California HealthCare Foundation

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Issue Brief

Limited Visibility: Making Information Available on Outpatient Surgery in California

Many surgical services have migrated from inpatient to outpatient settings in response to advances in technology, cost concerns, and greater focus on patient convenience. Today a large number of Californians go to outpatient surgery centers — instead of hospital inpatient settings — for colonoscopies, arthroscopies, eye surgeries, cosmetic and plastic surgeries, endoscopies, biopsies, and a wide variety of other procedures.

Yet very little is known about these facilities or the quality of care they provide.[1] To begin closing that information gap, the California HealthCare Foundation commissioned research on the state's outpatient surgery settings — including oversight, public availability of information, and quality-of-care information such as reporting adverse events. The research included a 50-state environmental scan to compare California to other states in terms of these issues.

The complete findings are contained in a companion report: *Outpatient Surgery Services in California: Oversight, Transparency, and Quality.* This issue brief provides an overview of the research and its key findings.[2]

Background and Three Key Issues

Outpatient surgery settings are facilities in which surgical procedures are performed and where patient stays must be less than 24 hours. In state law, "outpatient settings" (of which "outpatient surgery settings" are a subset) are categorized according to the level of anesthesia and/or sedation used for a procedure. The level of anesthesia for a particular procedure is guided by community medical standards of practice based on the complexity of the procedure and the health and safety of the patient. Procedures that use general anesthesia or deep sedation, or conscious or moderate sedation, can only be administered in an outpatient setting. Procedures that require only local anesthesia, peripheral nerve blocks, anxiolytics, or analgesics are not required to be performed in outpatient settings, and are permitted in other settings, such as physician offices.

There is a great deal of variety in ownership and operating models. Some outpatient settings are hospital-based, while others are free-standing clinics, surgery clinics, ambulatory surgery centers (ASCs), owned by physicians/dentists/podiatrists, or other

settings as defined in California's Health and Safety Code.[3]

The research examined all of the outpatient surgery settings models and the oversight and regulations that pertain to them. The issues that emerged fall into three main categories:

- Lack of consistency and equity in oversight.
- Inadequate communication and coordination of reporting by oversight entities.
- Insufficient information available to the public or policymakers.

ISSUE 1 Oversight

Oversight responsibilities and regulatory requirements for outpatient surgery settings vary according to who owns the setting and whether the owners seek federal program reimbursement. Hospital-based outpatient surgery settings, free-standing surgery clinics, ambulatory surgery centers seeking certification to allow for Medicare and Medi-Cal billing, and primary care clinics are regulated by the California Department of Public Health (CDPH). Almost all other outpatient settings are under the regulatory oversight of the Medical Board of California (MBC) which requires that facilities be accredited as an outpatient setting by an accrediting agency approved by the MBC.

There are different oversight rules for private dentists administering anesthesia, podiatrists, government-owned clinics and federally recognized tribal organizations. Dentists may administer higher levels of sedation and anesthesia in their dental practice with an individual permit from the Dental Board. Podiatric surgery must be done in settings prescribed in state law. Neither the Dental Board nor the Board of Podiatric Medicine regulates outpatient surgery settings. Government-owned clinics

Table 1. State Department or Board Oversight Authorities*

	SETTING CATEGORY NAME	NUMBER	CERTIFICATION, ACCREDITATION, LICENSURE
California Department of Public Health (CDPH)	Hospital-based outpatient surgery setting	Not available†	Both a state licensing and a federal certification category. Can be federally certified as a part of the overall hospital, or separately from the hospital as an ambulatory surgery center.
	Surgical clinic (not owned by physician, physician group, dentist, or dental group)	34	State licensing category. Federal certification as an ambulatory surgery center is optional.
	Ambulatory surgery center	740	Federal certification category. While 710 are certified-only, 30 are also licensed as surgical clinics.
	Correctional treatment center-based outpatient surgery center	0‡	State licensing category only.
Medical Board of California (MBC)	Outpatient surgery setting	938	MBC certification. This number includes settings reported to the MBC-approved accrediting agencies.
Dental Board of California	While the Dental Board does not regulate settings in which dentists perform surgery, it requires that individual dentists performing surgery obtain a permit based on the level of anesthesia administered.		
Board of Podiatric Medicine	Podiatrists may order all anesthetics and sedations, and may administer moderate or conscious sedation; they must perform ankle surgeries in specified settings. The Board of Podiatric Medicine does not regulate outpatient surgery settings in which podiatrists perform surgery, though such settings may seek Medicare or Medi-Cal certification by an MBC-approved accreditation agency.		

*Individual facilities may operate under multiple categories, so counts of settings are not additive.

†According to the most recent reports filed with OSHPD, 247 out of 427 hospitals reported that they had an organized surgical program, but 367 of 427 hospitals reported an outpatient surgery to OSHPD.

‡None of the 21 centers currently has approval to provide outpatient surgeries.

are exempt from state licensure, and outpatient clinics owned by a federally recognized tribe or tribal organization and located on tribal lands are largely regulated by the federal government. See Table 1, page 2.

The minimum standards for licensure, certification, or accreditation that must be met by each category of setting vary. Federal certification standards for ambulatory surgery centers and accreditation standards for outpatient surgery settings or ambulatory surgery centers are generally more up-to-date with community standards of practice. There are no state regulations for surgical clinics, but statute provides that these settings meet the same certification standards as ambulatory surgery settings.

As Table 2 shows, the frequency of onsite inspections for different categories of outpatient surgery settings varies, or may not take place at all.

The enforcement options imposed by government oversight agencies for failure to comply with these minimum standards are also different. (See Table 3.) There are no fines or monetary penalties for violations of minimum standards, except for serious violations that take place in hospital-based settings. There are also fines for failure to report adverse events.

Historical Context of Oversight

California law has long provided an exception from licensure for clinics, including surgical clinics, "operated by licensed health care practitioners." Historically, CDPH/Licensure and Certification (CDPH/L&C) had interpreted state law to require a surgical clinic license if the setting was partially owned (rather than wholly owned) by one or more

Table 2. Frequency of Onsite Inspections

SETTING CATEGORY	FREQUENCY
Hospital-based outpatient surgery	Once every 3 years
Surgical clinic	Once every 3 years
Ambulatory surgery center	Once every 4 years for non-accredited Once every 3 years for accredited (with deemed status)
Outpatient surgery setting (regulated by the MBC)	Once every 3 years
Dental settings (not regulated by the MBC or CDPH)	Variable, if DBC determines necessary to verify compliance with requirements for individual permits
Podiatric settings (not regulated by the MBC or CDPH)	Not applicable

Table 3. Enforcement Options

ENFORCEMENT TOOLS	SURGICAL CLINIC	AMBULATORY SURGERY CENTERS	OUTPATIENT SURGERY SETTINGS REGULATED BY MBC	HOSPITAL-BASED
Issue written deficiency	x	x	x	x
Require a plan of correction	x	x	x	x
Revisit to verify correction	x	x	x	x
Impose fines or monetary penalties				x
Remove deemed status*	N/A	x	N/A	x
Issue temporary suspension order†	x			x
Terminate certification for Medicare/Medi-Cal	N/A	x	N/A	x
Revoke license	x	N/A	N/A	
Deny, revoke, or suspend accreditation	N/A	N/A	x	

*Deemed status is explained on page 7.

†This permits the state to immediately suspend a license, which results in setting closure until/unless provider appeal is resolved. Used only in the most egregious circumstances.

physicians, or if the owners permitted physicians outside the practice to perform surgery at the setting.

In 2007, this interpretation was challenged in *Capen v. Shewry,* in which the California Court of Appeals held that all ASCs owned by a physician or group of physicians are excluded from licensure by CDPH. In response, CDPH/L&C stopped issuing surgical clinic licenses for facilities with any degree of physician or dentist ownership. Approximately 400 previously licensed surgical clinics were no longer under the authority of CDPH and no longer required to report data to California's Office of Statewide Health Planning and Development (OSHPD). Therefore, 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. These settings were then forced to be accredited by an accrediting agency approved by the MBC. Certified settings were required to have periodic onsite surveys by the accrediting agency to determine compliance with accreditation standards.

In 2011, legislation was introduced to address concerns about the lack of effective regulation of outpatient surgery settings not regulated by CDPH. Effective January 1, 2012, a new law took effect that clarified and enhanced the MBC's authority to regulate outpatient settings.[4]

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 the authority of the MBC.

There have been changes at the federal level as well. Following a Hepatitis C outbreak related to ASCs in Nevada in 2008, the Centers for Medicare & Medicaid Services (CMS) significantly revised the rules for ASCs participating in Medicare. CMS tested a 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. Subsequently, the workload priority and frequency of state survey agency periodic surveys of non-accredited ASCs was increased. States were required to implement the new survey protocol by no later than 2010.

CDPH/L&C has struggled for years to complete the workload required under state law as well as the federal CMS grant. Table 4 shows the average lag time between the receipt of a complaint or facility-reported event 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. While the overall lag time between receipt of an allegation and the start date of the investigation has improved over recent years, it is not an acceptable delay.

ISSUE 2 Communication and Coordination Issues

With disparate regulatory agencies having oversight responsibility for different kinds of individual practitioners and settings of care, coordination is key. However, the research showed that there are no formal communication and referral structures between the different state agencies with oversight responsibility for varying outpatient surgery settings.

Complaint and adverse event reporting policies and procedures differ by regulatory entity and are not well coordinated. Although there may be informal mechanisms for referring information to the

Table 4. Average Lag Time for Completion of Investigations*

	AVERAGE LAG TIME BETWEEN RECEIPT OF COMPLAINT AND INVESTIGATION...	
YEAR OF INTAKE RECEIPT	START DATE (DAYS)	CLOSE DATE (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**

*These data do not include complaints or facility-reported events that had a zero value in the fields. Some of the lapsed time for closing out the allegations may be due to delays in data entry.

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.

Such communication disconnects between oversight entitles can have significant implications for patient health and safety.

ISSUE 3 Public Availability of Information on Quality

Online information about many outpatient surgery settings is not available to the public, and some information about compliance with minimum standards is not considered public information. There is little published research that compares the quality of care for the same types of procedures across all outpatient surgery settings, and the public has little information about the quality of care provided in California's outpatient surgery settings.

Online public access to information about outpatient settings is available only for those settings regulated by the MBC. Consumers have the ability to search an online database (by keyword, setting name, or owner) for a specific outpatient setting for the following information:

- Basic demographic information including address, date of initial accreditation, effective dates of current accreditation, list of owners, types of specialties provided
- Confirmation that the setting has been accredited by an accrediting agency approved by the MBC
- Accrediting agency reports generated by onsite inspections, showing deficient practices identified, the corrective action plan, and outcome of the corrective action (if applicable)
- The accrediting agency that has accredited the setting

However, the MBC online database does not enable consumers to search by city or county, or to get information about complaints filed against facilities or adverse events reported by them.

There is no online information available to the public about outpatient surgery settings that are regulated by the CDPH Licensing and Certification Program. There are plans to post online information on survey and complaint investigation findings and related enforcement actions for hospitals (which would include hospital-based outpatient surgery settings) in 2015. However, there are no short-term plans to provide online information about any other category of outpatient setting under CDPH's oversight. California is the only state that does not provide some online information about outpatient surgery settings regulated by that state's CDPH-equivalent agency.

Some outpatient settings (including hospitals with outpatient services) seek Medicare or Medi-Cal certification by meeting standards established by accreditation organizations approved by CMS. Once proof of accreditation is obtained, the setting may apply for "deemed status" certification from CMS.[6] Although the accreditation reports for outpatient settings regulated by the MBC are considered to be public information and are posted online, the accreditation reports for hospitals and ambulatory surgery centers that have been granted deemed status by CMS are not considered to be public information, and are not even required to be shared with CDPH. Licensing surveys and surveys of non-accredited outpatient surgery settings conducted by CDPH are considered to be public information, but are not available online.

Promoting Quality of Care by Professional Associations

Professional associations abound at both nationwide and statewide levels. Many are based on the type of specialty services provided (e.g., cosmetic surgery). They share research, guidelines, and best practices with their membership in order to promote quality of care.

At the national level, a cooperative effort of organizations and companies was formed in 2006 — the ASC Quality Collaboration (ASC QC). They initiated a process to develop standardized ASC quality measures, and publish 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.

A California-based organization, the California Ambulatory Surgery Association (CASA), promotes member quality assessment and performance improvement benchmarking to illustrate best practices.

Promoting Quality of Care by 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.

Compliance with State, Federal, or Accreditation Standards

Compliance with minimum standards is measured upon initial licensure or certification, and periodically thereafter. State, federal, and accreditation standards all require some form of internal quality assurance process. For instance:

- ASCs 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 may track quality indicators such as infection rates, length of stay, readmission rates, risk-adjusted mortality rates, complication rate, transfers to hospitals, and other performance measures that have a direct impact on patient health, safety, and satisfaction with their care experience. Since licensed surgical clinics must meet ASC standards, surgical clinics are also required to have QAPI programs.
- California state licensing laws and regulations require some quality assurance/performance improvement processes for settings under their authority.

All accreditation organizations require that a quality assurance process is in place, whether the accreditation is for an office-based setting, for certification as an outpatient setting, or for accreditation of ASCs for deemed status. AAAASF is the only accrediting organization to require settings to report quality indicator data. These data must be submitted quarterly; however, the information is considered proprietary and is not available to the public.

Compliance Data as an Indicator of Quality

For this research, California Public Records Act requests were submitted to the CDPH, MBC, and CMS to obtain basic compliance information, such as the most common types of violations that occur in outpatient surgery settings and the number of settings with serious violations. The number and types of violations were only available for ASCs that do not have deemed status from CDPH and CMS. While accreditation survey reports for each individual setting regulated by the MBC are available online, there is no summary data from which to draw conclusions about the most frequently cited deficiencies. Table 5 provides a list of the top 10 most frequently cited deficiencies for ASCs regulated by CDPH from 2009 through 2013. A complete list is available in the companion report.[5]

Table 5. Deficiencies Cited Most Frequently by CDPH* in Ambulatory Surgery Centers

CATEGORY OF VIOLATION	NUMBER OF DEFICIENCIES CITED
Fire/Life Safety Code Standards	2,716
Administration of Drugs	432
Infection Control Program	373
Sanitary Environment	357
Organization and Staffing	326
Miscellaneous	306
Form and Content of Record	288
Governing Body and Management	283
Physical Environment	279
Membership and Clinical Privileges	253
Infection Control	246
Reappraisals	244
Admission Assessment	238
Disaster Preparedness Plan	229

*These same aggregate data are not available for settings regulated by the MBC.

Deficiency-Free Surveys

Approximately 6% of onsite surveys conducted by CDPH in ambulatory surgery centers resulted in a "deficiency-free" survey over a four-year period. CDPH may conduct sample validation surveys of ASCs with deemed status and report that only 30% of those settings are deficiency-free. In contrast, 66% of surveys conducted by accrediting agencies in outpatient settings regulated by the MBC were deficiency free from 2010 through September 2014. These outpatient surgery settings can perform identical types of surgical procedures. This significant difference in the percentage of deficiency-free surveys raises questions about the equity of oversight in the two types of settings:

- Are outpatient settings regulated by the MBC simply better in terms of compliance with minimum standards?
- Are accreditation standards for outpatient settings "easier" to meet than standards for ambulatory surgery centers?
- Are there differences in the rigor of surveys conducted by accrediting agencies and surveys conducted by CDPH?
- Are outpatient settings that are accredited providing better care than settings that are not accredited?

These questions do not lend themselves to simple answers, but may indicate an inequity in oversight by different agencies responsible for oversight.

As shown in Table 6, CDPH cited, on average, a higher number of deficiencies per ASC survey than the national average, according to CMS data.

Table 6. Number of Deficiencies per ASC Survey

FEDERAL FISCAL YEAR	AVERAGE NUMBER OF DEFICIENCIES CITED PER SURVEY	
	NATIONWIDE	CALIFORNIA
2011	5.3	8.4
2012	5.2	9.5
2013	5.2	7.5

Consequences of Serious Violations

The consequences of violating minimum standards vary with the severity of the violation and whether the provider is able to correct the deficient practice. All deficient practices must be corrected and the provider must submit an acceptable Plan of Correction. The oversight agency has the authority to conduct a revisit to verify that the deficient practice has been corrected. Beyond that, the consequences of serious violations or inability to correct serious deficiencies can result in terminating Medicare and/or Medi-Cal certification, revoking a license, or denying, suspending, or revoking accreditation.

The overwhelming majority of outpatient settings are able to correct serious deficient practices. For ambulatory surgery centers and outpatient settings regulated by the MBC, Table 7 shows the consequences of the most serious violations.

Reporting Adverse Events, Health-Acquired Infections, and Other Data

All categories of hospitals and outpatient settings must all report adverse events as defined in state law. ASCs or clinics that are not also regulated by the MBC are not required to report adverse events. These are events that are considered to be

Table 7. Consequences of Serious Violations

NUMBER OF FACILITIES WITH:	AMBULATORY SURGERY CENTERS* (OUT OF 740)	OUTPATIENT SETTINGS REGULATED BY THE MBC† (OUT OF 938)
Conditions of participation not met	210	N/A
Involuntary termination of Medicare/Medi-Cal certification	16	N/A
Accreditation denied	N/A	3
Accreditation suspended	N/A	195
Accreditation revoked	N/A	16

*Over a three-year period: 2011 through 2013. During this period there were 24 ASCs that voluntarily terminated certification.

†From 2010 through September 2014.

preventable and may indicate serious quality of care issues in the facility. Not all states require adverse event reporting. Even though most state dental boards do not regulate outpatient settings, 38 states do require dentists to report some types of adverse events related to the administration of anesthesia and sedation to the dental board. In California, dentists are not required to report such events. While only two state podiatry boards regulate outpatient surgery settings, no states require reporting of adverse events to the podiatry board.

The criterion for adverse event reporting was designed for hospital-based services and does not entirely account for events that might occur in outpatient settings. Many states require outpatient surgery settings to report surgery-related events that result in

an unanticipated transfer to a hospital, but California does not include this criterion.

Infections that are acquired in health care settings can be a significant indication of quality problems. In California, only hospitals are required to report health-acquired infections. Because hundreds of outpatient settings are no longer mandated to report patient encounter and financial data to OSHPD, there has been a significant decrease in the information publically available about patient outcomes, the types of procedures performed, payment for procedures, and other important utilization data. This information is essential to California decisionmakers and stakeholders for identifying the type and quality of care provided by this major segment of the health care delivery system.

Conclusion

This examination of California's outpatient surgery settings suggests that there is a need for more consistent oversight, better communication and coordination among regulators, and more information about quality available to the public. Specifically, facilities in which the same types of outpatient surgical procedures are performed should have:

- The same or equivalent minimum standards
- Equity in oversight and accountability
- Public availability of information about compliance with minimum standards
- Mechanisms for the public and health policy decisionmakers to compare the quality of care being provided in each of those settings

The movement of surgical services out of inpatient settings is going to continue, and this trend can serve the Triple Aim national policy goals of lowest cost, most convenience, and highest quality of care. But regulatory infrastructure must keep pace with the national policy goals. In California, outpatient surgery settings require the short-term and ongoing attention from health policy decisionmakers and lawmakers. At the same time, the public needs to have assurances that the state's outpatient settings are operating in a consistently safe manner.

About the Author

Brenda G. Klütz is managing principal of B & R Klütz Consulting, which specializes in public health policy and regulatory compliance. She has more than 30 years of California state administrative, legislative, and health policy experience. Klütz previously served as deputy director of the Licensing and Certification Program for the former California Department of Health Services.

About the Foundation

The California HealthCare Foundation (CHCF) is leading the way to better health care for all Californians, particularly those whose needs are not well served by the status quo. We work to ensure that people have access to the care they need, when they need it, at a price they can afford.

CHCF informs policymakers and industry leaders, invests in ideas and innovations, and connects with changemakers to create a more responsive, patient-centered health care system.

For more information, visit www.chcf.org.

Endnotes

1. See California HealthCare Foundation's *Ambulatory Surgery Centers: Big Business, Little Data*, June 2013, www.chcf.org.
2. See California HealthCare Foundation's *Outpatient Surgery Services in California: Oversight, Transparency, and Quality*, June 2015, www.chcf.org.
3. California Health and Safety Code, Division 2, Chapter 1.3., Sections 1248 through 1248.75. See: leginfo.legislature.ca.gov.
4. SB 100 (Price), Chapter 645, Statutes of 2011.
5. See note 2.
6. If a complaint is filed against an ASC with deemed status and a CDPH investigation suggests that federal conditions of participation may not be met, it follows a protocol for requesting a "complaint validation survey" of the facility. If the deficiency is confirmed, the ASC loses its deemed status until it corrects the deficient practice.