

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-25-04 – Failure to Report Adverse Events Regs Petition

October 28, 2025

VIA ELECTRONIC MAIL

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

RE: Response to Petition Requesting Rulemaking for Failure to Report Adverse Event 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 the proposed regulations are unnecessary. The bases for denial are set forth below.

The petition proposes adding section X100 (Public Registry of Late-Reported Adverse Events) mandating the creation and maintenance of a new public-facing website for displaying failures to report Adverse Events. The proposed regulations subdivisions (a)-(g) describe how information regarding the late reporting would be identified on the website and maintained for five years. The petition also proposes establishing a five-year records retention period.

The proposed website content and searchable feature is available on CDPH's Cal Health Find Database and enforcement dashboard.¹ As you note, facilities are required to report Adverse Events, and CDPH may levy a fine for a failure to timely report the Adverse Event for general acute care hospitals, acute psychiatric hospitals, and specialty hospitals. (Health & Saf. Code, §§ 1279.1, 1280.4.) Findings related to failure to report an Adverse Event are posted online, such as the state 2567 form describing the Adverse Event, which includes a violation for failure to report, plans of correction, and records of penalties assessed to the facility.

¹ https://www.cdph.ca.gov/Programs/CHCQ/LCP/calhealthfind/pages/home.aspx

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Further, CDPH follows the records retention schedules approved and posted on the California Secretary of State's <u>website</u>. To change the records retention schedule, CDPH can submit a new schedule for the Secretary of State's approval. The current schedule applies to records related to failures to report Adverse Events that are posted on Cal Health Find. As such, promulgating the proposed regulations is unnecessary.

In sum, the proposed website content is already available on CDPH's website and CDPH's records retention schedule is already established. Moreover, CDPH does not need a regulation to change content and features on its website nor to update the records retention schedule. For these reasons, the proposed regulations are unnecessary.

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.

Sincerely,

Keith Van Wagner Assistant Chief Counsel Office of Legal Services