

Who can do what where? California Law and Ambulatory Surgery Centers

The recent history of ambulatory surgery center regulation in California is confusing, to say the least. Are ambulatory surgery centers (ASC's) required to be licensed? Accredited? Certified? What's the difference? Who can do what where?

1. Licensing

Licensing refers to the issuance of a state license permitting the operation of a surgery center. Until 2008, the California Department of Public Health (CDPH) and, before 2007, its predecessor agency, the California Department of Health Services (DHS), issued ASC licenses to nearly 500 ASC's.[\[1\]](#)

In 2007, however, a physician challenge to the licensing requirement led to a California Court of Appeal decision that ended state licensure for physician-owned ASC's. The physician, Dr. Capen, sought to open a surgery center that he would own and lease to other physicians. He contended that his surgery center was not required to be licensed because he qualified for the exception in California Health & Safety Code Section 1204, Subsection (b)(1) as a physician-owned clinic. Section 1204 mandated that California ASC's meet licensing requirements and obtain surgical clinic licenses, with limited exceptions for physician-owned or physician-leased clinics. The Department took the position that the clinic required licensure because its use by non-owner leasing physicians made the exception inapplicable.

After the trial court voided the Department's interpretation on administrative procedure grounds and the Department appealed, the Court of Appeal issued its decision in favor of the physician. *Capen v. Shewry* (2007) 155 Cal.App.4th 378. The court found administrative rule-making to be unnecessary based on the existing statutes, stripping the Department of authority to promulgate regulations defining which clinics were subject to licensure. According to the decision, the Department lacked authority to license a surgical clinic, if a physician or group of physicians owns the clinic in whole or in part.

In the aftermath of the *Capen v. Shewry* decision, CDPH took the position that it had no jurisdiction over physician-owned ASC's, and stopped issuing new licenses to all but a handful of non-physician owned ASC's. As ASC licenses expired, CDPH would not renew them. This places California at odds with most other states, which license ASC's.

In the aftermath of several highly publicized cases of patient safety issues, including one in which Donda West, the mother of rapper Kanye West, died following complications at a surgery center, there have been several proposed bills to mandate licensure of physician-owned ASC's or, alternatively, to limit the procedures that physicians may perform in an unlicensed ASC. To date, all such efforts have failed. As a result, only a handful of non-physician owned ASC's are licensed by the State of California.

2. Certification

Certification is a voluntary procedure by which the Center for Medicare and Medicaid Services (CMS) confirms that ASC's meet the requirements to be reimbursed for treatment of Medicare beneficiaries. In order for procedures performed in ASC to be reimbursed by Medicare, an ASC must be certified and approved to enter into a written agreement with CMS. Medicare certification is limited to ASC's that provide outpatient services to patients with an expected stay in the ASC less than 24 hours. California ASC's that do not seek reimbursement from Medicare are not required to be certified.

In order to be Medicare-certified, an ASC is required to comply with federal standards (located at 42 CFR Part 416) regulating patient safety, as well as the quality of the center, its physician medical staff, and all aspects of its operations. ASC's are required to demonstrate compliance with Medicare standards in order to be certified, and then are required to be surveyed on at least a triennial basis to maintain certification.

As a result of the limited resources that Medicare dedicates to review ASC's, much of the review process necessary for

certification has been effectively delegated to state agencies and private accreditation agencies. As described under “Accreditation” below, ASC’s may attain and maintain Medicare participation through accreditation by a CMS-approved accrediting organization. Typically, after being accredited, an ASC that seeks Medicare certification is required to notify its state survey (in California, CDPH) of its deemed status and interest in certification.

Despite its decision to “stand down” on licensing of physician-owned ASC’s, CDPH continues to perform a limited number of Medicare certification surveys for unlicensed ASC’s. Although in theory ASC’s can be certified without being accredited, the process can be extremely slow and contingent upon a demonstrated need for Medicare beneficiary access, and is not recommended.

3. Accreditation

Accreditation is a voluntary process of reviewing and approval by an independent accrediting organization that confirms via onsite inspections that an ASC meets specific standards of patient safety and quality of care.

Medicare has recognized four accreditation organizations that meet or exceed Medicare standards: (1) the Joint Commission on Accreditation of Healthcare Organizations (the “Joint Commission,” formerly JCAHO); (2) the Accreditation Association for Ambulatory Health Care (AAAHC); (3) the American Association for the Accreditation of Ambulatory Surgery Facilities (AAAASF); and (4) the American Osteopathic Association (AOA). ASC’s accredited by the foregoing organizations are official “deemed” to meet Medicare conditions of coverage (CFC’s) for ASC’s. For ASC’s that seek accreditation without requiring Medicare certification, the state Institute For Medical Quality (IMQ) also offers accreditation.

All accrediting organizations require ASC’s to undergo survey and re-accredit every 3 years. Accreditation organizations typically update their standards to push for continuous quality and safety improvements, as well as to meet regularly changing regulatory requirements.

4. Do unlicensed ASC’s need to be accredited or certified?

Accreditation or certification is not required for all unlicensed surgery centers. California law mandates that unlicensed ASCs be accredited only if they treat patients with general anesthesia. (California Health & Safety Code Section 1248.1.) No accreditation is needed for outpatient ASC’s that operate strictly with local anesthesia or peripheral nerve blocks. (Business & Professions Code Section 2216.) Nor is accreditation required for clinics that use strictly anxiolytics (e.g. Xanax) and analgesics, provided their use is within community standards and at dosage levels that do not place patients at risk for loss of life-preserving protective reflexes.

As a result, many unlicensed, uncertified, and unaccredited ASC’s and medical offices lawfully perform a wide ranges of procedures in California. In response, California has enacted a number of laws that restrict ASC’s. For example, in 2009, the Donda West Law was enacted, which requires an appropriate physical examinations and medical clearance in advance of surgical procedures. (Business & Professions Code Sections 1638.2 and 2259.8.) In October 2011, California enacted Senate Bill 100, which tightens requirements for accredited ASC’s and prohibits ASC’s that lose accreditation from simply re-accrediting with a different agency. In addition, many procedures performed in unaccredited ASC’s, such as liposuction, have detailed and specific regulations as to how they are performed.

The oversight and regulatory compliance issues for ASC’s in California are confusing. It is anticipated that more legal and regulatory changes are ahead, as the State grapples with the challenge of balancing patient safety and provider rights.

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[1] The CDPH was formed in 2007, when California split the former California Department of Health Services into two agencies, CDPH, which oversees health facility licensure and public health matters, and the Department of Health Care Services (DHCS), which oversees the Medi-Cal Program.