From: Tobias B Gilk <tgilk@MRIpatientsafety.com>
Sent: Wednesday, October 8, 2025 11:55 AM
To: CDPH Ofc of Regulations <Regulations@cdph.ca.gov>
Subject: GOV § 11340.6 Petition - 'Failure to Report' Registry

Sir or Madam, What follows is a petition, submitted to CDPH pursuant to GOV § 11340.6, for rulemaking to develop a registry of state licensees who fail to meet their statutory obligations for self-reporting of adverse events. Please acknowledge,

Sir or Madam,

What follows is a petition, submitted to CDPH pursuant to GOV § 11340.6, for rulemaking to develop a registry of state licensees who fail to meet their statutory obligations for self-reporting of adverse events.

Please acknowledge, on behalf of CDPH, receipt of this petition.

At your earliest convenience, please advise of the acceptance of this petition for consideration, or identify any defects or shortcomings which will require correction for consideration, as well as the most expedient means of having any corrected defects reconsidered by CDPH.

Respectfully,

Tobias Gilk

PETITION FOR RULEMAKING

Submitted Pursuant to Government Code § 11340.6

I. Petitioner

Tobias Gilk

II. Agency Petitioned

California Department of Public Health (CDPH)

Licensing and Certification Division

III. Purpose and Subject of Petition

Petitioner requests that CDPH adopt regulations establishing a **public registry of adverse events** that were **required to be self-reported by licensed facilities under 22 CCR § 70972**, but were **not reported within the statutory reporting period**.

The registry would promote transparency, support timely compliance with Health and Safety Code §§ 1279.1–1279.3, and reinforce that failure to report adverse events within required timeframes is a **stand-alone violation of state licensure law**, subject to administrative action.

IV. Background and Legal Authority

Statutory Basis:
Health & Safety Code § 1279.1 — requires hospitals to report defined adverse events to CDPH.
Health & Safety Code § 1279.3 — authorizes CDPH to investigate and impose administrative penalties.
22 CCR § 70972(a) — mandates reporting through CDPH's secure internet system within:
24 hours for urgent/emergent threats or sexual assault allegations, and
5 calendar days for all other adverse events.
Problem Identified:
Facilities sometimes fail to self-report within these statutory deadlines.
Many such events are first revealed through **public complaints or whistleblower reports**.

When CDPH substantiates these complaints, the public lacks visibility into the fact that the facility failed to timely report—a violation separate from the underlying event.

V. Proposed Regulation

§ X100. Public Registry of Late-Reported Adverse Events

(a) Scope

This section applies to adverse events required to be reported to the Department under **Health and Safety Code § 1279.1**and **22 CCR § 70972** that were not reported by the licensee within the timeframes prescribed in § 70972(a).

(b) Registry Creation

The Department shall establish and maintain on its public website a **searchable and sortable electronic registry** of adverse events meeting the criteria in subsection (a).

(c) Inclusion Criteria

An adverse event shall be listed in the registry when:

The event was first brought to the Department's attention through a **public complaint or adverse event report** not initiated by the facility; and
The Department has substantiated the general facts of the event; and
The Department determines that the facility failed to report the event within the required timeframe under § 70972(a).

(d) Information Displayed

For each entry, the registry shall include:

The facility's licensed name and address;
Date of the adverse event;
Date the Department was first notified (and whether by facility or complainant);
A concise description of the adverse event, including:
The general nature of the event (e.g., retained foreign object, wrong-site procedure, patient fall resulting in death);
The associated risk or harm;
Any **CDPH-determined categorization or stratification of risk or severity**, including whether the Department determined the event represented an **Immediate Jeopardy** under state criteria;
Whether CDPH substantiated the complaint claim;

Whether CDPH conducted a formal investigation; and
Whether the Department initiated administrative or enforcement action related to the failure to report.

(e) Clarification of Violation

Each registry entry shall include the statement:

"Failure to timely self-report an adverse event constitutes a violation of the facility's state license conditions and may result in administrative action by the Department, independent of any enforcement related to the adverse event itself."

(f) Updates and Maintenance

The Department shall update the registry at least quarterly and retain records for not less than five (5) years.

(g) Confidentiality

The Department shall redact individually identifiable patient information and any data protected under applicable privacy laws.

VI. Expected Benefits

Transparency: Enables the public to identify facilities with repeated or significant failures to self-report.
Accountability: Reinforces timely compliance with reporting obligations.
Public Trust: Demonstrates that CDPH monitors both event prevention and regulatory compliance.

VII. Editorial and Policy Considerations

Privacy Safeguards: Patient identifiers must be fully redacted to comply with HIPAA and state confidentiality statutes.
Due Process: Facilities should be listed only after CDPH's substantiation and completion of any appeal period for findings of late reporting.
Data Maintenance Burden: CDPH may raise concerns about workload; automation of data entry from existing internal systems could mitigate this.
Consistency with § 70972: The petition's focus is solely on reporting timeliness; it does not expand the definition of adverse events or modify facility reporting duties.

VIII. Requested Action

Petitioner respectfully requests that CDPH:

Initiate rulemaking under **Government Code § 11346 et seq.** to add new regulatory text as set forth above;
Develop a publicly accessible, searchable online registry of adverse events meeting the described criteria; and
Issue guidance clarifying that untimely self-reporting is a license violation subject to administrative action independent of the underlying event.