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Title 22@ Social Security

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Division 5@ Licensing and Certification of Health Facilities, Home Health Agencies, Clinics, and Referral Agencies

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Chapter 1@ General Acute Care Hospitals

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Article 11@ Adverse Event Reporting Requirements

|-&gt;

Section 70971@ Definitions

## 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). (5) "Culture of safety" means the actions and behaviors in the hospital that are rewarded, supported, expected, and accepted in the hospital as it relates to patient safety. (6) "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). (7) "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. (8) "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. (9) "Infant" means a child under the age of one year. (10) "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. (11) "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. (12) "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. 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. (13) "Nationally recognized survey tool" means a valid and reliable survey tool identified by the Agency for Healthcare Research and Quality (AHRQ), or another survey tool which raises awareness of patient safety, assesses status of culture of safety, evaluates impact of patient safety interventions, and identifies strengths and areas for culture of safety improvement. (14) "Normal, healthy patient" means a person without a systemic disease. (15) "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. (16) "Patient safety event" shall have the meaning defined in Health and Safety Code section 1279.6(c). (17) "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. (18) "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.

(19) "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. (20) "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. (21) "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). (22) "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.

(23) "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. (24) "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). (25) "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. (26) "Surgery begins" at the point of surgical incision, tissue puncture, or insertion of an instrument into tissues, cavities, or organs. (27) "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. (28) "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. (29) "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. (30) "Unsubstantiated" means the Department determined the reported incident did not meet the definition of adverse event in Health and Safety Code section 1279.1(b)(1-7). (31) "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.

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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.

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"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.

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