

**Reportable Adverse Events & TJC Sentinel Events
CDPH Reporting Requirements (SB 1301/Health and Safety Code (HSC) 1279.1)**

1279.1 (d) defines “Serious disability” as 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.

CAT	CDPH Reportable Events	TJC Reviewable Sentinel Events and Examples	
Surgical Events	1	Surgery performed on a <u>wrong body part</u> 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.	Invasive procedure, including surgery, on the wrong patient, wrong site, or wrong procedure.
	2	<u>Surgery performed on the wrong patient.</u>	As above
	3	The <u>wrong surgical procedure</u> 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.	As above
	4	<u>Retention of a foreign object</u> 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.	Unintended retention of a foreign object in a patient after surgery or invasive procedure.
	5	<u>Death</u> during or up to <u>24 hours after induction of anesthesia after surgery</u> 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	6	Patient <u>death or serious disability</u> associated with the use of <u>a contaminated drug, device, or biologic</u> 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.	
	7	Patient <u>death or serious disability</u> associated with the use or function of a <u>device</u> 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.	
	8	Patient <u>death or serious disability</u> associated with <u>intravascular air embolism</u> 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.	
Protection Events	9	<u>An infant discharged to the wrong person.</u>	Discharge of an infant to the wrong family.
	10	Patient <u>death or serious disability</u> associated with <u>patient disappearance</u> for more than four hours, excluding events involving adults who have competency or decision-making capacity.	TJC Example: Any elopement, unauthorized departure, of a patient from an around-the-clock care setting resulting in a temporally related death (suicide, accidental death, or homicide) or major permanent loss of function.
	11	A patient <u>suicide or attempted suicide</u> resulting in <u>serious disability</u> 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.	Suicide of any patient receiving care, treatment and services in a staffed around-the-clock care setting or within 72 hours of discharge.
Care Management Events	12	A <u>patient death or serious disability</u> associated with a <u>medication error</u> , 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.	TJC Example: Any patient death, paralysis, coma, or other major permanent loss of function associated with a medication error.
	13	A patient <u>death or serious disability</u> associated with a <u>hemolytic reaction</u> due to the administration of ABO-incompatible blood or blood products.	Hemolytic transfusion reaction involving administration of blood or blood product having major blood group incompatibility (ABO, Rh, other blood groups).
	14	<u>Maternal death or serious disability</u> associated with labor or delivery <u>in a low-risk pregnancy</u> while being cared for in a facility, including events that occur within 42 days post-delivery and excluding deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy, or cardiomyopathy.	TJC Example: Any intrapartum maternal death.
	15	Patient <u>death or serious disability</u> directly related to <u>hypoglycemia</u> , the onset of which occurs while the patient is being cared for in a health facility.	
	16	<u>Death or serious disability</u> , including kernicterus, associated with failure to identify and treat <u>hyperbilirubinemia</u> in neonates during the first 28 days of life. For purposes of this subparagraph, "hyperbilirubinemia" means bilirubin levels greater than 30 milligrams per deciliter.	Severe neonatal hyperbilirubinemia (bilirubin >30 milligrams/deciliter)
	17	A <u>Stage 3 or 4 ulcer</u> , acquired after admission to a health facility, excluding progression from Stage 2 to Stage 3 if the Stage 2 was recognized upon admission. Additionally (per AFL 08-09), all <u>unstageable ulcers</u> are reportable if acquired after admission, excluding progression from Stage 2 to Stage 3 if the Stage 2 was recognized and noted upon admission.	

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	18 A patient <u>death or serious disability</u> due to <u>spinal manipulative therapy</u> performed at the health facility.	
Environmental Events	19 A patient <u>death or serious disability</u> associated with an <u>electric shock</u> while being cared for in a health facility, excluding events involving <u>planned treatments</u> , such as electric countershock.	
	20 Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the <u>wrong gas</u> or is contaminated by a toxic substance.	
	21 A patient <u>death or serious disability</u> associated with a <u>burn</u> incurred from any source while being cared for in a health facility.	
	22 A patient <u>death</u> associated with a <u>fall</u> while being cared for in a health facility.	TJC Example: A fall that results in death or major permanent loss of function as a direct result of injuries sustained from the fall.
	23 A patient <u>death or serious disability</u> associated with the use of <u>restraints or bedrails</u> while being cared for in a health facility.	
Criminal Events	24 Any instance of care ordered by or provided by someone <u>impersonating a physician, nurse, pharmacist</u> , or other licensed health care provider.	
	25 The <u>abduction</u> of a patient of any age.	Abduction of any patient receiving care, treatment or services.
	26 The <u>sexual assault</u> on a patient within or on the grounds of a health facility.	Sexual abuse/assault (including rape).
	27 The <u>death or significant injury</u> of a patient or staff member resulting from a physical assault that occurs within or on the grounds of a facility.	TJC Example: Assault, homicide, or other crime resulting in patient death or major permanent loss of function.
Adverse Event	28 An <u>adverse event</u> or <u>series of adverse events</u> that cause the <u>death or serious disability</u> of a patient, personnel, or visitor.	The event has resulted in an unanticipated death or major permanent loss of function not related to the natural course of the patient's illness or underlying condition.
Other	Title 22 occurrence which <u>threatens the welfare, safety or health of patients, personnel or visitors</u> shall be reported as soon as reasonably practical.	
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<p>An Adverse Event is defined as a medical occurrence that caused or is an ongoing threat of imminent danger of death or serious bodily harm at an acute general hospital. There are 28 "Adverse Events" defined by SB 1301. Source (CDPH Hospital Facility FAQs http://hfcis.cdph.ca.gov/faq/hospital.aspx)</p>		<p>TJC Example: Any perinatal death unrelated to a congenital condition, in an infant having a birth weight greater than 2500 G. (Unanticipated death of a full-term infant)</p> <p>TJC Example: Prolonged fluoroscopy with cumulative dose >1,500 rads to a single field or any delivery of radiotherapy to the wrong body region or >25% above the planned radiotherapy dose.</p>
<p>HSC § 1279.1 requires a General Acute Care Hospital (GACH) to report an adverse event to CDPH 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.</p> <p>1279.1 (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 (to CDPH).</p> <p>If the hospital has an adverse event as described in items 1-28 & Unusual Occurrence, please follow the steps outlined in MCP 561.1, Reporting Sentinel Events and Significant Adverse Event Policy.</p>		<p>TJC Examples of Non-Reviewable Sentinel Events. May still require internal RCA or investigation:</p> <ul style="list-style-type: none"> • Any close call ("near miss") • Full or expected return of limb or bodily function to the same level as prior to the adverse event by discharge or within two weeks of the initial loss of said function, whichever is the longer period. • Any sentinel event that has not affected a recipient of care (patient, individual, resident) • Medication errors that do not result in death or major permanent loss of function. • Suicide other than in an around-the-clock care setting or following elopement from such a setting. • A death or loss of function following a discharge against medical advice (AMA). • Unsuccessful suicide attempts unless resulting in major permanent loss of function. • Minor degrees of hemolysis not caused by a major blood group incompatibility and with no clinical sequelae.