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TO: General Acute Care Hospitals
Acute Psychiatric Hospitals
Special Hospitals

SUBJECT: Mandated Reporting and Investigation of Adverse Events

AUTHORITY: Senate Bill (SB) 1301 (Alquist, Chapter 647, Statutes of 2006)

This letter provides notification of the reporting requirements for adverse events pursuant to Health and Safety Code (HSC) Section 1279.1 and in addition, information regarding the investigation procedures mandated by HSC Section 1279.2.

Statutory Mandates

HSC § 1279.1 requires a General Acute Care Hospital (GACH), Acute Psychiatric Hospital (APH), or Special Hospital (SH) to report an adverse event to the department no later than five (5) 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.

The term “Adverse Event” is defined in HSC § 1279.1(b) and includes any one of 28 events (see attachment A).

HSC § 1279.2 (a)(1) requires that in any case in which the department receives a report of an adverse event from a GACH, APH, or a SH, or a written or oral complaint, as defined (HSC § 1279.2 (d)) involving a GACH, APH, or SH, that indicates an ongoing threat of imminent danger of death or serious bodily harm, the department shall make an onsite inspection or investigation within 48 hours or two business days, whichever is greater, of the receipt of the report or complaint and shall complete that investigation within 45 days.

Further, HSC § 1279.2(b) requires that in any case in which the department is able to determine 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, the department shall complete an investigation of the report within 45 days.

Reporting and Investigation Background

Consequent to HSC § 1279.2 (a)(1) and HSC § 1279.2 (b), the department relies on specific information in order to determine and adhere to the most appropriate investigation deadline.

In the recent past, many hospitals have taken to reporting adverse events using a letter template that utilizes check boxes, each indicating one of the 28 adverse event categories. The familiarity produced by the use of a commonly used template is helpful to the department and allows for prompt recognition of reported information, and although it is not required, it is valued.

With such frequent use of a common template, the department has been able to identify common errors of inaccurate reporting and additional information that would assist in determining the most appropriate investigative response.

HSC § 1279.1 (b) (7) describes an adverse event to include: "An adverse event or series of adverse events that cause the death or serious disability of a patient, personnel, or visitor." The department has received a significant number of reported events for this category that do not actually meet the criteria. Correct use of this category will ensure the most accurate reporting. The department encourages GACHs, APHs, and SHs to consult the complete list of adverse events, (HSC § 1279.1(b); provided in this document as Attachment A) prior to categorizing the event for reporting purposes.

Usually, upon receipt of a report submitted by a GACH, APH, or SH, the department must make contact with the reporting facility to gather additional information to determine if the reported adverse event meets the criteria described in HSC § 1279.2 (a) (1), requiring on-site inspection within 48 hours or two business days.

While not an exhaustive list, the department has identified the following information as beneficial to making such determinations:

- Hospital/Facility name
- Location of facility; Address and City
- Contact person; including name, telephone number and fax number
- Date adverse event occurred or date detected
- Date the adverse event is being reported
- Identification of adverse event category
- A brief description of the event (for events categorized under 1279.1 (b)(7))

Objectives

As the department and reporting hospitals gain more experience with, and knowledge of, the statutes and implementation process, procedures can be streamlined to enhance and expedite the accurate reporting of adverse events. In addition, report accuracy will provide the department greater ability to track reported events, both substantiated and unsubstantiated, consistently across the state. The department has begun efforts to reclassify unsubstantiated reported events as "Entity Reported Incidents" rather than as an adverse event, as determined by the investigation. This modification will allow departmental reports to reflect the most accurate information possible concerning adverse events and their dispositions.

A review of the number of adverse events by individual hospitals indicates that there may be some level of underreporting of adverse events (based on the size of the hospital versus number of adverse events reported or the absence of any adverse event reported since the implementation of this reporting requirement). We encourage all hospital providers to regularly review the reporting mandates of SB 1301 with all appropriate hospital staff to ensure that your facility is meeting its statutory obligation.

The department invites reporting facilities (GACHs, APHs, and SHs) to provide assistance in improving the accuracy of adverse event reporting. As such, the department would value hospitals' consideration of providing the additional information previously described when hospitals report the occurrence and detection of an adverse event. By providing the requested specific information, reporting facilities will assist the department to conduct the required investigations with the least disruption to facility operations.

If you have any questions about the reporting of adverse events or classification categories, please do not hesitate to contact your local district office.

Sincerely,

Original Signed by Pamela Dickfoss for Kathleen Billingsley, R.N.

Kathleen Billingsley, R.N.
Deputy Director
Center for Health Care Quality

Attachment A

Health and Safety Code 1279.1

(a) A health facility licensed pursuant to subdivision (a), (b), or (f) of Section 1250 shall report an adverse event to the department 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 purposes of this section, "adverse event" includes any of the following:

(1) Surgical events, including the following:

(A) Surgery 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) Surgery performed on the wrong patient.

(C) 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. 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 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.

(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 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.

(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 a facility, excluding deaths associated with neurosurgical procedures known to present a high risk of intravascular air embolism.

- (3) Patient protection events, including the following:
 - (A) An infant discharged to the wrong person.
 - (B) Patient death or serious disability associated with patient disappearance for more than four hours, excluding events involving adults who have competency or decisionmaking capacity.
 - (C) 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 admission to the health facility.
- (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) 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.
 - (D) 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.
 - (E) 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.
 - (F) 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.
 - (G) A patient death or serious disability due to spinal manipulative therapy performed at the health facility.
- (5) Environmental events, including the following:
 - (A) 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.
 - (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 a health facility.
 - (D) A patient death associated with a fall while being cared for in a health facility.
 - (E) A patient death or serious disability associated with the use of restraints or bedrails while being cared for in a health facility.
- (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 a health facility.

(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 a facility.

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

(c) The facility 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) Nothing in this section shall be interpreted to change or otherwise affect hospital reporting requirements regarding reportable diseases or unusual occurrences, as provided in Section 70737 of Title 22 of the California **Code** of Regulations. The department shall review Section 70737 of Title 22 of the California **Code** of Regulations requiring hospitals to report "unusual occurrences" and consider amending the section to enhance the clarity and specificity of this hospital reporting requirement.