APPENDIX HS-2

Adverse Event Reporting Requirement

Adverse Events Reporting

In response to media attention on medical errors, the California Legislature passed, and the Governor signed, legislation requiring general acute care hospitals, psychiatric hospitals, and special hospitals to report specified adverse events to CDPH. [Health and Safety Code Sections 1279.1, 1279.2, 1279.3 and 1280.4]

Outpatient settings must also report adverse events. **"Outpatient settings"** are defined as:

1. Any facility, clinic, unlicensed clinic, center, office, or other setting that is not part of a general acute care facility, as defined in [Health and Safety Code] Section 1250, and where anesthesia, except local anesthesia or peripheral nerve blocks, or both, is used in compliance with the community standard of practice, in doses that, when administered have the probability of placing a patient at risk for loss of the patient's life-preserving protective reflexes. A clinic or ambulatory surgery center that does not meet this definition — i.e., does not use general anesthesia — is not subject to this reporting requirement.
2. Facilities that offer in vitro fertilization, as defined in Health and Safety Code Section 1374.55(b).

Outpatient settings do not include, among other settings, any setting where anxiolytics and analgesics are administered, when done so in compliance with the community standard of practice, in doses that do not have the probability of placing the patient at risk for loss of the patient's life-preserving protective reflexes.

[Health and Safety Code Section 1248 and 1248.15]

CDPH has confirmed that distinct-part nursing facilities (DP-NFs) need not report adverse events under this law. However, other reporting requirements may apply (for example, the "unusual occurrences" reporting requirement may apply); *see "Relationship With Other Reporting Requirements," page 5.*

Types of Events that Must be Reported

For purposes of this reporting requirement, **"adverse event"** includes the surgical events, product or device events, patient protection events, care management events, environmental events, criminal events, and one other item described below. The term **"serious disability,"** which is used in many places in the list of adverse events, 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 7 days or is still present at the time of discharge from an inpatient health facility, or the loss of a body part.

The list of adverse events includes the following.

Surgical Events

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 the obtaining of 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.

Product or Device Events

1. 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.
2. 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 requirement, **"device"** includes, but it not limited to, a catheter, drain, or other specialized tube, infusion pump, or ventilator.
3. 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.

Patient Protection Events

1. An infant discharged to the wrong person.
2. 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.
3. 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.

Care Management Events

1. 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.
2. A patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products.
3. 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.
4. 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.
5. 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 requirement, **"hyperbilirubinemia"** means bilirubin levels greater than 30 milligrams per deciliter.
6. 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. *(See AFL 15-03.1 regarding unstageable pressure ulcers at* https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/AFL-15-03.aspx*.)*
7. A patient death or serious disability due to spinal manipulative therapy performed at the health facility.

Environmental Events

1. 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.
2. 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.
3. A patient death or serious disability associated with a burn incurred from any source while the patient is being cared for in a health facility.
4. A patient death associated with a fall while the patient is being cared for in a health facility.
5. A patient death or serious disability associated with the use of restraints or bedrails while being cared for in a health facility.

Criminal Events

1. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider.
2. The abduction of a patient of any age.
3. The sexual assault of a patient within or on the grounds of a health facility.
4. 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.

Final Item

The list of adverse events specified in the law contains a final item that contains a circular definition. The final "catchall" category to be reported is "an adverse event or series of adverse events that cause the death or serious disability of a patient, personnel, or visitor." However, an **"adverse event"** is defined as those events listed above (surgical events, product or device events, patient protection events, care management events, environmental events, and criminal events). Therefore, the final category arguably does not capture any events that are not already described in the law. Hospitals that are considering reporting an event under the "catchall" category should consult legal counsel to determine whether a report under this law is required. Even if a report under this law is determined not to be required, however, hospitals may need to report the incident pursuant to another reporting requirement. *(See "Relationship With Other Reporting Requirements," page .)*

Required Time Frame for Reporting

The report must be made no later than five days after the adverse event has been detected. However, if the adverse event is an ongoing urgent or emergent threat to the welfare, health, or safety of patients, personnel, or visitors, the report must be made not later than 24 hours after the adverse event has been detected.

How to Report

CDPH has developed a web-based reporting tool that health care facilities may use to report adverse events as well as privacy breaches, called the "California Healthcare Event and Reporting Tool" (CalHEART). Information about the online reporting tool may be found in CDPH All Facilities Letter 13-12 at https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/LNCAFL2013.aspx. Hospitals are not required to use this tool; a paper form may be submitted instead. CHA has developed a form, "Adverse Event Report Form" (CHA Form 20-1), that hospitals may use to report an adverse event to CDPH. CDPH has stated it will accept the CHA form. However, CDPH has issued proposed regulations about adverse event reporting. After the regulations are finalized and in effect, hospitals will be required to report electronically and additional information may be required.

Communication With Affected Patient(s)

The hospital must inform the patient or the party responsible for the patient of the adverse event by the time the report is made. In addition, The Joint Commission requirement regarding informing the patient of unanticipated outcomes of care may apply. *(See CHA's* Consent Manual*, chapter 19.)*

Relationship With Other Reporting Requirements

This law does not change or otherwise affect other hospital reporting requirements regarding reportable diseases or unusual occurrences. Hospitals may also need to report adverse events according to the following requirements:

1. Unusual occurrences — *see CHA Appendix HS-4.*
2. Safe Medical Devices Act — *see CHA's* Consent Manual*, chapter 19.*
3. Restraint death reporting — *see CHA's* Consent Manual*, chapter 19.*
4. Medication errors — *see CHA's* Consent Manual*, chapter 19.*
5. Injuries by firearm or assaultive or abusive conduct — *see CHA's* Consent Manual*, chapter 17.*
6. Violence against hospital personnel — *see CHA's* guidebook, "*Healthcare Workplace Violence Prevention - How to Comply with the Cal/OSHA Regulation," available at https://www.calhospital.org/publication/healthcare-workplace-violence-prevention.*
7. Radiation overdose — *see CHA's* Consent Manual*, chapter 19.*

In addition, a root cause analysis pursuant to The Joint Commission's sentinel event requirements may be required. *(See CHA's* Consent Manual*, chapter 19.)*

CDPH Investigations and Reports

Ongoing Threat of Imminent Danger

CDPH must make an on-site inspection or investigation whenever it receives an adverse event report or a complaint indicating an ongoing threat of imminent danger of death or serious bodily harm. The on-site inspection or investigation must take place within 48 hours or two business days (whichever is greater) after receipt of the report or complaint. The investigation must be completed within 45 days. If CDPH does not meet this timeframe, it must provide written notice to the facility and the complainant (if any) of the basis for the extenuating circumstances preventing it from meeting the timeframe, and the anticipated completion date. Until CDPH determines by on-site inspection that the adverse event has been resolved, CDPH must conduct an unannounced inspection at least once per year of any hospital that has reported an adverse event.

No Threat of Imminent Danger

If CDPH receives a complaint or report but determines from the information available to it that there is no threat of imminent danger of death or serious bodily harm to that patient or other patients, no on-site inspection is required, but an investigation must be undertaken and completed within 45 days. If CDPH does not meet this time frame, it must provide written notice to the facility and the complainant (if any) of the basis for the extenuating circumstances preventing it from meeting the time frame, and the anticipated completion date.

Definition

For purposes of this law, a **"complaint"** means any oral or written notice to CDPH (other than an adverse event report from the hospital) of an alleged violation of any applicable state or federal law, or an allegation of facts that might constitute such a violation.

Follow-Up

CDPH must notify the hospital and the complainant in writing of its determination as a result of its investigation.

CDPH Public Reporting of Adverse Events

CDPH provides information about substantiated adverse events and the outcomes of inspections and investigations on its website by posting the hospital's Statement of Deficiencies (CDPH Form 2567) and the hospital's plan of correction.

The information provided by CDPH names individual hospitals and may include compliance information history. The names of patients, health care professionals and other health care workers will not be divulged by CDPH.

Penalties for Failure to Report

The adverse event reporting law contains specific penalties for failure to report. A hospital that fails to report an adverse event may be assessed a civil penalty in an amount not to exceed $100 per day for each day that the adverse event is not reported following the initial five-day period or 24-hour period, as applicable. If the hospital disputes a determination by CDPH regarding an alleged failure to report an adverse event, the hospital may, within 10 days, request a hearing pursuant to Health and Safety Code Section 100171. Penalties do not have to be paid until all appeals have been exhausted.

CDPH has additional authority to fine hospitals for failing to comply with hospital licensing requirements. It is unclear whether both fines may apply, or if CDPH is limited to assessing penalties under this provision.