Business and Professions Code section 2216.3.

(a) An outpatient setting accredited pursuant to Section 1248.1 of the Health and Safety Code 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. Disclosure of individually identifiable patient information shall be consistent with applicable law.

(b) For the purposes of this section, "adverse event" includes any of the following:

(1) Surgical or other invasive procedures, including the following:

(A) Surgical or other invasive procedure performed on a wrong body part that is inconsistent with the documented informed consent for that patient. A reportable event under this subparagraph does not include a situation requiring prompt action that occurs in the course of surgery or a situation that is so urgent as to preclude obtaining informed consent.

(B) Surgical or other invasive procedure performed on the wrong patient.

(C) The wrong surgical or other invasive procedure performed on a patient, which is a procedure performed on a patient that is inconsistent with the documented informed consent for that patient. A reportable event under this subparagraph does not include a situation requiring prompt action that occurs in the course of surgery, or a situation that is so urgent as to preclude the obtaining of informed consent.

(D) Retention of a foreign object in a patient after surgery or other procedure, excluding objects intentionally implanted as part of a planned intervention and objects present prior to surgery that are intentionally retained.

~~(E) Death of a patient during or up to 24 hours after admittance of a patient to an outpatient~~ setting that follows induction of anesthesia after surgery of a normal, healthy patient who has no organic, physiologic, biochemical, or psychiatric disturbance and for whom the pathologic processes for which the operation is to be performed are localized and do not entail a systemic disturbance.

(F) 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, as defined in subdivision (a) of Section 1250 of the Health and Safety Code.

(2) Product or device events, including the following:

(A) Patient death or serious disability associated with the use of a contaminated drug, device, or biologic provided by the outpatient setting when the contamination is the result of generally detectable contaminants in the drug, device, or biologic, regardless of the source of the contamination or the product.

(B) Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended. For purposes of this subparagraph, "device" includes, but is not limited to, a catheter, drain, or other specialized tube, infusion pump, or ventilator.

(C) Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in an outpatient setting, excluding deaths associated with neurosurgical procedures known to present a high risk of intravascular air embolism.

(3) Patient protection events, including the following:

(A) A minor discharged to the wrong person.

(B) A patient suicide or attempted suicide resulting in serious disability while being cared for in an outpatient setting due to patient actions after admission to the outpatient setting.

(4) Care management events, including the following:

(A) A patient death or serious disability associated with a medication error, including, but not limited to, an error involving the wrong drug, the wrong dose, the wrong patient, the wrong time, the wrong rate, the wrong preparation, or the wrong route of administration, excluding reasonable differences in clinical judgment on drug selection and dose.

(B) A patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products.

(C) Patient death or serious disability directly related to hypoglycemia, the onset of which occurs while the patient is being cared for in an outpatient setting.

(D) A patient death or serious disability due to spinal manipulative therapy performed at the outpatient setting.

(5) Environmental events, including the following:

(A) A patient death or serious disability associated with an electric shock while being cared for in an outpatient setting, excluding events involving planned treatments, such as electric countershock.

(B) Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by a toxic substance.

(C) A patient death or serious disability associated with a burn incurred from any source while being cared for in an outpatient setting.

(D) A patient death associated with a fall while being cared for in an outpatient setting.

(E) A patient death or serious disability associated with the use of restraints or bed rails while being cared for in an outpatient setting.

(6) Criminal events, including the following:

(A) Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider.

(B) The abduction of a patient of any age.

(C) The sexual assault on a patient within or on the grounds of an outpatient setting.

(D) The death or significant injury of a patient or staff member resulting from a physical assault that occurs within or on the grounds of an outpatient setting.

(7) An adverse event or series of adverse events that cause the death or serious disability of a patient, personnel, or visitor.

(c) The outpatient setting shall inform the patient or the party responsible for the patient of the adverse event by the time the report is made.

(d) "Serious disability" means a physical or mental impairment that substantially limits one or more of the major life activities of an individual, or the loss of bodily function, if the impairment or loss lasts more than seven days or is still present at the time of discharge from an inpatient health care facility, or the loss of a body part.

(e) "Surgical or other invasive procedures" are defined for the purposes of this section 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.

MEDICAL BOARD OF CALIFORNIA

ADVERSE EVENT REPORTING FORM FOR ACCREDITED OUTPATIENT SURGERY SETTINGS

Business and Professions Code (B&P) section 2216.3 makes accredited outpatient surgery settings subject to adverse events reporting requirements as follows:

- Facilities shall report an adverse event 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, **no later than 24 hours** after the adverse event has been detected.

Facility Information		
Facility Name:		
Facility Address:		
Contact Person Preparing Report:		
Contact Phone Number:		
Practitioner Information		
Name of Practitioner Performing Procedure:		
License Type/ License Number:		
***Patient Information**		
Patient's Name: (Last, First, Middle)		
Patient's Address: (Street, City, State, Zip)		
Patient's DOB:	**Patient's Phone Number:**	**Medical Record Number:**
Patient Deceased? ☐ **Yes** ☐ **No**	**Patient's Next of Kin or Legal Representative (if applicable):**	

***Note**: Under the federal Health Insurance Portability and Accountability Act ("HIPAA") the Medical Board of California is deemed a "health oversight agency" (see 45 CFR 501). The disclosure of patient identification information is required for official use, including investigation and possible administrative proceedings regarding any violations of the laws of the State of California.

(REVISED 01/2018)

Adverse Event Information		
Type of Procedure Performed:		
Date and Time Event Occurred:	**Date and Time Event Detected:**	**Date of Report:**
Patient Transferred to Hospital? ☐ **Yes** ☐ **No**	**Name and address of hospital (if applicable):**	

Please check the appropriate Adverse Event Category. In addition, check the Adverse Event Detail from the options listed below. Please provide a description of the event in the Description of Event box on page 3.

☐ Surgical or Other Invasive Procedure	☐ Product/Device Event	☐ Patient Protection Event
☐ Care Management Event	☐ Environmental Event	☐ Criminal Event

ADVERSE EVENT DETAIL

(please check the appropriate box)

Surgical or Other Invasive Procedure*:

- ☐ Surgery or other invasive procedure performed on a wrong body part inconsistent with the documented informed consent.
- ☐ Surgery or other invasive procedure performed on the wrong patient.
- ☐ Wrong surgical or other invasive procedure performed on a patient.
- ☐ Retention of foreign object in a patient after surgery or other invasive procedure.
- ☐ Death during or up to 24 hours after induction of anesthesia in a normal, healthy patient.
- ☐ 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.
- ☐ Other (Include description in Description of Event box):

Product or device events:

- ☐ A patient death or serious disability** associated with the use of a contaminated drug, device, or biologic provided by the facility.
- ☐ A patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended. For purposes of this section, "device" includes, but is not limited to, a catheter, drain, or other specialized tube, infusion pump, or ventilator.
- ☐ A patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a facility, excluding deaths associated with neurosurgical procedures known to present a high risk of intravascular air embolism.
- ☐ Other (Include description in Description of Event box):

Patient protection events:

- ☐ A minor discharged to the wrong person.
- ☐ A patient suicide or attempted suicide resulting in serious disability while being cared for in a facility due to patient actions after admission to the facility.
- ☐ Other (Include description in Description of Event box):

* "Surgical or other invasive procedures" are defined for the purposes of this section 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.

** "Serious disability" means a physical or mental impairment that substantially limits one or more of the major life activities of an individual, or the loss of bodily function, if the impairment or loss lasts more than seven days or is still present at the time of discharge from an inpatient health care facility, or the loss of a body part.

ADVERSE EVENT DETAIL (cont.)

Care management events:

- ☐ A patient death or serious disability associated with a medication error, including, but not limited to, an error involving the wrong drug, the wrong dose, the wrong patient, the wrong time, the wrong rate, the wrong preparation, or the wrong route of administration.
- ☐ A patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products.
- ☐ Patient death or serious disability directly related to hypoglycemia, the onset of which occurs while the patient is being care for in an outpatient setting.
- ☐ A patient death or serious disability due to spinal manipulative therapy performed at the facility.
- ☐ Other (Include description in Description of Event box):

Environmental events:

- ☐ A patient death or serious disability associated with an electric shock while being cared for in a facility.
- ☐ Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by a toxic substance.
- ☐ A patient death or serious disability associated with a burn incurred from any source while being cared for in a facility.
- ☐ A patient death associated with a fall while being cared for in a facility.
- ☐ A patient death or serious disability associated with the use of restraints or bedrails while being cared for in a facility.
- ☐ Other (Include description in Description of Event box):

Criminal events:

- ☐ Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider.
- ☐ The abduction of a patient of any age.
- ☐ Sexual assault on a patient within or on the grounds of a facility.
- ☐ The death or significant injury of a patient or staff member resulting from a physical assault that occurred within or on the grounds of the facility.
- ☐ Other (Include description in Description of Event box):

Other:

- ☐ An adverse event or series of adverse events that cause the death or serious disability of a patient, personnel, or visitor (Include description in Description of Event box):

Description of Event:

Signature of Person Preparing Report **Date**

NOTE: Penalty for Failure to Report Adverse Event: Under BPC section 2216.4, if a setting fails to report an adverse event pursuant to B&P Section 2216.3, the Medical Board may assess a civil penalty in the amount not to exceed $100 for each day that the adverse event is not reported following the initial five-day period or 24-hour period, as applicable.

Mail completed form to:

Medical Board of California
ATTN: Ramona Carrasco
2005 Evergreen Street Suite 1200
Sacramento, CA 95815

For questions or additional information, please contact Ramona Carrasco at (916) 263-2452 or email **Ramona.Carrasco@mbc.ca.gov**.