

Health and Human Services Agency California Department of Public Health



Erica Pan, MD, MPHDirector and State Public Health Officer

Gavin Newsom
Governor

30 DAY RESPONSE TO PETITIONER P-25-02 – Adverse Events Regs Petition

October 16, 2025

VIA ELECTRONIC MAIL

Attn: Mr. Tobias Gilk Radiology / MRI Consultant MRIPatientSafety.com tgilk@MRIpatientsafety.com

RE: Response to Petition Requesting Rulemaking for Adverse Events Regulations

Dear Tobias Gilk:

On September 24, 2025, the California Department of Public Health (CDPH) received your petition for rulemaking under Government Code section 11340.6. Pursuant to Government Code section 11340.7, CDPH denies this petition because CDPH does not have authority to promulgate the requested regulations. The bases for denial are set forth below.

The petition proposes to add section X100 (Scope and Applicability) and section X101 (Definitions) to create new definitions, including for "Adverse Events," which would apply to multiple facility types. However, Health and Safety Code section 1279.1 already defines Adverse Events to include seven specific types of incidents. In addition, the Adverse Events definition applies only to three facility types, general acute care hospitals, acute psychiatric hospitals, and special hospitals. As such, there is no statutory authority to 1) redefine the term and 2) expand the list of facilities that Adverse Events cover.¹

The petition proposes to add section X102 (Complainant Participation) to allow complainants to participate in an Adverse Event investigation, including the option to attend the licensee's interview. Health and Safety Code section 1279.2, subdivision

¹ Long-term healthcare facilities already have an existing complaint investigation process in Chapter 2.4 of Division 2 of the Health and Safety code. The severity levels for incidents at the facility are already defined in Health and Safety Code section 1424.

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(a)(1), specifies the timeframes within which "the <u>department</u> shall make an onsite inspection or investigation." (Emphasis added.) Moreover, existing law authorizes "any officer, employee, or agent of the state department" only, as opposed to a complainant, to enter and inspect the health facility upon presenting proper identification. (Health & Saf. Code, § 1278.) As such, there is no statutory authority for CDPH to bring a third party, such as a complainant, to an interview with the licensee.

The petition proposes to add sections X103 (Disclosure of Findings) and X104 (Retroactive Disclosure) to address disclosure of the following information related to complaint investigations: "jurisdictional determination," "immediate jeopardy status," "categorization of the adverse event," "statement of deficiencies," "administrative penalty," and "corrective action plan." Some of these terms are undefined. California state and local agency disclosures of public records are already governed by the California Public Records Act (PRA) at Government Code sections 7920.000 through 7931.000. Because CDPH provides these or similar types of information for state-only records² pursuant to the PRA, this part of the proposed regulation is unnecessary.

The petition proposes to add section X105 (Records Retention and Access) to create a records retention and access schedule. CDPH follows the records retention schedules approved and posted on the Secretary of State's website. To change the records retention schedule, CDPH submits a new schedule for approval to the Secretary of State. As such, promulgating regulations is unnecessary.

Finally, the petition proposes to add section X106 (Enforcement) to create a departmental violation. Because this pertains to enforcement of the provisions summarized above, this is denied for the same reasons.

Under Government Code section 11340.7, subdivision (d), any interested person has the right to obtain a copy of the petition submitted to the agency. A copy of the petition and this letter will be posted on the CDPH Office of Regulations website at the following:

https://www.cdph.ca.gov/Programs/OLS/Pages/Petitions for Regulatory Action.aspx

In addition, interested persons may request a copy by contacting the Office of Regulations by email: regulations@cdph.ca.gov, by phone: (916) 558-1710, or by mail: California Department of Public Health, 1415 L Street, Suite 500, Sacramento, CA 95814.

If you have any questions, please reach me at Keith.VanWagner@cdph.ca.gov. Thank you.

² For records from federal investigations that CDPH performs on behalf of the Centers for Medicare and Medicaid Services, the public must request information from CMS through the Freedom of Information Act.

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Sincerely,

Keith Van Wagner Assistant Chief Counsel Office of Legal Services