



MARK B HORTON, MD, MSPH
Director

State of California—Health and Human Services Agency
California Department of Public Health



ARNOLD SCHWARZENEGGER
Governor

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TO: GENERAL ACUTE CARE HOSPITALS
ACUTE PSYCHIATRIC HOSPITALS
SPECIAL HOSPITALS

SUBJECT: REPORTING OF ADVERSE EVENTS (SENATE BILL 1301, ALQUIST,
CHAPTER 647, STATUTES OF 2006)

Adverse healthcare events are a leading cause of morbidity and mortality in the United States. The 1999 Institute of Medicine (IOM) report *To Err is Human; Building a Safer Health System* recommended the establishment of mandatory reporting systems for state governments for the collection of standardized information about adverse events that result in death and serious harm.

The National Quality Forum (NQF) was funded and tasked by the federal government to identify a list of preventable adverse healthcare events that should never occur in a hospital, and to define them in such a way that, should they occur, the information that had to be reported would be clear. The NQF published a list of 27 preventable adverse healthcare events in its 2002 report *Serious Reportable Events in Healthcare*. The NQF encouraged adoption of this list of serious reportable events by states.

Senate Bill 1301 was introduced and chaptered to promote patient safety by ensuring that there is a system in place for early detection of, and response to, systemic problems that cause adverse healthcare events leading to death or serious disability. Senate Bill 1301 defines the errors that must be reported, sets timelines for reporting and inspection/investigation, and requires the posting of substantiated event information for consumers on the California Department of Public Health (CDPH) website.

Passage of Senate Bill 1301 requires all General Acute Care Hospitals (GACHs), Acute Psychiatric Hospitals (APHs) and Special Hospitals (SHs), effective July 1, 2007, to report the occurrence of the defined adverse events to CDPH, formerly known as the California Department of Health Services.

The types of adverse events to be reported to the CDPH are defined at Health and Safety Code (HSC) Section 1279.1 (b) (1-7). A list of the reportable adverse events is attached for your convenience. Upon detection of a reportable adverse event, a hospital is required to report no later than five (5) days, or, if the event is an ongoing urgent or emergent threat to the welfare, health, or safety of patients, personnel, or visitors, no later than twenty-four (24) hours after the adverse event is detected. Hospitals shall report adverse events to their local Licensing and Certification Program district office.

In addition to reporting the event to the CDPH, the hospital must also inform the patient or the party responsible for the patient of the adverse event by the time the report is made.

If a hospital fails to report an adverse event, the department may assess a civil penalty in an amount not to exceed one hundred dollars (\$100) for each day that the adverse event was not reported following the initial five (5) day or twenty-four (24) hour period. If the hospital disputes a determination by the department regarding alleged failure to report an adverse event the hospital may, within 10 days, request a hearing.

The enactment of the new statute will lead to improvements in patient safety and healthcare quality for the residents of California. If you have questions regarding this requirement, please contact your local Licensing and Certification district office.

Sincerely,

Original Signed by Kathleen Billingsley, R.N.

Kathleen Billingsley, R.N.
Deputy Director

Attachment

REPORTABLE ADVERSE EVENTS

Health and Safety Code, Section 1279.1 (b) (1) – (7) reflects the following:

1279.1.

(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.