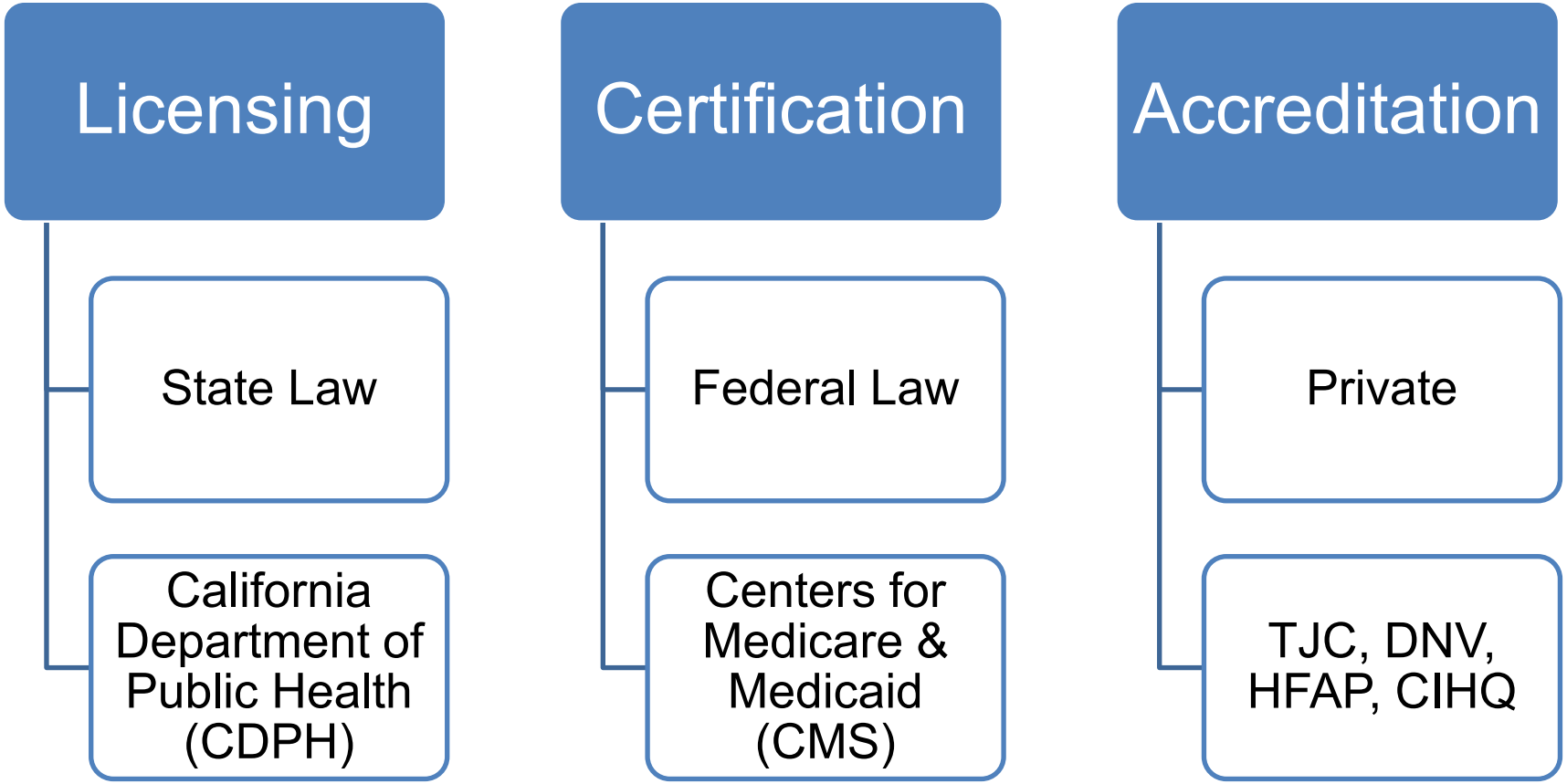
Licensing, Certification & Surveys

Licensing, Certification and Accreditation



California Hospital Association

CDPH Licensing

- Hospitals in California must obtain and maintain a license from CDPH.
- CDPH's Licensing and Certification (L&C) Program is responsible for issuing the license and assessing a hospital's compliance with state licensing laws.
- Types of California hospitals:
  - General acute care hospitals;
  - Acute psychiatric hospital;
  - Special (not specialty) hospitals

CMS Certification

To treat Medicare and Medicaid patients, hospitals must comply with federal requirements including the Conditions of Participation (CoPs):

CMS Certification

- Undergo a certification survey by CMS or its contractor
- CDPH is CMS' contractor (sometimes referred to as "State Agency" or "State Survey Agency"

Deemed Status

- Become accredited by a CMS-approved private accrediting body
- Accreditation organizations must demonstrate to CMS that the requirements hospitals must meet for accreditation are equivalent to CMS' requirements

California Hospital Association

Accreditation

- Hospitals may choose to be accredited by one or more accreditation organizations (AOs).
- AOs are private entities.
- Some AOs have deeming authority, others do not.
- Some managed care plans require a hospital to be accredited to be included in the plan's network.

California Hospital Association

REGULATORY REPORTING

Overview of Regulatory Reporting Requirements

What is reported?	To whom?	When?	Authority
Sentinel events	Joint Commission	5 days	
Adverse events	CDPH	5 calendar days after detection (some must be reported within 24 hours)	HSC 1279.1, 22 CCR 70971
Unusual occurrences	CDPH	Immediately via telephone	22 CCR 70746, 70737
Medical device incidents	FDA	As soon as practicable, no later than 10 business days after becoming aware	21 CFR 803.11
Death associated with use of restraint or seclusion	CMS	No later than close of business day of next business day following death	42 CFR 482.13(g), 485.614(g)

California Hospital Association

Privacy Breach Reporting

HIPAA/HITECH (42 USC 17932; 45 CFR 164.400)	CMIA (Cal. Health & Safety Code 1280.15, 22 CCR 79900)
Notice required to the affected individuals and OCR* "without unreasonable delay" and in no case later than 60 calendar days from time the CE or its BA knew or should have known of the breach. Media notice if breach affects more than 500 residents of a jurisdiction.	Notice required to the affected individuals and CDPH **no later than 15 business days** after detection of breach by CE or BA

California Hospital Association

Joint Commission Sentinel Event

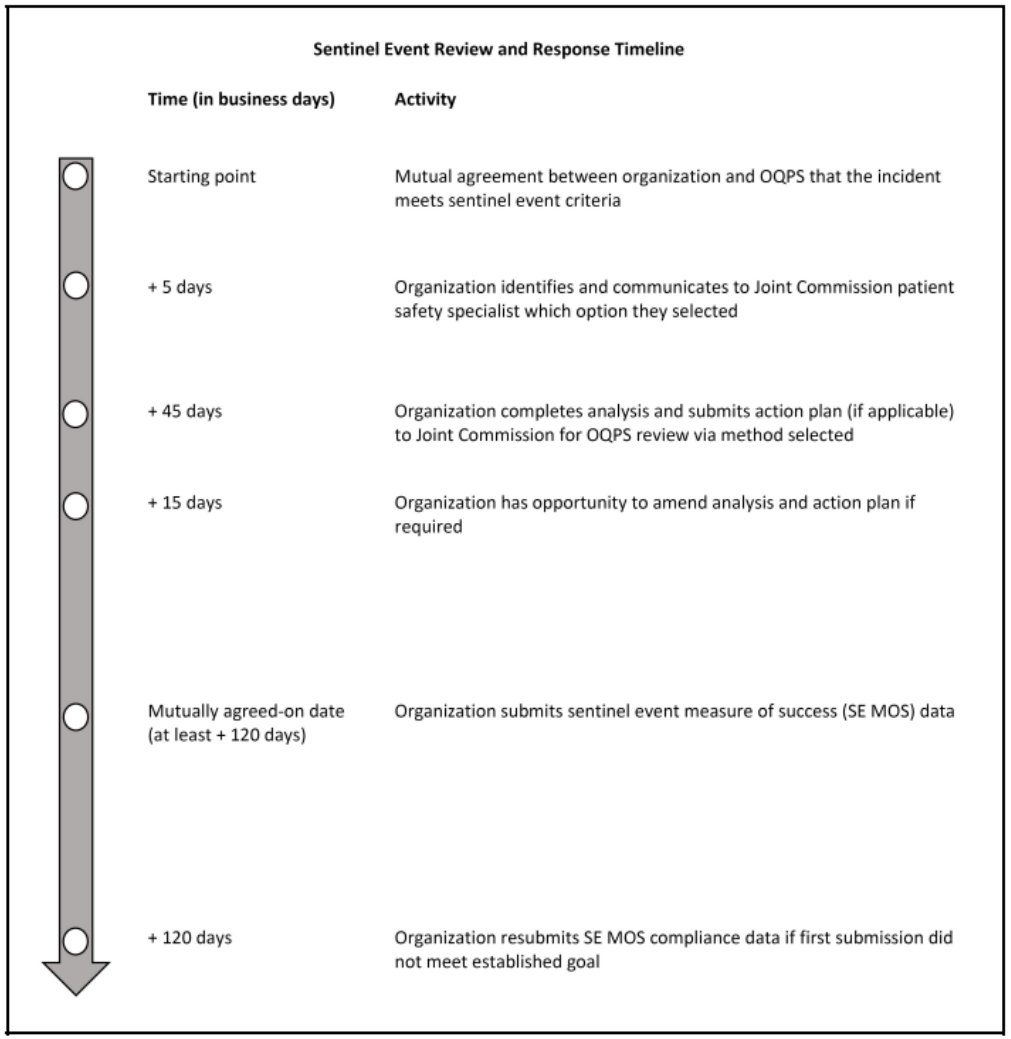
A ***sentinel event*** is a patient safety event (not primarily related to the natural course of a patient's illness or underlying condition) that reaches a patient and results in death, severe harm (regardless of duration of harm), or permanent harm (regardless of severity of harm).

- Death caused by self-inflicted injurious behavior if any of the following apply:
  - While in a health care setting
  - Within 7 days of discharge from inpatient services
  - Within 7 days of discharge from emergency department (ED)
  - While receiving or within 7 days of discharge from the following behavioral health care services: Day Treatment/Partial Hospitalization Program (PHP)/ Intensive Outpatient Program (IOP), Residential, Group Home, and Transitional Supportive Living
- Unanticipated death of a full-term infant
- Homicide of any patient receiving care, treatment, and services while on site at the organization or while under the care or supervision of the organization
- Homicide of a staff member, visitor, or vendor while on site at the organization or while providing care or supervision to patients
- Any intrapartum maternal death
- ***Severe maternal morbidity*** (leading to ***permanent harm*** or ***severe harm***)†
- ***Sexual abuse/assault*** of any patient receiving care, treatment, and services while on site at the organization or while under the care or supervision of the organization
- Sexual abuse/assault of a staff member, visitor, or vendor while on site at the organization or while providing care or supervision to patients
- Physical assault (leading to death, permanent harm, or severe harm) of any patient receiving care, treatment, and services while on site at the organization or while under the care or supervision of the organization
- Physical assault (leading to death, permanent harm, or severe harm) of a staff member, visitor, or vendor while on site at the organization or while providing care or supervision to patients
- Surgery or other ***invasive procedure*** performed at the wrong site, on the wrong patient, or that is the wrong (unintended) procedure for a patient regardless of the type of procedure or the magnitude of the outcome
- Discharge of an infant to the wrong family
- Abduction of any patient receiving care, treatment, and services
- Any elopement (that is, unauthorized departure) of a patient from a staffed around-the-clock care setting (including the ED), leading to death, permanent harm, or severe harm to the patient
- Administration of blood or blood products having unintended ABO and non-ABO (Rh, Duffy, Kell, Lewis, and other clinically important blood groups) incompatibilities,‡ hemolytic transfusion reactions, or transfusions resulting in death, permanent harm, or severe harm§
- Unintended retention of a foreign object in a patient after an invasive procedure, including surgery‖
- Severe neonatal hyperbilirubinemia (bilirubin >30 milligrams/deciliter)
- Fluoroscopy resulting in permanent tissue injury when clinical and technical optimization were not implemented and/or recognized practice parameters were not followed#
- Any delivery of radiotherapy to the wrong patient, wrong body region, unintended procedure, or >25% above the planned radiotherapy dose
- ***Fire***, flame, or unanticipated smoke, heat, or flashes occurring during direct patient care caused by equipment operated and used by the organization. To be considered a sentinel event, equipment must be in use at the time of the event; staff do not need to be present.
- Fall in a staffed-around-the-clock care setting or fall in a care setting not staffed around the clock during a time when staff are present resulting in any of the following:
  - Any fracture
  - Surgery, casting, or traction
  - Required consult/management or comfort care for a neurological (for example, skull fracture, subdural or intracranial hemorrhage) or internal (for example, rib fracture, small liver laceration) injury
  - A patient with coagulopathy who receives blood products because of the fall
  - Death or permanent harm because of injuries sustained from the fall (not from physiologic events causing the fall)

Source: https://www.jointcommission.org/-/media/tjc/documents/resources/patient-safety-topics/sentinel-event/2025/se-3-camhospital_se_jan_2025.pdf

California Hospital Association

Joint Commission Sentinel Event Reporting



Sentinel Event Review and Response Timeline

Time (in business days)	Activity
Starting point	Mutual agreement between organization and OQPS that the incident meets sentinel event criteria
+ 5 days	Organization identifies and communicates to Joint Commission patient safety specialist which option they selected
+ 45 days	Organization completes analysis and submits action plan (if applicable) to Joint Commission for OQPS review via method selected
+ 15 days	Organization has opportunity to amend analysis and action plan if required
Mutually agreed-on date (at least + 120 days)	Organization submits sentinel event measure of success (SE MOS) data
+ 120 days	Organization resubmits SE MOS compliance data if first submission did not meet established goal

Figure 1. *This general timeline provides an overview of the sentinel event response process.*

- Health care organizations are strongly encouraged, although not technically required to report sentinel events to the Joint Commission
- Can ask to clarify whether an event meets the sentinel events definition through its *Joint Commission Connect* extranet site

Adverse Events


Surgical Events (1)


Product or Device Events (2)


Patient Protection Events (3)


Care Management Events (4)


Environmental Events (5)


Criminal Events (6)


The Catchall (7)

California Health & Safety Code § 1279.1:

*A hospital shall report an adverse event to CDPH no later than 5 days after the adverse event has been **detected**, or if the event is an ongoing urgent or emergent threat not later than 24 hours after the adverse event has been detected.*

What about outpatient settings?

California Hospital Association

Adverse Event Reporting

2022 Regulatory Updates → *22 CCR § § 70970 – 70974*

- **Definition of detect**: the discovery of an adverse event, or the reasonable belief of a discovery of an adverse event, by a hospital, its personnel, or its agents. An adverse event shall be treated as detected as of the first business day on which such adverse event is known to the hospital, or by exercising reasonable diligence would have been known to the hospital. A hospital shall be deemed to have knowledge of an adverse event if such an adverse event is known, or by exercising reasonable diligence would have been known, to any person other than the person committing the adverse event, who is the personnel or agent of the hospital.
- **"Major life activity"** means any of the following:

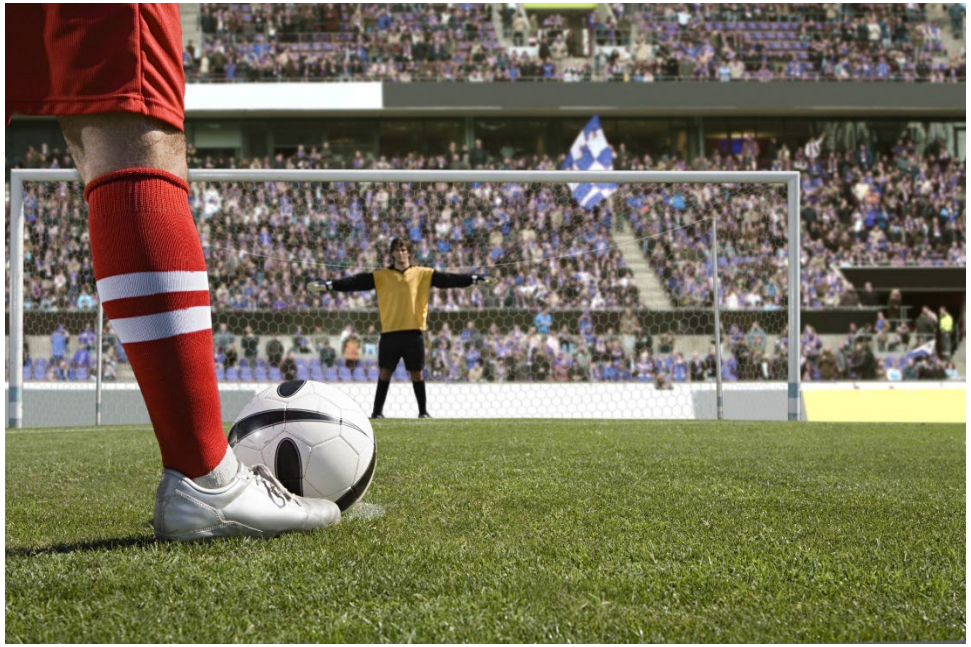
  (A) Caring for oneself, performing manual tasks, seeing, hearing, eating, sleeping, walking, standing, lifting, bending, speaking, breathing, learning, reading, concentrating, thinking, communicating, and working; or

  (B) A major bodily function, including functions of the immune system, normal cell growth, digestive, bowel, bladder, neurological, brain, respiratory, circulatory, endocrine, and reproductive functions.
- Sexual assault of a patient, including ***allegations of sexual assault***, shall be reported within 24 hours after detection
- **Retention of foreign object also excludes** objects not present prior to the surgery or other procedure that are intentionally left in place when the risk of removal exceeds the risk of leaving the object in place (e.g., microneedles, broken screws), and the physician/surgeon documents the risk of removal.

Adverse Event Reporting (cont.)

Penalties for failure to report

- CDPH may assess a civil penalty in an amount not to exceed $100 for each day following the initial 5-day/24-hour period
- May request a hearing within 10 days to dispute penalty



California Hospital Association

Unusual Occurrences/Other CDPH Reporting

Reportable	Description	Authority
Disruption of services	Intent of the discontinuance or disruption of services or upon the threat of a walkout of a substantial number of employees, or earthquake, fire, power outage or other calamity that causes damage to the facility or threatens the safety or welfare of patients or clients	22 CCR § 70746 (GACH); 22 CCR § 71544 (APH)
Unusual occurrences	All cases of reportable diseases and Any occurrence such as epidemic outbreak, poisoning, fire, major accident, disaster, other catastrophe or unusual occurrence which threatens the welfare, safety or health of patients, personnel or visitors	22 CCR § 70737 (GACH); 22 CCR § 70737 (APH);
Sentinel Events	Sentinel events as defined by the Joint Commission, even if the hospital does not report the event to the Joint Commission	CDPH interpretation
Restraint related death	A patient death that occurs while a patient is restrained or in seclusion for behavior management	CDPH interpretation
News media	Incidents that are covered by the news media	CDPH interpretation
Emergency or disaster causing evacuation	An emergency or disaster-related occurrence that results in a patient evacuation, transfer, or discharge	All Facilities Letter 17-06 (Mar. 13, 2017)
Power outages	Public Safety Power Shutoff power outages	All Facilities Letter 20-50 (July 13, 2020); All Facilities Letter 19-30.1 (November 14, 2019); All Facilities Letter 18-48 (Nov. 13, 2018)

Medical Device Incidents

Summary of Mandatory Reporting Requirements for User Facilities

REPORTER	WHAT TO REPORT	REPORT FORM #	TO WHOM	WHEN
User Facility	Device-related Death	Form FDA 3500A	FDA & Manufacturer	Within 10 work days of becoming aware
User Facility	Device-related Serious injury	Form FDA 3500A	Manufacturer. FDA only if manufacturer unknown	Within 10 work days of becoming aware
User Facility	Annual summary of death & serious injury reports	Form FDA 3419	FDA	January 1 for the preceding year

21 CFR Part 803

Restraint/Seclusion Related Deaths

Requirement	Report to	Authority
A patient death or serious disability associated with the use of restraints or bedrails while being cared for in a health facility. (Adverse Event)	CDPH	Cal. Health & Safety Code § 1279.1(5)(e)
Each death that occurs while a patient is in restraint or seclusion, ***excluding those in which only 2-point soft wrist restraints were used and the patient was not in seclusion at the time of death;*** Each death that occurs within 24 hours after the patient has been removed from restraint or seclusion, ***excluding those in which only 2-point soft wrist restraints were used and the patient was not in seclusion within 24 hours of their death***; and Each death known to the hospital that occurs within one week after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death, regardless of the type(s) of restraint used on the patient during this time.	CMS Regional Office	AFL 14-15 (June 20, 2014); AFL 20-21 (March 11, 2020)

SURVEYS

Types of Surveys

State Surveys

- Licensing/New Service
- Relicensing
  - At least every 3 years
- Complaint
  - Ongoing threat – 48 hours/2 business days
  - No imminent threat – 45 days
- Self-report
  - Privacy breach/unusual occurrence: not required, but may
  - Adverse event:
    - Ongoing– 48 hours/2 business days
    - No imminent threat – 45 days

Federal Surveys

- Certification/recertification
  - Cyclical – approximately every 3 years
  - If a hospital remains "deemed" in compliance by an AO, it is subject to a validation survey rather than certification/recertification survey
- Complaint/allegation
  - CMS receives a complaint it determines raise a "substantial allegation of noncompliance"
  - May refer to AO or CDPH
- Validation
  - Random basis to validate the AO's process/performance

California Hospital Association

State Surveys

- Surveyors assess hospital's compliance with state CA statutes and regulations (California Health & Safety Code 1250 et seq, Title 22 CCR)
  - Many Title 22 regulations require hospitals develop and implement specific **policies and procedures**
  - CDPH may cite a deficiency if the hospital does not comply with its own policies and procedures
- CDPH publishes "**All Facilities Letters**" (AFLs) to provide guidance to hospitals on new requirements, clarify interpretation, etc.
- **Program flexibility**: CDPH has authority to grant flexibility with Title 22 requirements. A hospital must submit CDPH 5000 explaining why a variance is appropriate under the circumstances.

California Hospital Association

Federal Surveys

- Surveyors assessing compliance with
  - Medicare "**Conditions of Participation**" (CoPs) (42 CFR Part 482)
    - Examples: 482.12 Governing Body; 482.13 Patients' Rights; 482.23 Nursing
  - **EMTALA** (42 CFR 489.20, 489.24)
  - **Life Safety Code**; Health Care Facilities Code
  - HIPAA
- *Interpretative Guidelines* to clarify surveyors' understanding of the CoPs and to keep surveyors consistent (Appendix A to the SOM)
- State Operations Manual (SOM) for surveyors to follow during the survey process
- CMS Survey and Certification (S&C) Memos to Surveyors

What to do When the Surveyors Show Up?

Entrance

Entrance Conference

Surveyor Processes

Exit Conference

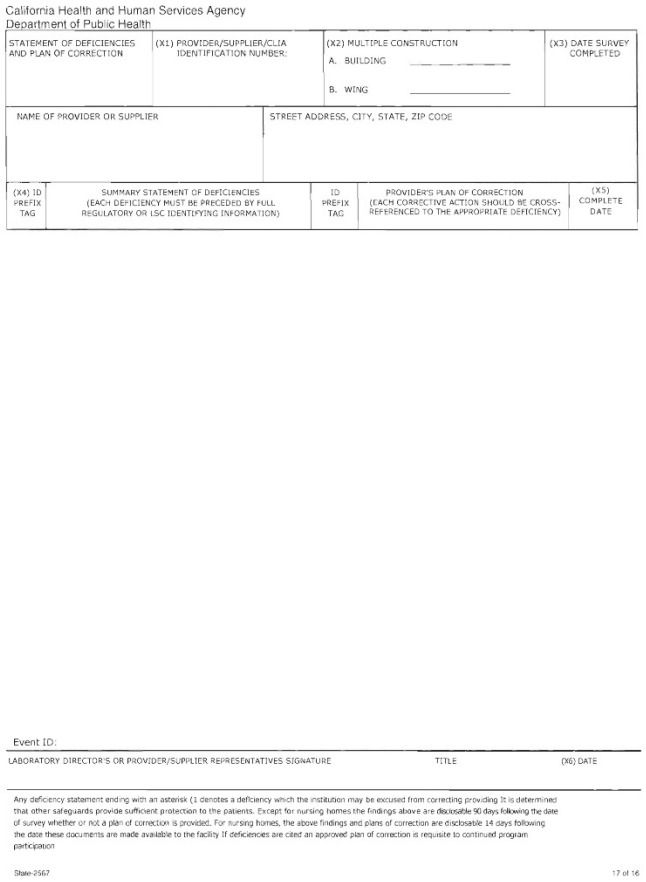
California Hospital Association

Survey Outcomes

- Nothing
- CMS-2567 Statement of Deficiencies
- Immediate Jeopardy (State v Federal)
- Penalties
- Termination

2567 Statement of Deficiencies

CDPH



California Health and Human Services Agency
Department of Public Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
		A. BUILDING _____ B. WING _____	

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE

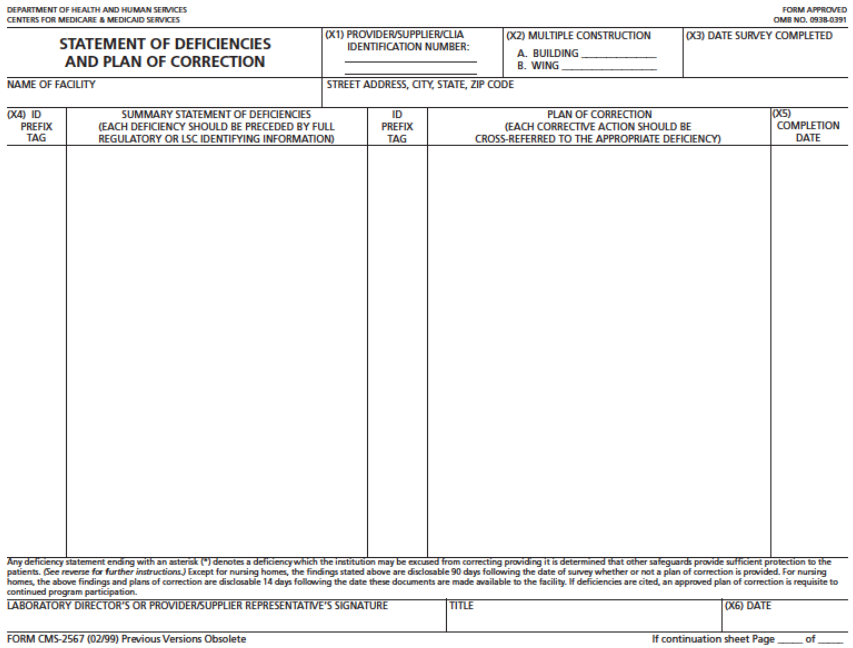
Event ID:

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVES SIGNATURE | TITLE | (X6) DATE

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. Except for nursing homes the findings above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited an approved plan of correction is requisite to continued program participation

State-2567 17 of 16

CMS



DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
		A. BUILDING _____ B. WING _____	

NAME OF FACILITY	STREET ADDRESS, CITY, STATE, ZIP CODE

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY SHOULD BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERRED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. *(See reverse for further instructions.)* Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

FORM CMS-2567 (02/99) Previous Versions Obsolete If continuation sheet Page ____ of ____

California Hospital Association

Plan of Correction (POC)

An acceptable PoC must contain the following elements:

1. The plan for correcting each specific deficiency cited;

2. The plan for improving the processes that led to the deficiency cited, including how the hospital is addressing improvements in its systems in order to prevent the likelihood of recurrence of the deficient practice;

3. The procedure for implementing the PoC, if found acceptable, for each deficiency cited;

4. A completion date for correction of each deficiency cited;

5. The monitoring and tracking procedures that will be implemented to ensure that the PoC is effective and that the specific deficiency(ies) cited remain corrected and in compliance with the regulatory requirements; and

6. The title of the person(s) responsible for implementing the acceptable PoC.

The Plan of Correction for each deficiency must contain the following:

a. A plan for correcting the specific deficiency, addressing the processes that led to the deficiency cited.
b. Procedures for implementing the plan of correction for the specific deficiency cited.
c. Monitoring procedures to ensure that the plan of correction is effective and in compliance with Department regulatory requirements.
d. Identify staff responsible for implementing the plan of correction (i.e., Administrator, Director of Nursing, Privacy Officer, or other responsible supervisory personnel).
e. The Plan of Correction completion date. This date shall be no more than 30 calendar days from the date the facility was notified of the non-compliance.

The plan of correction for each deficiency listed must contain the following:

A. The corrective action to be taken for each individual affected by the deficient practice, including any system changes that must be made;

B. The position of the person who will monitor the corrective action and the frequency of monitoring; and

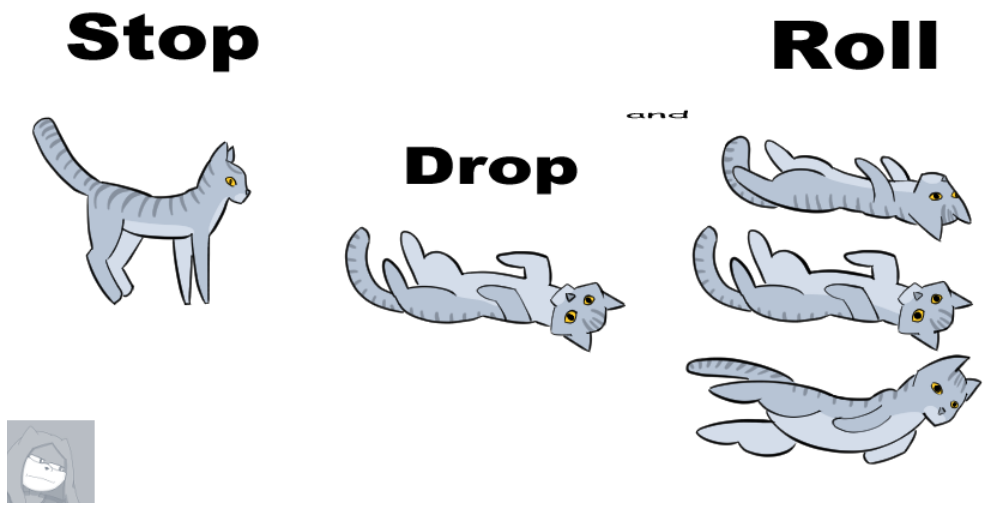
C. Dates each corrective action will be completed.

California Hospital Association

Immediate Jeopardy

Immediate jeopardy means a situation in which the licensee's noncompliance with one or more requirements of licensure has caused, or is likely to cause, serious injury or death to the patient. Cal. Health & Safety Code § 1280.1

Immediate jeopardy means a situation in which the provider's or supplier's non-compliance with one or more requirements, conditions of participation, conditions for coverage, or conditions for certification has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident or patient. 42 C.F.R. § 489.3



California Hospital Association

State Administrative Penalties

	ISOLATED	PATTERN	WIDESPREAD
SEVERITY LEVEL 6 (Immediate jeopardy to patient health or safety, resulting in death)	1st IJ penalty: **$75,000** 2nd IJ penalty: **$100,000** 3rd IJ penalty: **$125,000** (100% of maximum IJ penalty)	1st IJ penalty: **$75,000** 2nd IJ penalty: **$100,000** 3rd IJ penalty: **$125,000** (100% of maximum IJ penalty)	1st IJ penalty: **$75,000** 2nd IJ penalty: **$100,000** 3rd IJ penalty: **$125,000** (100% of maximum IJ penalty)
SEVERITY LEVEL 5 (Immediate jeopardy to patient health or safety, resulting in serious injury)	1st IJ penalty: **$45,000** 2nd IJ penalty: **$60,000** 3rd IJ penalty: **$75,000** (60% of maximum IJ penalty)	1st IJ penalty: **$52,500** 2nd IJ penalty: **$70,000** 3rd IJ penalty: **$87,500** (70% of maximum IJ penalty)	1st IJ penalty: **$60,000** 2nd IJ penalty: **$80,000** 3rd IJ penalty: **$100,000** (80% of maximum IJ penalty)
SEVERITY LEVEL 4 (Immediate jeopardy to patient health or safety, likely to cause serious injury or death)	1st IJ penalty: **$30,000** 2nd IJ penalty: **$40,000** 3rd IJ penalty: **$50,000** (40% of maximum IJ penalty)	1st IJ penalty: **$37,500** 2nd IJ penalty: **$50,000** 3rd IJ penalty: **$62,500** (50% of maximum IJ penalty)	1st IJ penalty: **$45,000** 2nd IJ penalty: **$60,000** 3rd IJ penalty: **$75,000** (60% of maximum IJ penalty)
SEVERITY LEVEL 3 (Actual harm that is not immediate jeopardy)	**$15,000** (60% of $25,000)	**$20,000** (80% of $25,000)	**$25,000** (100% of $25,000)
SEVERITY LEVEL 2 (No actual harm; potential for more than minimal harm, not immediate jeopardy)	**$5,000** (20% of $25,000)	**$12,500** (50% of $25,000)	**$17,500** (70% of $25,000)
SEVERITY LEVEL 1 (No actual harm; potential for no more than minimal harm)	No Penalty	No Penalty	No Penalty
MINOR VIOLATION	No Penalty	No Penalty	No Penalty

Privacy Breach Penalties

- May assess up to $25,000 per patient, and up to $17,500 per subsequent occurrence
- Total penalty shall not exceed $250,00 per reported event
- Late penalty - $100/day

California Hospital Association

Appealing

If a hospital wishes to appeal a state administrative penalty, the hospital must notify CDPH by letter within 10 calendar days after being notified of the penalty – that is, within 10 calendar days after the hospital mailroom signs the certified mail receipt.

The hospital may dispute:

1. A determination by CDPH regarding an alleged deficiency or alleged failure to correct a deficiency;
2. The reasonableness of the proposed deadline for correction; and
3. The reasonableness of the amount of the penalty.

Questions?