FORM 20-1

Adverse Event Report Form — *Sample*

[HOSPITAL LETTERHEAD]

(Must include hospital name and address elsewhere if this form is not reproduced on hospital letterhead)

[Date of report]

State of California, Department of Public Health
Licensing and Certification District Office
[Street Address]
[City], CA [ZIP]

To Whom It May Concern:

This hospital believes it may have detected the adverse event indicated below as defined in Health and Safety Code Section 1279.1, and is hereby reporting pursuant to Health and Safety Code Section 1279.1.

Due to the short time frame required for reporting in the law, the information this hospital has may be incomplete. If further investigation shows that no adverse event as defined in this law took place, you will be notified. However, in order to comply with the law's short time frame, this hospital is taking a precautionary measure and reporting accordingly.

This hospital may have detected the adverse event checked below:

- ☐ 1. Surgery performed on a wrong body part that is inconsistent with the documented informed consent for that patient. This 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.
- ☐ 2. Surgery performed on the wrong patient.
- ☐ 3. The wrong surgical procedure performed on a patient, which is a surgical procedure performed on a patient that is inconsistent with the documented informed consent for that patient. This 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.
- ☐ 4. 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.
- ☐ 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 and for whom the pathologic processes for which the operation is to be performed are localized and do not entail a systemic disturbance.

☐ 6. Patient death or serious disability associated with the use of a contaminated drug, device, or biologic provided by the health facility 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.

☐ 7. 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 it not limited to, a catheter, drain, or other specialized tube, infusion pump, or ventilator.

☐ 8. 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.

☐ 9. An infant discharged to the wrong person.

☐ 10. Patient death or serious disability associated with patient disappearance for more than four hours, excluding events involving adults who have competency or decision making capacity.

☐ 11. A patient suicide or attempted suicide resulting in serious disability while being cared for in a health facility due to patient actions after admission to the health facility, excluding deaths resulting from self-inflicted injuries that were the reason for the admission to the health facility.

☐ 12. 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.

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

☐ 14. A 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.

☐ 15. Patient death or serious disability directly related to hypoglycemia, the onset of which occurs while the patient is being cared for in a health facility.

☐ 16. 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 miligrams per deciliter.

☐ 17. 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.

☐ 18. A patient death or serious disability due to spinal manipulative therapy performed at the health facility.

☐ 19. A patient death or serious disability associated with an electric shock while being cared for in a health facility, excluding events involving planned treatments, such as electric countershock.

☐ 20. 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.

☐ 21. A patient death or serious disability associated with a burn incurred from any source while being cared for in a health facility.

☐ 22. A patient death associated with a fall while being cared for in a health facility.

☐ 23. A patient death or serious disability associated with the use of restraints or bedrails while being cared for in a health facility.

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

☐ 25. The abduction of a patient of any age.

☐ 26. The sexual assault of a patient within or on the grounds of a health facility.

☐ 27. The death or significant injury of a patient or staff member resulting from a physical assault that occurs within or on the grounds of a facility. [Note: if this item is checked because a staff member suffered death or significant injury due to a physical assault on the grounds of the facility, please indicate the staff member's name at the bottom of the form, rather than a patient's name.]

☐ 28. An adverse event or series of adverse events that cause the death or serious disability of a patient, personnel, or visitor. [Note: An "adverse event" is defined as the incidents described in items 1. through 27., above. Thus, this category probably does not capture any additional adverse events not described in items 1. through 27. above. If for some reason an adverse event report is made about an event not listed in items 1. through 27. above, a brief description of the event should be included on this form. If a hospital has an adverse event that causes the death or serious disability of a patient, personnel, or visitor but is not listed above in items 1. through 27., legal counsel should be consulted to determine whether it should be reported. A different reporting requirement may apply.]

Hospital's code to link this report to its file regarding this potential adverse event:

_____

_____

_____

Date hospital detected the adverse event: _____

Please contact me at [insert phone number] or at [insert fax number] if you require further information.

Sincerely,

[Name]

[Title]

(over)

NOTE: "Serious disability" means:

a. A physical or mental impairment that substantially limits one or more of the major life activities of an individual, if the impairment lasts more than seven days or is still present at the time of discharge from an inpatient health care facility, or

b. The loss of bodily function, if the loss lasts more than seven days or is still present at the time of discharge from an inpatient health care facility, or

c. The loss of a body part.

**Generally, this report must be made within five days of detection. However, if the adverse event is an ongoing or urgent threat to the welfare, health, or safety of patients, personnel or visitors, a report must be made within 24 hours of detection.*