Procedures

**Measures for CY 2016 Payment Determination**

- ASC-1 Patient Burn
- ASC-2 Patient Fall
- ASC-3 Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant
- ASC-4 Hospital Transfer/Admission
- ASC-5 Prophylactic Intravenous (IV) Antibiotic Timing
- ASC-6 Safe Surgery Checklist Use
- ASC-7 ASC Facility Volume Data on Selected ASC Surgical Procedures
- ASC-8 Influenza Vaccination Coverage Among Healthcare Personnel

# **Appendix J.** California State and Federal Laws and Regulations Related to Outpatient Surgery Settings

| SETTING CATEGORY | STATE STATUTES | STATE REGULATIONS | FEDERAL CERTIFICATION REQUIREMENTS (IF BILLING FOR MEDICARE/MEDI-CAL) |
|---|---|---|---|
| Hospital-Based Outpatient Services | Requirements related to all outpatient services but not specifically for outpatient surgery services | Title 22, §70525-70533 (Outpatient Service)* | 42 CFR 416.2-416.53 (ASC) |
| Freestanding Surgical Clinics (not owned by a physician or physician group, dentist, or podiatrist) | Health and Safety Code §1204(b)(1) — Definition, §1225(d)(2), in compliance with federal ASC requirements<br>§1226(f) — Fire Life Safety | Not applicable† | 42 CFR 416.2-416.53 (ASC) |
| Correctional Treatment Center-Based Outpatient Surgery Services | Health and Safety Code §1250(j)(2) | Title 22, §79729-79737 | Not applicable |
| Accredited Outpatient Settings Regulated by the Medical Board of California | Business and Professions Code §2215-2217 (Surgery in Certain Outpatient Surgery Settings — Physicians) | Title 16, §1313.2-1313.6 (Outpatient Setting Accreditation Agencies — Physicians) | Not applicable |
| Physician or Physician Group-Owned, Seeking Medicare/Medi-Cal Certification as an ASC | Not applicable | Not applicable | 42 CFR 416.2-416.53 (ASC) |
| Dentist or Dental Group-Owned‡ | Business and Professions Code:<br>• §1638-1638.7 (Oral and Maxillofacial Surgery — Dentists)<br>• §1646-1646.9 (Use of General Anesthesia — Dentists)<br>• §1647-1647.9 and 1647.18-1647.26 (Use of Conscious Sedation — Dentists)<br>• §1647.10-1647.17 (Use of Oral Conscious Sedation in Pediatric Patients — Dentists) | Title 16:<br>• §1043-1043.8 (General Anesthesia and Moderate [Conscious] Sedation — Dentists)<br>• §1044-1044.5 (Oral Conscious Sedation — Dentists) | 42 CFR 416.2-416.53 (ASC) |
| Podiatrist or Podiatry Group-Owned | No statutory requirements related to outpatient surgery settings | No statutory requirements related to outpatient surgery settings | 42 CFR 416.2-416.53 (ASC) |

*These apply to all outpatient services. §70527(c) deals specifically with outpatient surgery.

†Health and Safety Code §1225(d)(2) requires surgical clinics to meet federal standards for ASCs until CDPH promulgates regulations.

‡The Dental Board of California does not regulate settings, but rather the individual practice of dentistry for permit holders who administer varying levels of anesthesia or sedation. As a part of determining the qualifications of the individual permit holder, the board may conduct an onsite inspection of some, but not necessarily all, settings in which dental surgery is practiced.

## Endnotes


1. California HealthCare Foundation, *Ambulatory Surgery Centers: Big Business, Little Data,* June 2013, www.chcf.org.
2. Settings accredited by an agency approved by MBC can be owned by any entity (including physicians, dentists, or podiatrists) that is not otherwise exempt from clinic or other licensure (see Health and Safety Code §1206 for a list of entities exempt from clinic licensure).
3. Health and Safety Code §1248.1.
4. Settings accredited by an agency approved by MBC can be owned by any entity (including physicians, dentists, or podiatrists) that is not otherwise exempt from clinic or other licensure (see Health and Safety Code §1206 for a list of entities exempt from clinic licensure).
5. Appendix D contains information about the types of specialties provided in outpatient setting locations under the authority of the Medical Board of California. Please note: More than one specialty can be provided at a single location.
6. Health and Safety Code §1225(d)(2), (e), and (f), effective January 1, 2014. SB 524 (Hernandez) Chapter 722, Statutes of 2013.
7. The pharmacy compliance issued was finally resolved through passage of SB 1095 (Rubio), Chapter 454, Statutes of 2010.
8. California HealthCare Foundation, *Ambulatory Surgery Centers*.
9. SB 100 (Price), Chapter 645, Statutes of 2011.
10. From CMS Survey and Certification Letter 08-20 (Safe Injection Practices in Ambulatory Surgery Centers [ASCs]), May 16, 2008.
11. From CMS Survey and Certification Letter 09-37 (State Operations Manual [SOM] Appendix L, Ambulatory Surgical Centers [ASC] Comprehensive Revision), May 15, 2009.
12. Maryland, North Carolina, and Oklahoma.
13. From CMS Survey and Certification Letter 09-43 (American Recovery and Reinvestment Act of 2009 [Recovery Act] Ambulatory Surgical Center Healthcare-Associated Infection [ASC-HAI] Prevention Initiative), June 12, 2009.
14. Geoffrey R. Keyes et al., "Analysis of Outpatient Surgery Center Safety Using an Internet-Based Quality Improvement and Peer Review Program," *Plastic and Reconstructive Surgery* 113, no. 6 (May 2004): 1760-70.
15. Geoffrey R. Keyes et al., "Mortality in Outpatient Surgery," *Plastic and Reconstructive Surgery* 122, no. 1 (July 2008): 245-50.
16. A. S. Chukmaitov et al., "A Comparative Study of Quality Outcomes in Freestanding Ambulatory Surgery Centers and Hospital-Based Outpatient Departments: 1997-2004," *Health Services Research* 43 (October 2008): 1485-1504.
17. A. S. Chukmaitov et al., "Is There a Relationship Between Physician and Facility Volumes of Ambulatory Procedures and Patient Outcomes?," *Journal of Ambulatory Care Management* 31, no. 4 (October-December 2008): 354-69.
18. Nir Menachemi et al., "Quality of Care in Accredited and Nonaccredited Ambulatory Surgical Centers," *The Joint Commission Journal on Quality and Patient Safety* 34, no. 9 (September 2008): 354-69.
19. A. S. Chukmaitov et al., "Strategy, Structure, and Patient Quality Outcomes in Ambulatory Surgery Centers (1997-2004)," *Medical Care Research and Review* 68, no. 2 (April 2011): 202-25.
20. Based on data received from CDPH/L&C in September 2014. These do not include complaints that may have been filed directly with an accreditation organization for those ASCs with deemed status.
21. Data provided by CMS Region IX in April 2014. These data include only standard surveys and complaint surveys for ASCs and do not include information on surgical clinics.
22. Includes one provider who voluntarily terminated because it was at risk of involuntary termination.
23. National Quality Forum, "Serious Reportable Events," www.qualityforum.org.
24. SB 1301 (Alquist), Chapter 647, Statutes of 2006.
25. SB 304 (Lieu), Chapter 515, Statutes of 2013.
26. Centers for Medicare & Medicaid Services, "ASC Quality Reporting," www.cms.hhs.gov.
27. In California, the state survey agency is the California Department of Public Health's Licensing and Certification Program.
28. If hospital-based outpatient settings are counted.
29. See Appendix H for the adverse event reporting criteria required for hospitals, surgical clinics, ASCs, and outpatient settings regulated by MBC.
30. For the complete list of the National Quality Forum's Serious Reportable Events, see: www.qualityforum.org.