

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				
Street Address	City		State	Zip Code
Contact Person Preparing Report		Contact Telephone Number		

ACCREDITING AGENCY				
Select one	AAAHC	AAAASF	JC	HFAP
and/or	CDPH/CMS			

PRACTITIONER INFORMATION		
Name of Practitioner Performing Procedure	License Type and Number	

*PATIENT INFORMATION					
Patient's Name - Last	First	Middle			Suffix
Patient's Street Address	City		State	Zip Co	ode
Patient's DOB	Patient's Phone Number		Medical Record Number		
Patient Deceased?  Yes No	Patient's Next of Kin or Legal Rep	resentative	(if applica	ble)	

\*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.

ADVERSE EVENT INFORMATION	1	
Type of Procedure Performed:		
Date and Time Event Occurred:	Date and Time Event Detected:	Date of Report:
Patient Transferred to Hospital?	Name and address of hospital (if	fapplicable):
Yes No		
	e Event Category. In addition, check the ption of the event in the Description of Ev	
Surgical or Other Invasive Procedu	ure Product/Device Event	Patient Protection Event
Care Management Event	Environmental Event	Criminal Event
ADVERSE EVENT DETAIL (please	check the appropriate box in each f	ollowing section)
Surgical or Other Invasive Procedu	re*:	
Surgery or other invasive procedure	e performed on a wrong body part inconsis	tent 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):

\* "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 (continued)
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):
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 cared for in an outpatient setting.
A patient death or serious disability due to spinal manipulative therapy performed at the outpatient setting.
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 an outpatient setting, excluding events involving planned treatments, such as electric countershock.
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 an outpatient setting.
A patient death associated with a fall while being cared for in an outpatient setting.
A patient death or serious disability associated with the use of restraints or bedrails while being cared for in an outpatient setting.
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 an outpatient setting.
The death or significant injury of a patient or staff member resulting from a physical assault that occurred within or on the grounds of an outpatient setting.
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 visito (Include description in Description of Event box):			
escription of Ev	ent:		

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 <u>Ramona.Carrasco@mbc.ca.gov</u>.