From: <u>Tobias B Gilk</u>

To: <u>Van Wagner, Keith@CDPH</u>; <u>CDPH Ofc of Regulations</u>

Subject: GOV § 11340.6 Petition - Determination / Finding Information Disclosure to Complainants

Date: Friday, September 26, 2025 9:35:10 AM

Attachments: DRAFT REGULATORY TEXT - Adverse Event Complaint Process - Complainant Engagement and Disclosure.docx

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Sir or Madam,

What follows is a petition, submitted to CDPH pursuant to GOV § 11340.6, for rulemaking to adopt transparency / disclosure requirements relative to complaints of licensed healthcare facilities and regulated modalities. Additionally, attached to this message with this petition, please find a Word document with a proposed draft of the regulatory text which would follow from this petition.

Please acknowledge, on behalf of CDPH, receipt of this petition and attached proposed draft.

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

I. Introduction

- Petitioner: Tobias Gilk
- Respondent Agency: California Department of Public Health (CDPH), Licensing & Certification Program
- **Authority**: California Government Code §11340.6 authorizes interested persons to petition for the adoption, amendment, or repeal of a regulation.
- **Subject**: Request for rulemaking to enhance complainant participation and transparency in CDPH's state licensure adverse event investigations of General Acute Care Hospitals (GACHs) and all other CDPH-licensed health facilities.

II. Background & Current Regulatory Environment

• Adverse Event Reporting (State Law): Health & Safety Code §1279.1 requires hospitals to report defined adverse events to CDPH.

- State Administrative Penalties: Health & Safety Code §§1280.1–1280.3 authorize CDPH to investigate and impose administrative penalties on licensed facilities.
- Current CDPH Policies:
 - **P&P 800.3.3** Administrative Penalty Process (Immediate Jeopardy).
 - **P&P 800.3.4** Adverse Event Investigation Process.
 - **P&P 800.3.7** Non-Immediate Jeopardy Penalty Process
- Gap: These policies govern state enforcement against licensees but do not guarantee complainant engagement or release of findings.

III. Proposed Rulemaking

A. Scope

- 1. This rule applies **only** to CDPH's determinations and findings related to **California state licensure**.
- 2. This rule shall **not** apply to federal Centers for Medicare & Medicaid Services (CMS) investigations, even when CDPH staff or resources are used in the federal survey process.

B. Complainant Engagement

- 1. Complainants shall be notified of and provided the right to attend initial investigatory interviews with the licensee, if they choose.
- 2. This right applies across all CDPH-licensed facility types, including GACHs, acute psychiatric hospitals, special hospitals, clinics, and outpatient imaging centers.

C. Disclosure of Findings

Upon request, CDPH shall provide complainants with:

- 1. A copy of the jurisdictional determination (whether the event falls under state licensure authority).
- 2. The **State's determination of Immediate Jeopardy** status (as defined in state policy), if applicable.
- 3. Any **state-determined gradation or categorization of accident type or severity** (e.g., Immediate Jeopardy, non-Immediate Jeopardy, accident classifications used for penalty determinations).
- 4. The Statement of Deficiencies (if issued).
- 5. Notice of administrative penalties imposed, including penalty level and citation type.

6. Corrective action plans required by CDPH, with protected health information redacted.

D. Retroactive Application

- 1. Complainants may request disclosures for complaints submitted prior to the effective date of the new rule.
- 2. Retroactive disclosures are limited to **final state licensure determinations and penalties** and do not include draft investigative materials.

IV. Legal Authority

- Gov. Code §11340.6 Petition authority.
- Health & Safety Code §§1279.1, 1280.1–1280.3, 1280.5, 1280.6 CDPH authority for adverse event investigation and penalty imposition.
- Title 22 CCR §§70951–70958 Hospital administrative penalty regulations.
- **CDPH Policies** (P&P 800.3.3, 800.3.4, 800.3.7) Current internal procedures, which would be modified.

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