



MEDICAL BOARD OF CALIFORNIA

Executive Office



December 29, 2017

To: Outpatient Surgery Settings Accreditation Agencies

Subject: Senate Bill (SB) 798: Adverse Event Reporting Requirements

Authority: Business and Professions Code section 2216.3

Effective January 1, 2018, Senate Bill (SB) 798, (Hill, Chapter 775), redefines the requirements for adverse events reported by outpatient surgery settings to the Medical Board of California (Board).

The intent of this letter is to provide accreditation agencies information regarding amendments to the statutes and to ensure all facilities are properly noticed and will implement the prescribed changes.

Existing law provides that California Accredited Outpatient Settings shall “report an adverse event to the board no later than five days after the adverse event has been detected, or, if that event is an ongoing urgent or emergent threat to the welfare, health, or safety of patients, personnel, or visitors, not later than 24 hours after the adverse event has been detected.” Existing law also requires outpatient settings to notify the patient or individual responsible for the patient of the adverse event by the time the report is made.

Existing law under [Business and Professions Code \(BPC\) section 2216.3](#) defines “adverse event” as having the same meaning as in subdivision (b) of Section 1279.1 of the Health and Safety Code (HSC). HSC section 1297.1, however, was written to apply to general acute care hospitals and other facilities, as opposed to outpatient surgery settings. Accordingly, this bill makes changes to BPC section 2216.3 (see attached section) to clarify the adverse event reporting requirements for outpatient surgery settings. While the new reporting requirements are very similar to existing law, there are some differences. The Board encourages responsible parties at outpatient surgery settings and the accrediting agencies to review the changes to BPC section 2216.3, and ensure steps are taken to comply with the reporting requirements effective January 1, 2018. Some of the changes to BPC section 2216.3 are included below:

1. New Reporting Requirement:

- Subsection (b)(1)(f) adds the transfer of a patient to a hospital or emergency center for medical treatment for a period exceeding 24 hours following a scheduled procedure outside of a general acute care hospital to the list of adverse events.

2. New Definition:

- Subsection (e) defines “surgical or other invasive procedures” as operative procedures in which skin or mucous membranes and connective tissue are incised or an instrument is introduced through a natural body orifice. They include all procedures described by the codes in the surgery section of the Current Procedural Terminology. This definition is relevant to reporting requirements under subsection (b) (1).

3. The following adverse events have been eliminated for reporting by outpatient surgery settings:

- Patient death or serious disability associated with patient disappearance for more than four hours, excluding events involving adults who have competency or decisionmaking capacity. (HSC section 1279.1(b)(3)(B)).
- Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a facility, including events that occur within 42 days postdelivery and excluding deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy, or cardiomyopathy. (HSC section 1279.1(b)(4)(C)).
- Death or serious disability, including kernicterus, associated with failure to identify and treat hyperbilirubinemia in neonates during the first 28 days of life. For purposes of this subparagraph, “hyperbilirubinemia” means bilirubin levels greater than 30 milligrams per deciliter. (HSC section 1279.1(b)(4)(E)).
- A Stage 3 or 4 ulcer, acquired after admission to a health facility, excluding progression from Stage 2 to Stage 3 if Stage 2 was recognized upon admission. (HSC section 1279.1(b)(4)(F)).

In addition to those changes described above, there are several technical changes to the language to make the description of adverse events more consistent with outpatient surgery setting environments.

The Board has updated the “Adverse Event Reporting Form for Accredited Outpatient Surgery Settings” (enclosed), which is available on the Board’s website at:

http://www.mbc.ca.gov/Consumers/Outpatient_Surgery/outpatient_adverse_event_form.pdf. This form is to be completed and submitted to the Board to fulfill this new reporting requirement as specified in BPC section 2216.3.

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The Board is requesting all accrediting agencies to notify the outpatient surgery settings about the new provisions as described above and include a copy of the newly revised form no later than January 15, 2018.

Should you have further questions or concerns, please contact April Alameda, Chief of Licensing at telephone number (916) 263-2348 or via email at April.Alameda@mbc.ca.gov.

Sincerely,

A handwritten signature in blue ink that reads "Kimberly Kirchmeyer". The signature is written in a cursive style.

Kimberly Kirchmeyer
Executive Director