California Accredited Outpatient Setting Change re: Adverse Event Reporting
Effective January 1, 2014:

Governor Edmund G. Brown Jr. signed into law Senate Bill (SB) 304 (Lieu, Chapter 515, Statutes of 2013), which requires an outpatient surgery setting, accredited pursuant to Section 1248.1 of the Health and Safety Code, to report an adverse event to the Medical Board of California (Board). This change in adverse event reporting requirements will take effect January 1, 2014.

Prior to the passage of SB 304, these accredited outpatient surgery settings were required to report adverse events, as defined in California Health and Safety Code (HSC) Section 1279.1, to the California Department of Public Health.

Beginning, January 1, 2014, an accredited outpatient surgery setting will be required to report adverse events, as defined in HSC Section 1279.1, to the Board:
1. no later than five days after the adverse event has been detected; or
2. if that event is an ongoing urgent or emergent threat to the welfare, health, or safety of patients, personnel, or visitors, no later than 24 hours after the adverse event has been detected.

The definition of an adverse event includes but is not limited to the following:
1. Surgery performed on a wrong body part
2. Surgery performed on the wrong patient
3. The wrong surgical procedure performed on a patient
4. Retention of a foreign object in a patient after surgery or other procedure
5. 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
6. Patient death or serious disability associated with the use of a contaminated drug, device, or biologic provided by the health facility
7. A patient death or serious disability associated with a medication error
8. A patient death or serious disability associated with a burn incurred from any source while being cared for in a health facility

The Board has established the "ADVERSE EVENT REPORTING FORM FOR ACCREDITED OUTPATIENT SURGERY SETTINGS" to be completed and submitted to the Board to fulfill this new reporting requirement as specified in Business and Professions Code Section 2216.3.

If an accredited outpatient surgery setting fails to report an adverse event, the Board may assess a civil penalty in an amount not to exceed one hundred dollars ($100) for each day that the adverse event is not reported following the initial five-day period or 24-hour period, as applicable.

A copy of the letter, the reporting form, and the Senate Bill can be accessed via the Medical Board’s Web site at http://www.mbc.ca.gov/outpatient_surgery.html.

The full text of HSC 1279.1 can be found at http://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?lawCode=HSC&sectionNum=1279.1.

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