CALIFORNIA HOSPITAL ASSOCIATION

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c/o Office of Regulations
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Submitted via email to Heidi Steinecker and the CDPH Office of Regulations (regulations@cdph.ca.gov)

Subject: DPH-11-023 Adverse Events Reporting

Dear Ms. Steinecker:

On behalf of our more than 400 member hospitals and health systems, the California Hospital Association (CHA) respectfully offers the following comments on the proposed Title 22 adverse events reporting regulations. CHA's goal in providing these comments is to promote consistent and timely reporting that promotes learning from these events and improving the quality of patient care.

Section 70971. Definitions.
CHA appreciates that the California Department of Public Health (CDPH) has modeled the definitions of adverse events after the national standards released by the National Quality Forum (NQF) in its 2011 update of Serious Reportable Events in Health Care, when compatible with Health and Safety Code section 1279.1 adverse event categories and terms. However, because these proposed regulations do not adopt the definitions by cross reference, these regulations will be outdated once the NQF next updates its recommendations. Indeed, between the time in 2010 when CDPH initially released proposed regulations on adverse events reporting and present now, NQF has updated its definitions. CDPH may want to consider proposing legislation that adopts the most current NQF definitions of serious reportable events in health care by cross reference.

In the absence of a statutory change, CHA recommends the following revisions to the definitions in the proposed regulations to better align with current statute, more closely mirror NQF definitions where appropriate, and provide greater clarity.

- **"Detect":** State statute requires hospitals to report adverse events within 24 hours or five days after they have been detected, as applicable (Health and Safety Code Section 1279.1. (a)). However, the proposed regulations define detection so broadly that a hospital would be required to report an adverse event about which it does not have knowledge. This impossibility would lead to broad non-compliance by hospitals that simply could not report that which they do not know.

  As an example, the definition uses the term "agent" of the hospital without defining it. Furthermore, it specifies that an adverse event would have been known by a hospital exercising reasonable

diligence. Neither of these provisions considers that a hospital, nonetheless, did not have the knowledge and was unable to report it.

Hospitals have internal reporting structures to identify adverse events, report them to CDPH, and assess them for quality improvement in keeping with hospital policies and procedures as well as national accreditation and quality standards. CHA recommends the following revisions in Section 70971 to clarify when detection is feasibly known, in order to promote timely and consistent reporting to CDPH:

(a)(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.~~

- **"Major life activity":** CDPH proposes a highly subjective and new definition of "major life activity" that could be interpreted in any number of different ways by hospitals and CDPH surveyors in determining whether an adverse event resulted in serious disability. The issue with that determination is not what activity is substantially limited but, rather, if a major life activity has been substantially limited.

  Of note, this is a term NQF does not define in its standards, Serious Reportable Events in Healthcare 2011. Similarly, CHA does not recommend CDPH define it here.

  Rather, given that state statute already defines the overarching term of "serious disability" in a way that is broadly understood within the hospital field and by CDPH surveyors, CHA recommends adoption of the definition of "serious disability," which the proposed regulations do not currently define, by cross reference in Section 70971:

  (a)(9) ~~"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.~~ "Serious disability" shall have the meaning defined in Health and Safety Code Section 1279.1(d).

- **"Medication error**": While CHA appreciates that CDPH adopted NQF's definition, state statute on adverse events is more focused and appropriate for hospital inpatient settings. The authorizing statute provides several examples of medication errors, none of which (unlike the proposed regulation) include instances where the patient or consumer is in control of the drug. The authorizing statute instead focuses on errors based on the clinician's selection, administration, or dose. Specifically, these are identified as, "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" (Health and Safety Code Section 1279.1: (b)(4)(A)).

It is beyond the scope of the statute to require hospitals to report medication errors made by patients. As such, CHA recommends revising the definition to remove medication errors when the drug is in control of the patient or consumer, which could be a non-authorized use. Instead, medication error would be more appropriately defined for an inpatient setting as when the medication is in the control of the health care professional. The following revisions should be made to Section 70971:

(a)(10) "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.

- **"Root cause analysis"**: These regulations also create a new definition of root cause analysis, defining it as "a range of approaches, tools, and techniques used to identify causes of complex problems." CHA recommends aligning this definition with a national standard such as that of The Joint Commission, which defines it as, "a process for identifying the basic or causal factor(s) underlying variation in performance, including the occurrence or possible occurrence of a sentinel event — and all of its related tools."

  The proposed definition goes on to state that, "In addition, root cause analysis identifies the circumstances of the adverse event, including a timeline, to confirm or refute a presumed preventable adverse event." CHA recommends removal of "to confirm or refute a presumed preventable adverse event." This goes beyond the scope of the statute, which does not require root cause analyses for the purposes of refuting a presumed preventable adverse event. As such, Section 70971 would be revised as follows:

  (a)(16) "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~~ a process for identifying the basic or causal factor(s) underlying variation in performance, including the occurrence or possible occurrence of a sentinel event — and all of its related tools.

- **"Stage 2 pressure ulcer," "Stage 3 pressure ulcer," and "Stage 4 pressure ulcer"**: These definitions adopt the National Pressure Injury Advisory Panel (NPIAP) definitions. So that the regulation continues to be current with these definitions, CHA recommends cross referencing them to be as defined by NPIAP:

  Delete contents of Section 70971 (a)(19), (20), and (21), and replace with:

  (a)(19) "Stage 2 pressure ulcer," "stage 3 pressure ulcer," and "stage 4 pressure ulcer" shall have the meaning defined by the National Pressure Injury Advisory Panel.

- **"Significant injury"**: One of the adverse events specified in the statute is, "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." (Health and Safety Code Section 1279.1(b)(6)(D)). These proposed regulations create a new definition of "significant injury" that is very broad, including an injury on the basis that it causes physical pain. As an example, someone may fall with pain but have no other injury. However, under these proposed regulations, that would constitute a significant injury. NQF does not define "significant injury," and CHA recommends that CDPH not do so, as well. As such, the following deletions should be made to Section 70971:

  ~~*(a)(18) "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.*~~

- **"A patient death or serious disability associated with the use of restraints"**: Health and Safety Code Section 1279.1 (b)(5)(E) specifies that one of the adverse events is, "A patient death or serious disability associated with the use of restraints or bedrails while being cared for in a health facility." There has been inconsistent interpretation of the restraints portion of this provision by CDPH Licensing and Certification Program district offices. For example, a patient who dies of an unrelated cause, but who happened to be in restraints, sometimes has been interpreted to be reportable, and other times, interpreted to not be reportable by district offices. The circumstance of an unrelated physical restraint alone should not qualify as a death or serious disability as an adverse event.

  CHA recommends CDPH define "associated with the use of restraints" to be clear that the reportable events are those where the death or serious disability is related to the use of the restraints. Moreover, CDPH recommends, that as NQF clarified in its 2011 update, CDPH specify that restraints are physical restraints, as opposed to chemical restraints. NQF noted that the "difficulty in defining" chemical restraints makes their inclusion infeasible at present (page 11, NQF, Serious Reportable Events in Healthcare 2011). This additional definition would be included in Section 70971, to read:

  (a)(x) "A patient death or serious disability associated with the use of restraints" means a patient death or serious disability directly related to the use of physical restraints. The circumstance of the patient having been in physical restraints at the time of death is not sufficient to require its reporting as an adverse event.

Section 70972. Adverse Event Reporting Requirements

- **Electronic submission:** This requires electronic reporting as the sole method of submission. While CDPH has had the California Healthcare Event Reporting Tool (CalHEART) available as an option, many hospitals and health systems report not having used it. With a significant increase in uptake in the system, there could be technical challenges that make it unavailable at times. Given the 24-hour reporting requirements for some adverse events, a system outage could render the hospital unable to submit the required information to CDPH.

  CHA recommends having alternative options to email, call, or fax in adverse events to CDPH if the CalHEART system is experiencing difficulties. This will allow for continuous and timely reporting to CDPH. CHA recommends adding this language to Section 70972:

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

- **Reporting of sexual assault:** The authorizing statute specifies reporting of adverse events no later than five days after detection, or no later than 24 hours if the event is an "ongoing urgent or emergent threat to the welfare, health, or safety of patients, personnel, or visitors." (Health and Safety Code Section 1279.1(a)). However, proposed Section 70972 (a)(2) requires the specific adverse event of sexual assault of a patient to be reported within 24 hours of allegation or detection, which lacks statutory authority and is inconsistent with the statutory framework. For instance, reporting within 24 hours would be required even if the event is not an ongoing urgent or emergent threat, such as if the assailant has already been identified and is not at large.

  Sexual assault of a patient is a very serious adverse event, which must be reported and addressed to avoid any patient ever experiencing it again. However, this recategorization of the timeframe for reporting this adverse event is contrary to the framework established by the Legislature and Governor in enacting the statute. That framework specifically provides for no more than 24 hours to report those events that are an ongoing urgent or emergent threat to patients, personnel, or visitors, and no more than five days for all other events.

  Moreover, this provision specifies that the timeframe is no more than 24 hours not from detection as are all other adverse events, but rather from "allegation or detection." Allegation has no basis in statute and could lead to reporting of a significant number of events later determined to not be confirmed. As an example, a patient may allege that a nurse touched her chest area. However, an investigation determines it was not the nurse but the electrocardiograph technician who was adjusting the leads, and the alleged sexual assault was resolved between all parties.

  For these reasons, CHA recommends removal of Section 70972 (a)(2):

  ~~*(a)(2) 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.*~~

  As a result of this revision, hospitals would report sexual assault of a patient, along with all other adverse events, within five days, or within 24 hours if there is an urgent or emergent threat.

- **Required information**: These proposed regulations lay out the information hospitals are required to submit to CDPH when they report an adverse event. However, given that reports must be made within 24 hours or five days, respectively, hospitals will in many cases be unable to provide much of this information.

  Specifically, the date and time the adverse event occurred and names of any patients, personnel, visitors, and witnesses involved, may not be known at the time the report must be filed. Moreover, the hospital will likely not have been able to develop and finalize its corrective or mitigation action in response by the time the report must be filed. Finally, the regulations require any additional information as it becomes available. That goes far beyond the statutory authority for adverse event reports and ought to be removed. Instead, following an adverse event, CDPH has the authority to investigate and conduct a thorough examination of the event, including information the hospital becomes aware of subsequent to its reporting of the adverse event within 24 hours or five days.

To address these concerns, CHA recommends the following revisions to Section 70972(b):

(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 corrective or mitigating action in response to the adverse event, if any.
~~(9) Any additional information as it becomes available regarding the adverse event.~~

Section 70973 Adverse Events – Adverse Event Investigation

- **Confidentiality of root cause analyses:** The proposed regulations require hospitals to conduct a root cause analysis for patient safety events in accordance with Health and Safety Code Section 1279.6. It is important that CDPH educate its surveyors and other personnel about the legal protections conferred by state and federal law to root cause analyses and related documents. The hospital's root cause analysis is protected from discovery by California Evidence Code 1157 and may not be made available to attorneys — even in response to a subpoena — as articulated by the California Supreme Court in *Fox v. Kramer*, 22 Cal.4th 531 (2000).

  In addition, these documents are protected by the Patient Safety and Quality Improvement Act of 2005 [Pub. L. 109-41, 42 U.S.C. 299b-21 through 299b-26; see also 42 C.F.R. part 3], which preempts any federal, state, tribal, or local law that allows or requires disclosure of patient safety work product, as defined. The preemption and federal protections are designed to "provide a mechanism to protect sensitive information that could improve patient quality, safety and outcomes by fostering a non-threatening environment in which information about adverse medical events and near misses can be discussed." [73 Fed. Reg. 70732, 70795 (Nov. 21, 2008)]. A state may not require patient safety work product to be disclosed, even to state surveyors [42 C.F.R. Sections 3.204-3.212].

  Furthermore, according to the Centers for Medicare & Medicaid Services (CMS), in its Guidance for Performing Root Cause Analysis (RCA) with Performance Improvement Projects, confidentiality is critical to conducting any root cause analysis. CMS encourages facilities to, "Make it clear to everyone involved that the RCA process is confidential. This reassurance helps people feel safer discussing the process and system breakdowns that may have caused an inadvertent mistake."

CHA recommends that CDPH clarify in its regulations that root cause analyses shall remain confidential, and the hospital shall not be required to produce any such documents. Instead, CDPH could add a new subdivision (b) to Section 70973:

(b) A hospital shall, upon inquiry by the department, inform the department about whether it completed a root cause analysis in relation to a patient safety event under investigation. The hospital shall not be required to produce the root cause analysis or related documents that are protected by Evidence Code 1157 or the Patient Safety and Quality Improvement Act of 2005, Pub. L. 109-41.

Section 70974. Adverse Events – Policies and Procedures

- **Annual culture of safety requirement:** The regulation creates a new requirement, not specified in statute, to assess the hospital's culture of safety annually. It is not clear on what basis CDPH recommends that this occur annually. CHA recommends that CDPH remove this, or else revise to align with the national standard from The Joint Commission, "Leaders regularly evaluate the culture of safety and quality using valid and reliable tools." (LD.03.01.01, EP 1). As such, Section 70797 would be revised to read:

  (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:
  …
  (4) ~~Assessing the hospital's culture of safety every 12 months using a nationally recognized survey tool for safety culture assessment.~~ Leaders to regularly evaluate the culture of safety and quality using valid and reliable tools.
  A conforming revision to the definition of the term "nationally recognized survey tool" in the proposed regulation would also need to be made. CHA notes that the proposed definition cites a specific vendor, the National Association for Healthcare Quality, that certifies health care quality professionals, as opposed to patient safety and quality tools. CDPH may have intended to cite the federal Agency for Healthcare Research and Quality (AHRQ). CHA recommends citing AHRQ, but in recognition that AHRQ lists its tools, as opposed to any that might be proprietary in nature, allows for other valid and reliable tools that are nationally recognized. As such, the revision of that definition in Section 70971 would read:

  (a)(11) ~~"Nationally recognized survey tool" means a valid and reliable survey tool identified by the National Association for Healthcare Quality (NAHQ), or equivalent.~~ "Valid and reliable tools" means nationally recognized tools, including, but not limited to, those identified by the Agency for Healthcare Research and Quality.

Section 71567. Adverse Event Reporting Requirements

- **Apply same requirements for acute psychiatric hospitals:** These regulations adopt the same definitions as used for general acute care hospitals for acute psychiatric hospitals by reference. However, they do not for adverse event reporting requirements. CHA recommends that these provisions for acute psychiatric hospitals also adopt the same provisions as those for general acute care hospitals by replacing the contents of Section 71567 with:

  The provisions in Chapter 1, Article 11, section 70972 shall apply to reportable adverse events in acute psychiatric hospitals.

Section 71568 Adverse Event Investigation

- **Apply same requirements for acute psychiatric hospitals:** Similar to the comment above, CHA recommends that these provisions for acute psychiatric hospitals also adopt the same provisions as those for general acute care hospitals by replacing the contents of Section 71568 with:

  The provisions in Chapter 1, Article 11, section 70973 shall apply to reportable adverse events in acute psychiatric hospitals.

Section 71569. Adverse Events – Policies and Procedures

- **Apply same requirements for acute psychiatric hospitals**: Lastly, similar to the comments above, CHA recommends that these provisions for acute psychiatric hospitals also adopt the same provisions as those for general acute care hospitals by replacing the contents of Section 71569 with:

  The provisions in Chapter 1, Article 11, section 70974 shall apply to reportable adverse events in acute psychiatric hospitals.

Thank you for the opportunity to comment on these important regulations. We look forward to working with you. If you have any questions, please do not hesitate to contact me at kburchill@calhospital.org or (916) 552-7575.

Sincerely,

Kiyomi Burchill
Vice President, Policy