CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

April 6, 2021

Cassie Dunham, Acting Deputy Director
Center for Health Care Quality
California Department of Public Health
c/o Office of Regulations
1415 L Street, Suite 500
Sacramento, CA 95814

Submitted via email to the CDPH Office of Regulations (regulations@cdph.ca.gov)

Subject: Adverse Events Reporting DPH-11-023

Dear Ms. Dunham:

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 released March 23, 2021. CHA's goal in providing these comments is to promote consistent and timely reporting that promotes learning from these events and improvement in 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 However, because these proposed regulations do not adopt the definitions by cross reference, they will be outdated once the NQF next updates its recommendations.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 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 reasonably known, in order to promote timely and consistent reporting to CDPH:

(a)(6) "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)(10) ~~"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).

- **"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)(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~~ 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)(20), (21), and (22), and replace with:

  (a)(20) "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)(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.~~

- **"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, the event of 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 recommended 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, CHA recommended, 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). CDPH added this definition to specify use of physical restraints, however, still uses the ambiguous term, "associated." CHA requests that Section 70971 be further revised to read:

(a)(1) "A patient death or serious disability associated with the use of restraints" means a patient death or serious disability directly related to ~~associated with~~ 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

- **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, including allegations of sexual assault, to be reported within 24 hours of 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, the recategorization of the time frame 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 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 time frame is no more than 24 hours from detection and includes *allegations of sexual assaults* in the definition of sexual assault. This is different from all other adverse events. 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, if an investigation determines it was not the nurse but the electrocardiograph technician who was adjusting the leads, the alleged sexual assault could be resolved between all parties.

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

~~*(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.*~~

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.

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 71567: Adverse Event Reporting Requirements

- **Apply same requirements for acute psychiatric hospitals:** These regulations adopt the same definitions for general acute care hospitals and acute psychiatric hospitals by reference. However, they do not adopt the same adverse event reporting requirements for acute psychiatric hospitals. CHA recommends that these provisions apply to both acute psychiatric hospitals and 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 apply to both acute psychiatric hospitals and 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.

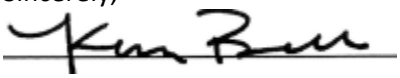
Section 71569: Adverse Events – Policies and Procedures

- **Apply same requirements for acute psychiatric hospitals**: Lastly, similar to the comments above, CHA recommends that these provisions apply to both acute psychiatric hospitals and 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
Group Vice President, Policy