

California Tightens Accreditation Requirements for Surgery Centers

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Effective January 1, 2012, California law will impose additional requirements on the accreditation of ambulatory surgery centers. The same bill, SB 100, also addresses the issue of physician supervision of cosmetic laser procedures performed by non-physicians.

Licensure Limbo

For several years now, California surgery centers owned in whole or in part by physicians have been in a licensure limbo. Notwithstanding that California Health & Safety Code § 1204(b) provides: "physicians or dentists may, at their option, apply for licensure" of a surgical clinic, even though such clinics operated by physicians are not required to be licensed, the California Department of Public Health has declined to issue them licenses since early 2008. The DPH's position is based on its interpretation of *Capen v. Shewry* (2007) 155 Cal.App.4th 378, which the DPH reads as completely removing from its jurisdiction any ambulatory surgery center in California that has any physician ownership. The DPH has maintained this position even though no language of the *Capen* decision requires it or even suggests it.

Since early 2008, California surgery centers owned in whole or in part by physicians, even surgery centers that were previously licensed under the authority of Health & Safety Code § 1204(b), have been unable to renew their licenses and could not obtain a state surgical clinic license. Instead, the DPH decreed that such surgical clinics were the responsibility of the California Medical Board to regulate. Since that time, the California Medical Board has not assumed the mantle of regulating the surgical clinics, and the vast majority of California ASC's have operated based on Medicare certification and accreditation by one of three recognized accrediting bodies for surgery centers.

Regulation of "Outpatient Settings"

On October 9, 2011, Governor Brown signed SB 100, which approaches regulation of surgical clinics not through licensure but through an independent regulatory scheme under the Health & Safety Code: that of "outpatient settings." Under California law, ambulatory surgery centers are defined as "surgical clinics" and are subject to licensure (or are exempt from licensure) under the clinic licensure provisions of § 1204. In addition, any surgery center that employs general anesthesia, rather than merely conscious sedation, is subject to regulation as an "outpatient setting."

In order to function as an outpatient setting, an ambulatory surgical center must be Medicare-certified, licensed under §1204 of the Health & Safety Code or accredited by an approved accreditation agency. Therefore, because surgery centers that have physician

owners cannot now obtain a license under §1204, they must be either Medicare-certified or accredited. To the extent that any surgery center is Medicare-certified but not also accredited (because accreditation is not a legal requirement for such surgery centers), SB 100 does not affect it. However, many surgery centers find it useful to be both Medicare-certified and accredited, and they will therefore be subject to SB 100 like any other accredited surgery center.

Additional Accreditation Standards

SB 100 applies additional standards to the accreditation prong of this regulatory scheme. Existing law, at Health & Safety Code § 1248.15 already required the California Medical Board to adopt standards for accreditation and the accreditation agencies. In order to address perceived shortcomings in the existing regulatory scheme, SB 100 imposes additional requirements to be satisfied in the accreditation process. For example, § 1248.15 now requires each outpatient setting to submit at the time of accreditation a detailed plan, standardized procedures and protocols to be followed in the event of serious complications or side effects from surgery that would place a patient at high risk for injury or harm. The plan is required to include, at a minimum, that in the event of transfer to a local licensed acute care hospital, the outpatient setting must do all of the following: notify the individual designated by the patient to be notified; insure that the mode of transfer is consistent with the patient's medical condition; insure that all relevant clinical information is documented and accompanies the patient; and continue to provide appropriate care to the patient until the transfer is completed. In addition, any outpatient setting that maintains multiple service locations must have all of the sites inspected as part of its accreditation. Previously, multiple site inspections were at the option of the outpatient setting. SB 100 also directed the Medical Board to adopt standards for outpatient settings that offer in vitro fertilization.

Prior law permitted the accreditation agency and the Medical Board to inspect outpatient settings. Under SB 100, every outpatient setting that is accredited is required to be inspected by the accreditation agency and may also be inspected by the Medical Board. Inspections are required to be conducted no less often than once every three years by the accreditation agency and as often as necessary by the Medical Board to insure that quality of care is provided. Further, the statute specifically provides that the Medical Board or the accreditation agency may "enter and inspect any outpatient setting that is accredited by an accreditation agency at any reasonable time to insure compliance with, or investigate an alleged violation of, any standard of the accreditation agency."

If an accreditation agency determines, as a result of its inspection, that an outpatient setting is not in compliance, it can require correction of any identified deficiencies within a specified time frame. This ability to require a plan of correction is new. Previously, the accreditation agency could only issue a reprimand, place the outpatient setting on probation or suspend or revoke the outpatient setting's certification or accreditation. Under SB 100, the plan of correction is an interim step. If an outpatient setting does not comply with the corrective action, the accrediting agency is required to issue a reprimand and may either place the outpatient setting on probation or suspend or revoke its accreditation. In addition, the accreditation agency must report to the Medical Board if the outpatient setting has been issued a reprimand or if the outpatient setting certification has been suspended or revoked.

Public Information

SB 100 also made a number of changes intended to insure that the public has complete and up-to-date information on outpatient settings. Health & Safety Code § 1204.2 previously required the Medical Board to post on its website information regarding outpatient settings, including whether an outpatient setting is accredited or whether the setting's accreditation has been revoked or suspended. SB 100 added a requirement to inform the public if an outpatient setting has been placed on probation or the setting has received a reprimand by the accreditation agency.

In addition, the list of outpatient settings posted on the Medical Board website is required to include all of the following information:

- Name,
- Address,
- Telephone number of any owners and their medical license numbers,
- Name and address of the facility,
- Name and telephone number of the accreditation agency,
- The effective and expiration dates of the accreditation.

Accrediting agencies approved by the Board are required to notify the Medical Board and update the Medical Board on all outpatient settings that they accredit. Accreditation agencies now have a requirement to report within three business days to the Medical Board if an outpatient setting's certificate for accreditation has been denied.

If the accreditation agency receives a complaint from the Medical Board that an outpatient setting poses an immediate risk to public safety, it is required to inspect the outpatient setting and report its findings to the Medical Board within five business days. If the accreditation agency receives any other complaint from the Medical Board, it is required to investigate the outpatient setting and report its findings of investigation to the Board within thirty days. Reports on the results of any such inspections are required to be kept on file with the Medical Board and the accreditation agency. All final inspection reports, which include the list of deficiencies, plans of correction or requirements for improvements

and correction, and corrective action completed, are public records and are open to public inspection.

SB 100 also took steps to prevent "accreditation shopping." It provides that if one accrediting agency denies accreditation or revokes or suspends the accreditation of an outpatient setting, the action shall apply to all other accrediting agencies. An outpatient setting that is denied accreditation is permitted to reapply for accreditation with the same accreditation agency. The outpatient setting may also apply for accreditation from another accreditation agency but only if it discloses the full accreditation report that denied accreditation. The statute requires the new accrediting agency to insure that all deficiencies have been corrected and to conduct a new onsite inspection consistent with the standards specified in the statute. Further, if an outpatient setting's accreditation has been suspended or revoked or if the accreditation has been denied, the accreditation agency is required to notify the Medical Board of the action, send a notification letter to the outpatient setting (which letter must advise the outpatient setting that it may no longer perform procedures that require outpatient setting accreditation, i.e. general anesthesia) and required outpatient setting to post the notification letter in a conspicuous location accessible to public view.

Complaints to be Investigated

The Medical Board is charged with investigating all complaints concerning a violation of the outpatient setting requirements. Where appropriate, the Medical Board, through or in conjunction with the local district attorney, is directed to bring an action to enjoin the outpatient setting's operation.

Physician Supervision of Laser Procedures

In addition to the changes outlined above with respect to outpatient settings, SB 100 also addresses physician supervision of the use of laser or intense light pulse devices for elective cosmetic procedures, including laser hair removal. In connection with these procedures, SB 100 requires the Medical Board to adopt regulations by January 1, 2013 regarding the appropriate level of physician availability needed within clinics or other settings using laser or intense pulse light devices for elective cosmetic procedures.



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