

## *California Passes Law to Increase Medical Board Oversight of Accredited Ambulatory Surgery Centers*

On October 9, Governor Jerry Brown signed S.B. 100, enacting a new law that tightens scrutiny of California ambulatory surgery centers through increased oversight by the Medical Board of California (the Medical Board) and its approved accrediting agencies. Under the new law, which goes into effect January 1, 2012, accredited outpatient surgery centers will be subject to increased investigation, increased accountability for adverse actions, heightened requirements for obtaining and maintaining accreditation, and heightened consequences for accreditation violations.

In California, physicians are only permitted to perform surgery using general anesthesia in an outpatient setting if the setting is licensed by the California Department of Public Health (CDPH), certified by Medicare, or accredited by an accrediting agency approved by the Medical Board. Historically, all ambulatory surgery centers (ASCs), other than those operated by physicians or medical groups in their own offices, were required to be licensed by CDPH. However, following a 2007 Court of Appeals decision in *Capen v. Shewry*, CDPH took the position that it no longer had the authority to license ASCs with any physician ownership at all, and began declining to renew the licenses of ASCs with any physician ownership.

CDPH deferred regulation of these sites to the Medical Board, which is responsible for overseeing the accreditation process for ASCs and approving agencies to grant accreditation. As a result, many physician-owned ASCs have obtained and maintained accreditation in order to operate in California. Although there are California statutes that provide for Medical Board oversight over the accreditation process for ASCs, accredited ASCs have not historically been as closely scrutinized as licensed ASCs.

This lower level of regulatory oversight for accredited sites, which was highlighted by the

occurrence of a number of highly publicized deaths that occurred in accredited ASCs in recent years, was a driving force for this new law, which revises existing law to strengthen accreditation standards and give the Medical Board a more active role in overseeing ASCs. As a result of this new law, ASCs can expect the Medical Board and the accrediting agencies they approve to more closely monitor their operations, as described in detail below.

### **Increased Investigation**

Under the new law, accrediting agencies are now required to conduct a reasonable investigation of the prior history of ASCs, as well as of their physician owners, to determine whether there have been any adverse accreditation decisions made against them. This investigation process will involve querying the Medical Board and the Osteopathic Medical Board of California, as appropriate, to inquire whether the ASC or any of the physician owners have been subject to any adverse accreditation decisions.

Further, under prior law the Medical Board and the approved accrediting agencies were permitted, upon reasonable prior notice and presentation of identification, to enter and inspect any accredited ASC to ensure compliance with, or investigate an alleged violation of, any standards of the accrediting agency or any provision of the relevant laws. Under the new law, every ASC that is accredited must be inspected by the accrediting agency at least once every three years, and may also be inspected by the Medical Board as often as necessary to ensure the quality of care being provided. In addition, the notice and identification requirements have been eliminated, so that the Medical Board and accrediting agencies can now perform unannounced inspections of accredited ASCs as they deem necessary. The new law also requires ASCs with multiple service locations to have all sites surveyed for accreditation purposes, whereas the previous law allowed ASCs to elect to only have a sample of their sites surveyed.

### **Increased Transparency for Accreditation Status**

Under prior law, the Medical Board was required to obtain and maintain a list of all accredited, certified and licensed ASCs and to notify the public, upon inquiry, about the ASC's accreditation, certification or licensure status. Under the new law, the Medical Board is required to obtain and maintain a list of all accredited ASCs and to post accreditation status information (i.e. whether the ASC's accreditation is active or whether it has been revoked, suspended, placed on probation, or the setting has received a reprimand) on its website.

The new law also limits the ability of ASCs to re-apply for accreditation after being initially denied. Under prior law, accreditation could be denied if an ASC did not meet specified standards, but the ASC could reapply for accreditation at any time after receiving notice of denial, without limitation. As a result, an ASC could immediately "shop" for a new

accrediting agency following a denial decision, without revealing the denial to the new agency.

Under the new law, the denial of accreditation, or the revocation or suspension of accreditation by an accrediting agency, is applicable to all other approved accrediting agencies as well. Thus, when an ASC is denied accreditation by one accrediting agency, it may still re-apply for accreditation from the same agency, or it may apply for accreditation from another accrediting agency, but only if it discloses the full accreditation report of the accrediting agency that denied accreditation.

Under those circumstances, the new accrediting agency is required to ensure that all deficiencies have been corrected and conduct a new onsite inspection prior to granting accreditation. Further, in the case of denials, the accrediting agencies are now required to report to the Medical Board within three business days if an ASC's accreditation certificate has been denied.

### **Heightened Requirements for Obtaining and Maintaining Accreditation**

While prior law required the Medical Board to adopt standards for accreditation of ASCs, and in approving agencies to perform this accreditation, to ensure that the accreditation programs included standards for specified aspects of the ASC's operation, the new law specifically requires ASCs seeking accreditation to submit to the agency a detailed plan, standardized procedures, and protocols to be followed in the event of serious complication or side effects from surgery.

The new law also allows an accrediting agency that determines that an accredited ASC is not in compliance with the standards to require correction of any identified deficiencies within a set timeframe. The failure to comply within that time frame will result in reprimand suspension or revocation of the ASC's accreditation. Further, before suspending or revoking a certificate of accreditation, an accrediting agency is required to provide the ASC with the opportunity to agree with the accrediting agency on a plan of correction that gives the ASC reasonable time to supply information demonstrating compliance with the standards of the accrediting agency, or to request a hearing on the matter. During the allotted time, the ASC must post the plan of correction in a location accessible to public view. Within ten days of the adoption of the plan of correction, the accrediting agency must send the list of deficiencies and the corrective action plan to the Medical Board.

If the ASC does not comply with a corrective plan within the specified time frame, the accrediting agency must issue a reprimand and either place the setting on probation or suspend or revoke the accreditation. Further, the agency must report to the Medical Board within twenty-four hours if the ASC's accreditation has been suspended or revoked or if the ASC has been placed on probation.

In addition, if an accrediting agency receives a complaint from the Medical Board that an ASC poses an immediate risk to public safety, it must now investigate the ASC and report its findings of the investigation to the Medical Board within five days. If an accrediting agency receives any other type of complaint from the Medical Board that does not constitute an immediate risk to public safety, it must investigate the ASC and report its findings of investigation to the Medical Board within thirty days.

### **Heightened Consequences for Accreditation Violations**

While prior law authorized the Medical Board or the local district attorney to bring an action to enjoin a violation or threatened violation of the relevant statutory provisions, the new law requires the Medical Board to investigate all complaints concerning violations of the relevant statutes. Further, with respect to any complaints relating to a violation of a certain provision of the law, or upon discovery that the ASC is not in compliance with that provision the Medical Board is now required to investigate, and where appropriate, to bring an action to enjoin the ASC's operation.

Finally, the new law does not provide for increased funding to the Medical Board, so it is unclear where the Board will obtain the resources necessary to undertake this amplified role in overseeing accreditation.

Unlicensed, accredited ASCs should familiarize themselves with the heightened requirements for obtaining and maintaining accreditation under this new law. For more information, please contact [David Henninger](#), [David Hatch](#), [Hope-Levy Biel](#) or [Nina Adatia](#) in the Los Angeles office at 310.551.8111; [Steve Phillips](#) in the San Francisco office at 415.875.8500, or [Kitty Juniper](#) in the San Diego office at 619.744.7300.

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