



September 24, 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 September 9. CHA's goal in providing these comments is to support consistent and timely reporting that promotes learning from these events and improvement in the quality of patient care.

For the purpose of this letter, CHA will comment on the revisions for which CDPH is seeking comments. However, CHA continues to reiterate the comments from our [April 6, 2021, letter](#).

Assessment of Culture of Safety

The first issue in these most recent proposed revisions is the change from the requirement that hospitals assess their "culture of safety" at least every two years using a nationally recognized survey tool to a requirement for hospitals to assess their "patient safety culture." While it may seem a minor change, it is substantive in that it removes the common awareness of the term "culture of safety" in the health care field. This phrasing is used by many of the nationally recognized survey tools, and this revision could create confusion for the hospital field on how to comply with the new assessment requirement.

CHA recommends the following revisions in Sections 70971 and 70974 to restore the use of the term of art "culture of safety":

Section 70971 (a)(15) "~~Patient safety culture~~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.

Section 70974. (4) Assessing the hospital's ~~patient safety culture~~culture of safety at least every 24 months using a nationally recognized survey tool.

Secure System for Submission of Adverse Events

The prior version of this proposed regulation required that hospitals submit reports of adverse events through the department's secure electronic web-based portal. This was understood to be the department's CalHEART system, or a subsequent system to it. However, the most recent revision would describe it instead as "an internet website maintained by the Department."

This raises concerns about the removal of the word "secure." Will the system no longer be secure?

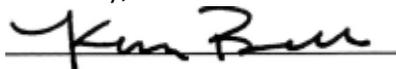
Given that adverse events are related directly to patients, we recommend that "secure" be re-inserted:

Section 70972 (a) Pursuant to Health and Safety Code sections 1279.1 and 1279.3, adverse events shall be reported by the hospital through ~~an~~ a secure internet website maintained pursuant to the following timelines:

(c) In the event the Department's secure internet website is not operational, the hospital shall report an adverse event to the Department by email or telephone.

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