

Methodology to Indicate Changes to  
**DPH-11-023 – Adverse Events Reporting**

The proposed changes for comment that are the subject of this 15-day public comment period are indicated as follows:

- Deleted text is indicated by double strike-through (~~strike-through~~).
- Additions to the regulation text are indicated by double underline (underline).

Regulation text not subject to this 15-day public comment period are presented for the reader's convenience and are indicated as follows:

- Deleted text as initially proposed is indicated by single strike-through (~~strike-through~~)
- Added text as initially proposed is indicated by single underline (underline).

**Title 22. Social Security**  
**Division 5. Licensing and Certification of Health Facilities, Home Health Agencies,**  
**Clinics, and Referral Agencies**  
**Chapter 1. General Acute Care Hospital**  
**Adopt Article 11. Adverse Event Reporting Requirements**

**Adopt Article 11 to read as follows:**

**Adopt Section 70970 to read as follows:**

Section 70970. Applicability.

(a) This article applies to reportable adverse events in general acute care hospitals and special hospitals pursuant to subdivision (a) of Health and Safety Code section 1279.1.

(b) For the purposes of this Article:

(1) General acute care hospitals and special hospitals shall be called “hospital” and include any outpatient services on the hospital’s license.

(2) The “hospital” does not include a distinct part operated pursuant to section 70503 or 70627.

Note: Authority cited: Sections 1275, 131050, 131051, 131052 and 131200, Health and Safety Code. Reference: Sections 1250 and 1279.1, Health and Safety Code.

**Adopt Section 70971 to read as follows:**

Section 70971. Definitions.

(a) As used in Health and Safety Code sections 1279.1, 1279.2, 1279.6 and this article:

(1) "A patient death or serious disability associated with the use of restraints" means a patient death or serious disability associated with the use of physical restraints.

(~~2~~) "Adverse event" shall have the meaning defined in Health and Safety Code section 1279.1(b)(1-7).

(~~3~~) "Biologic" means medical products made from a variety of natural sources (human, animal, or microorganism). Like drugs, some biologics are intended to treat diseases and medical conditions. Other biologics are used to prevent or diagnose diseases. Examples of biologics include vaccines, blood and blood products, gene therapies, and allergenic extracts.

(~~4~~) "Countershock" means an electric shock intended to restore normal rhythm of the heart (i.e., cardioversion and/or defibrillation).

(45) "Decision-making capacity" means the ability to understand information relevant to a decision and the ability to appreciate the reasonably foreseeable consequences of a decision (or lack of a decision).

(~~5~~) "Detect" means the discovery of an adverse event, or the reasonable belief of a discovery of an adverse event, by a hospital, its personnel, or its agents. An adverse event shall be treated as detected as of the first business day on which such adverse event is known to the hospital, or by exercising reasonable diligence would have been known to the hospital. A hospital shall be deemed to have knowledge of an adverse event if such an adverse event is known, or by exercising reasonable diligence would have been known, to any person other than the person committing the adverse event, who is the personnel or agent of the hospital.

(~~6~~) "Device" means a medical instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related medical product or device, including a component part or accessory that is recognized in the United States Pharmacopeia and the National Formulary (USP-NF) or any supplement, intended for

use in the diagnosis of disease or other conditions, or in the care, mitigation, treatment, or prevention of disease, in humans or other animals; or intended to affect the structure or any function of the body of humans or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of humans or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.

(78) “Infant” means a child under the age of one year.

(89) “Low-risk pregnancy” means the pregnancy of a woman aged 18-39, with no previous diagnosis of essential hypertension, renal disease, collagen-vascular disease, liver disease, cardiovascular disease, placenta previa, multiple gestation, intrauterine growth retardation, smoking, pregnancy-induced hypertension, premature rupture of membranes, or other previously documented condition that poses a high risk of poor pregnancy outcome.

(910) “Major life activity” means any of the following:

(A) Caring for oneself, performing manual tasks, seeing, hearing, eating, sleeping, walking, standing, lifting, bending, speaking, breathing, learning, reading, concentrating, thinking, communicating, and working; or

(B) A major bodily function, including functions of the immune system, normal cell growth, digestive, bowel, bladder, neurological, brain, respiratory, circulatory, endocrine, and reproductive functions.

(1011) “Medication error” means any preventable incident that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such incidents may be related to professional practice, products, procedures, and systems, including prescribing, order communication, product labeling, packaging and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use.

(1112) “Nationally recognized survey tool” means a valid and reliable survey tool identified by the Agency for Healthcare Research and Quality (AHRQ), National Association for Healthcare Quality (NAHQ), or equivalent.

(1213) “Normal, healthy patient” means a person without a systemic disease.

(~~13~~14) “Party responsible for the patient” means an adult who is expressly authorized to act on the patient’s behalf within the scope and duration of the authority granted and is documented in the patient’s medical record.

(~~14~~15) “Patient safety event” shall have the meaning defined in Health and Safety Code section 1279.6(c).

(~~15~~16) “Retention of a foreign object” refers to an item introduced into the body during a surgical or other invasive procedure, without removal prior to the end of the surgery or procedure, which the surgeon or other practitioner did not intend to leave in the body. This definition excludes (a) objects intentionally implanted as part of a planned intervention, (b) objects present prior to the surgery or other procedure that are intentionally left in place, (c) objects not present prior to the surgery or other procedure that are intentionally left in place when the risk of removal exceeds the risk of leaving the object in place (e.g., microneedles, broken screws), and the physician/surgeon documents the risk of removal.

(~~16~~17) “Root cause analysis” means a range of approaches, tools, and techniques used to identify causes of complex problems. In addition, root cause analysis identifies the circumstances of the adverse event, including a timeline, to confirm or refute a presumed preventable adverse event.

(~~17~~18) “Serious bodily harm” means injuries creating substantial risk of death or serious, permanent disfigurement or prolonged loss or impairment of the function of any body part or organ.

(~~18~~19) “Significant injury” means an injury involving physical pain, substantial risk of death, or prolonged loss or impairment of function of a body member, organ, or of mental faculty, or requiring medical intervention, including, but not limited to, hospitalization, surgery, or physical rehabilitation.

(~~19~~20) “Stage 2 pressure ulcer” means a partial-thickness loss of skin with exposed dermis. The wound bed is viable, pink or red, moist, and may also present as an intact or ruptured serum-filled blister. Adipose (fat) is not visible and deeper tissues are not visible. Granulation tissue, slough, and eschar are not present. These ulcers commonly result from adverse microclimate and shear in the skin over the pelvis and shear in the

heel. This stage should not be used to describe moisture-associated skin damage (MASD) including incontinence-associated dermatitis (IAD), intertriginous dermatitis (ITD), medical adhesive related skin injury (MARS), or traumatic wounds (skin tears, burns, abrasions).

(~~20~~21) "Stage 3 pressure ulcer" means a full-thickness loss of skin, in which adipose (fat) is visible in the ulcer and granulation tissue and epibole (rolled wound edges) are often present. Slough or eschar or both may be visible. The depth of tissue damage varies by anatomical location; areas of significant adiposity can develop deep wounds. Undermining and tunneling may occur. Fascia, muscle, tendon, ligament, cartilage, or bone are not exposed. If slough or eschar obscures the extent of tissue loss, this is an Unstageable Pressure Ulcer.

(~~21~~22) "Stage 4 pressure ulcer" means a full-thickness skin and tissue loss with exposed or directly palpable fascia, muscle, tendon, ligament, cartilage, or bone in the ulcer. Slough or eschar or both may be visible. Epibole (rolled wound edges), undermining, or tunneling often occur. Depth varies by anatomical location. If slough or eschar obscures the extent of tissue loss, this is an Unstageable Pressure Ulcer.

(~~22~~23) "Substantiated" means the Department determined the reported incident met the definition of adverse event at Health and Safety Code section 1279.1(b)(1-7).

(~~23~~24) "Surgery" means an invasive operative procedure in which skin or mucous membranes and connective tissue is incised or the procedure is carried out using an instrument that is introduced through a natural body orifice. It includes minimally invasive procedures involving biopsies or placement of probes or catheters requiring the entry into a body cavity through a needle or trocar. Surgeries include a range of procedures from minimally invasive dermatological procedures (e.g., biopsy, excision, and deep cryotherapy for malignant lesions) to vaginal birth or Caesarian delivery to extensive multi-organ transplantation. It does not include use of medical devices such as otoscopes and procedures such as drawing blood.

(~~24~~25) "Surgery begins" at the point of surgical incision, tissue puncture, or insertion of an instrument into tissues, cavities, or organs.

(~~25~~26) “Surgery ends” after all incisions or procedural access routes have been closed in their entirety, devices such as probes or instruments have been removed, and, if relevant, final surgical counts confirming accuracy of counts and resolving any discrepancies have concluded and the patient has been taken from the operating or procedure room. A vaginal birth ends after the delivery of the fetus and the placenta, and all surgical repairs have been completed.

(~~26~~27) “Suspected deep tissue pressure ulcer” means an intact or non-intact skin with localized area of persistent non-blanchable deep red, maroon, or purple discoloration or epidermal separation revealing a dark wound bed or blood filled blister. Pain and temperature change often precede skin color changes. Discoloration may appear differently in darkly pigmented skin. This injury results from intense and/or prolonged pressure and shear forces at the bone-muscle interface. The wound may evolve rapidly to reveal the actual extent of tissue injury, or may resolve without tissue loss. If necrotic tissue, subcutaneous tissue, granulation tissue, fascia, muscle, or other underlying structures are visible, this indicates a full thickness pressure injury (Unstageable, Stage 3, or Stage 4). Do not use deep tissue pressure injury to describe vascular, traumatic, neuropathic, or dermatologic conditions.

(~~27~~28) “Unstageable pressure ulcer” means a full-thickness skin and tissue loss in which the extent of tissue damage within the ulcer cannot be confirmed because it is obscured by slough or eschar. If slough or eschar is removed, a Stage 3 or Stage 4 pressure ulcer will be revealed.

(~~28~~29) “Unsubstantiated” means the Department determined the reported incident did not meet the definition of adverse event at Health and Safety Code section 1279.1(b)(1-7).

(~~29~~30) “Wrong person” as used pursuant to Health and Safety Code section 1279.1(b)(3)(A), means a person without a “right to custody” as that term is defined under California Penal Code Section 277.

Note: Authority cited: Sections 1275, 131050, 131051, 131052 and 131200, Health and Safety Code. Reference: Sections 277 and 278, California Penal Code; Division 12,

Part 3 (commencing with Section 7600), Family Code; Sections 1250, 1279.1, 1279.2 and 1279.6, Health and Safety Code; and Sections 15610.17(a) and 15610.67, Welfare and Institutions Code.

**Adopt Section 70972 to read as follows:**

Section 70972. Adverse Event Reporting Requirements.

(a) Pursuant to Health and Safety Code sections 1279.1 and 1279.3, adverse events shall be reported by the hospital to the Department's secure electronic web-based portal pursuant to the following timelines:

(1) Adverse events that are ongoing urgent or emergent, threatening the welfare, health, or safety of patients, personnel, or visitors, shall be reported within 24 hours after the adverse event is detected.

(2) Sexual assault of a patient, including allegations of sexual assault of a patient, provided for under Health and Safety Code section 1279.1(b)(6)(C), shall be reported within 24 hours after ~~allegation or~~ detection.

(3) All other adverse events shall be reported to the Department no later than 5 calendar days after the adverse event is detected.

(b) When reporting adverse events, the hospital shall provide to the Department the following information:

(1) Name and address of the hospital.

(2) Location and service area where the adverse event occurred.

(3) Date and time the adverse event occurred and was detected, if known.

(4) Name of each individual affected by the adverse event and any patients, personnel, and visitors involved or a witness to the adverse event, if known.

(5) Description of the circumstances surrounding the adverse event, including the nature and extent of injury or harm.

(6) If an individual affected by the adverse event is a patient, the date the patient, or the party responsible for the patient, was informed of the adverse event. This date shall not be later than the date the hospital reported the adverse event to the Department.

(7) Name, title, area code, and telephone number of a hospital representative for the Department to contact for additional information.

(8) Hospital's immediate corrective or mitigating action in response to the adverse event.

(9) Any additional information as it becomes available regarding the adverse event.

(c) In the event the Department's secure electronic web-based portal is not operational, the hospital shall report an adverse event to the Department by email or telephone.

Note: Authority cited: Sections 1275, 131050, 131051, 131052 and 131200, Health and Safety Code. Reference: Sections 1279.1, 1279.2, 1279.3 and 1279.6, Health and Safety Code.

**Adopt Section 70973 to read as follows:**

Section 70973 Adverse Event Investigation.

(a) The hospital shall provide the requisite information necessary for the Department to determine if an adverse event is substantiated or unsubstantiated, pursuant to the following process:

(1) If the reported adverse event or complaint is determined by the Department to be an ongoing threat of imminent danger of death or serious bodily harm, the hospital shall be subject to an onsite investigation, initiated within 48 hours or 2 business days of receipt of the report or complaint, whichever is greater.

(2) If the Department determines there is no ongoing threat of imminent danger of death or serious bodily harm, the hospital shall be subject to one or both of the following:

(A) An onsite inspection.

(B) An offsite investigation that includes interviews, records reviews, or other investigatory means the Department determines necessary.

Note: Authority cited: Sections 1275, 131050, 131051, 131052 and 131200, Health and Safety Code. Reference: Sections 1279.1, 1279.2, 1279.3 and 1279.6, Health and Safety Code.

**Adopt Section 70974 to read as follows:**

Section 70974. Adverse Events - Policies and Procedures.

(a) Each hospital shall develop, implement, maintain, and comply with policies and procedures for a written patient safety plan, pursuant to Health and Safety Code section 1279.6, that specifies systemic processes for:

(1) Internally reporting preventable patient safety events, as defined in Health and Safety Code section 1279.6 (c).

(2) Documenting reportable patient safety events.

(3) Conducting a root cause analysis for the patient safety event. A root cause analysis, or any other investigation, shall not change reporting requirements regarding reportable diseases or unusual occurrences as provided in Section 70737.

(4) Assessing the hospital's culture of safety ~~at least every 12 months~~24 months using a nationally recognized survey tool.

Note: Authority cited: Sections 1275, 131050, 131051, 131052 and 131200, Health and Safety Code. Reference: Sections 1279.1 and 1279.6, Health and Safety Code.

**Title 22. Social Security**  
**Division 5. Licensing and Certification of Health Facilities, Home Health Agencies,**  
**Clinics, and Referral Agencies**  
**Chapter 2. Acute Psychiatric Hospital**  
**Adopt Article 6.5. Adverse Event Reporting Requirements**

**Adopt Article 6.5 to read as follows:**

**Adopt Section 71565 to read as follows:**

Section 71565. Applicability.

This article applies to reportable adverse events in acute psychiatric hospitals pursuant to subdivision (a) of Health and Safety Code section 1279.1.

Note: Authority cited: Sections 1275, 131050, 131051, 131052 and 131200, Health and Safety Code. Reference: Sections 1250 and 1279.1, Health and Safety Code.

**Adopt Section 71566 to read as follows:**

Section 71566. Definitions.

The definitions in Chapter 1, Article 11, section 70971 shall apply to reportable adverse events in acute psychiatric hospitals.

Note: Authority cited: Sections 1275, 131050, 131051, 131052 and 131200, Health and Safety Code. Reference: Sections 277 and 278, California Penal Code; Division 12, Part 3 (commencing with Section 7600), Family Code; Sections 1250, 1279.1, 1279.2 and 1279.6, Health and Safety Code; and Sections 15610.17(a) and 15610.67, Welfare and Institutions Code.

**Adopt Section 71567 to read as follows:**

Section 71567. Adverse Event Reporting Requirements.

(a) Pursuant to Health and Safety Code sections 1279.1 and 1279.3, adverse events shall be reported by the hospital to the Department's secure electronic web-based portal pursuant to the following timelines:

(1) Adverse events that are ongoing urgent or emergent, threatening the welfare, health, or safety of patients, personnel, or visitors, shall be reported within 24 hours after the adverse event is detected.

(2) Sexual assault of a patient, including allegations of sexual assault of a patient, provided for under Health and Safety Code section 1279.1(b)(6)(C), shall be reported within 24 hours after ~~allegation or~~ detection.

(3) All other adverse events shall be reported to the Department no later than 5 calendar days after the adverse event is detected.

(b) When reporting adverse events, the hospital shall provide to the Department the following information:

(1) Name and address of the hospital.

(2) Location and service area where the adverse event occurred.

(3) Date and time the adverse event occurred and was detected, if known.

(4) Name of each individual affected by the adverse event and any patients, personnel, and visitors involved or a witness to the adverse event, if known.

(5) Description of the circumstances surrounding the adverse event, including the nature and extent of injury or harm.

(6) If an individual affected by the adverse event is a patient, the date the patient, or the party responsible for the patient, was informed of the adverse event. This date shall not be later than the date the hospital reported the adverse event to the Department.

(7) Name, title, area code, and telephone number of a hospital representative for the Department to contact for additional information.

(8) Hospital's immediate corrective or mitigating action in response to the adverse event.

(9) Any additional information as it becomes available regarding the adverse event.

(c) In the event the Department's secure electronic web-based portal is not operational, the hospital shall report an adverse event to the Department by email or telephone.

Note: Authority cited: Sections 1275, 131050, 131051, 131052 and 131200, Health and Safety Code. Reference: Sections 1279.1, 1279.2, 1279.3 and 1279.6, Health and Safety Code.

**Adopt Section 71568 to read as follows:**

Section 71568 Adverse Event Investigation.

(a) The hospital shall provide the requisite information necessary for the Department to determine if an adverse event is substantiated or unsubstantiated, pursuant to the following process:

(1) If the reported adverse event or complaint is determined by the Department to be an ongoing threat of imminent danger of death or serious bodily harm, the hospital shall be subject to an onsite investigation, initiated within 48 hours or 2 business days of receipt of the report or complaint, whichever is greater.

(2) If the Department determines there is no ongoing threat of imminent danger of death or serious bodily harm, the hospital shall be subject to one or both of the following:

(A) An onsite inspection.

(B) An offsite investigation that includes interviews, records reviews, or other investigatory means the Department determines necessary.

Note: Authority cited: Sections 1275, 131050, 131051, 131052 and 131200, Health and Safety Code. Reference: Sections 1279.1, 1279.2, 1279.3 and 1279.6, Health and Safety Code.

**Adopt Section 71569 to read as follows:**

Section 71569. Adverse Events - Policies and Procedures.

(a) Each hospital shall develop, implement, maintain, and comply with policies and procedures for a written patient safety plan, pursuant to Health and Safety Code section 1279.6, that specifies systemic processes for:

(1) Internally reporting preventable patient safety events, as defined in Health and Safety Code section 1279.6(c).

(2) Documenting reportable patient safety events.

(3) Conducting a root cause analysis for the patient safety event. A root cause analysis, or any other investigation, shall not change reporting requirements regarding reportable diseases or unusual occurrences as provided in section 71535.

(4) Assessing the hospital's culture of safety ~~at least every 12 months~~ at least every 24 months using a nationally recognized survey tool for safety culture assessment.

Note: Authority cited: Sections 1275, 131050, 131051, 131052 and 131200, Health and Safety Code. Reference: Sections 1279.1, 1279.2 and 1279.6, Health and Safety Code.