# FINAL STATEMENT OF REASONS

As authorized by Government Code section 11346.9(d), the California Department of Public Health (Department) incorporates by reference all contents of the Initial Statement of Reasons (ISOR) into the Final Statement of Reasons. The information contained in the ISOR at the time of the initial public notice remains unchanged except for the following modifications:

## Section 70972

### Subsection (a)(1)

In response to public comment, the Department proposes to define the term, "A patient death or serious disability associated with the use of restraints" to clarify that 'restraints' as described in HSC section 1279.1 (b)(5)(E) is related to physical restraints. This provides clarification to the regulated community and is necessary to align with statute HSC section 1279.1 (b)(5).

### Subsection (a)(2)

Renumber existing subsection (a)(1) to subsection (a)(2).

### Subsection (a)(3)

Renumber existing subsection (a)(2) to subsection (a)(3).

### Subsection (a)(4)

Renumber existing subsection (a)(3) to subsection (a)(4).

### Subsection (a)(5)

Renumber existing subsection (a)(4) to subsection (a)(5).

### Subsection (a)(6)

Renumber existing subsection (a)(5) to subsection (a)(6).

### Subsection (a)(7)

Renumber existing subsection (a)(6) to subsection (a)(7).

### Subsection (a)(8)

Renumber existing subsection (a)(7) to subsection (a)(8).

### Subsection (a)(9)

Renumber existing subsection (a)(8) to subsection (a)(9).

### Subsection (a)(10)

Renumber existing subsection (a)(9) to subsection (a)(10).

**Subsection (a)(11)**
Renumber existing subsection (a)(10) to subsection (a)(11). In response to public comment, the Department proposes to remove the phrase "patients and consumers" used in the definition of "medication error." The change was made to align with HSC section 1339.63 (d) that defines a medication-related error as an event occurring in an inpatient setting and being related to professional practice. The Department acknowledges that it is beyond the scope of the statute to require the hospital to report a medication-related error that occurs while in possession of a patient or consumer as an adverse event.

**Subsection (a)(12)**
Renumber existing subsection (a)(11) to subsection (a)(12). In response to public comment, the Department proposes to change the organization referenced in the definition of "nationally recognized survey tool" from National Agency for Healthcare Quality (NAHQ) to Agency for Healthcare Research and Quality (AHRQ). This change rectifies the definition to refer to the correct organization that publishes tools and programs that assess a hospital's culture of safety. This amendment is necessary to avoid confusion among the regulated community.

**Subsection (a)(13)**
Renumber existing subsection (a)(12) to subsection (a)(13).

**Subsection (a)(14)**
Renumber existing subsection (a)(13) to subsection (a)(14).

**Subsection (a)(15)**
Renumber existing subsection (a)(14) to subsection (a)(15).

**Subsection (a)(16)**
Renumber existing subsection (a)(15) to subsection (a)(16).

**Subsection (a)(17)**
Renumber existing subsection (a)(16) to subsection (a)(17).

**Subsection (a)(18)**
Renumber existing subsection (a)(17) to subsection (a)(18).

**Subsection (a)(19)**
Renumber existing subsection (a)(18) to subsection (a)(19).

**Subsection (a)(20)**
Renumber existing subsection (a)(19) to subsection (a)(20).

**Subsection (a)(21)**
Renumber existing subsection (a)(20) to subsection (a)(21).

**Subsection (a)(22)**
Renumber existing subsection (a)(21) to subsection (a)(22).

**Subsection (a)(23)**
Renumber existing subsection (a)(22) to subsection (a)(23).

**Subsection (a)(24)**
Renumber existing subsection (a)(23) to subsection (a)(24).

**Subsection (a)(25)**
Renumber existing subsection (a)(24) to subsection (a)(25).

**Subsection (a)(26)**
Renumber existing subsection (a)(25) to subsection (a)(26). In response to public comment, the Department proposes to add a provision to the definition of "surgery ends" to include when vaginal birth ends. The proposed provision states that vaginal birth ends after the delivery of the fetus, the delivery of the placenta, and all surgical repairs are completed. This definition is supported by a peer-reviewed article, *Stages of Labor* (Hutchinson et al.) that is intended to provide a universal definition of the stages of labor for medical professionals. This definition is also confirmed by Department subject matter experts. This amendment is necessary to avoid confusion among the regulated community in determining when a vaginal birth ends.

**Subsection (a)(27)**
Renumber existing subsection (a)(26) to subsection (a)(27).

**Subsection (a)(28)**
Renumber existing subsection (a)(27) to subsection (a)(28).

**Subsection (a)(29)**
Renumber existing subsection (a)(28) to subsection (a)(29).

**Subsection (a)(30)**
Renumber existing subsection (a)(29) to subsection (a)(30).

**Section 70972**

**Subsection (a)(2)**
In response to public comment, the Department proposes to amend the text to clarify that allegations of sexual assault are included in reportable adverse events. The initial text did not make clear that in addition to the detection of sexual assault, allegations of sexual assault made by the patients are also reportable adverse events. Requiring a report within 24 hours of when the hospital is first aware of the sexual assault is necessary to protect the health, safety and welfare of the victim, patients, personnel, and visitors.

**Subsection (b)(3)-(b)(4)**
In response to public comment, the Department proposes to add the conditional clause, "if known". The Department recognizes that the amount of information available within 24 hours of the detection of an adverse event may be limited. The hospital will submit

additional information pertaining to the adverse events after the 24-hour period in accordance with Title 22 CCR section 70972(b)(9).

**Subsection (b)(8)**
The Department proposes to add a provision for the reporting of *immediate* corrective or mitigating actions in response to the adverse event. This change was made to distinguish between the corrective action the hospital will take immediately upon detection of the adverse event and any long-term corrective action that may be made as a result of the root cause analysis. The proposed provision will ensure the hospital reports the full range of approaches when responding to an adverse event. The immediate corrective action the hospital takes and reports to the Department may be supplemented with long-term action that is captured in a root cause analysis. This provision is necessary to eliminate burdensome and continuous reporting of incoming details regarding an adverse event.

**Subsection (c)**
In response to public comment, the Department proposes to add a provision for the submission of an adverse event by email or telephone. In the event the Department's secure electronic web-based portal is not operational, this change allows the hospital to report adverse events, and maintain regulatory compliance, in accordance with Title 22 CCR section 70972(a)(1).

**Section 70974**
**Subsection (a)(4)**
In response to public comments stating that assessing the hospital's culture of safety every 12 months is too frequent, the Department proposes to revise the requirement to assess the hospital's culture of safety to every 24 months. The Department recognizes that assessing a culture of safety every 12 months may not allow enough time to capture changes in patient safety culture. This amendment aligns with industry standards for hospitals that participate in the AHRQ culture of safety surveys who, on average, submit survey results every 24 months.

**Section 71567**
**Subsection (a)(2)**
In response to public comment, the Department proposes to amend the text to clarify that allegations of sexual assault are included in reportable adverse events. The initial text did not make clear that in addition to the detection of sexual assault, allegations of sexual assault made by the patients are also reportable adverse events. Requiring a report within 24 hours from when the hospital is first aware of the sexual assault is necessary to protect the health, safety and welfare of the victim, patients, personnel, and visitors.

**Subsection (b)(3)-(b)(4)**
In response to public comment, the Department proposes to add the conditional clause, "if known". The Department recognizes that the amount of information available within

24 hours of the detection of an adverse event may be limited. The hospital will submit new information pertaining to the adverse events after the 24-hour period in accordance with Title 22 CCR section 71567(b)(9).

**Subsection (b)(8)**
The Department proposes to add a provision for the reporting of *immediate* corrective or mitigating actions in response to the adverse event. This change was made to distinguish between the corrective action the hospital will take immediately upon detection of the adverse event and any long-term corrective action that may be made as a result of the root cause analysis. The proposed provision will ensure the hospital reports the full range of approaches when responding to an adverse event. The immediate corrective action the hospital takes and reports to the Department may be supplemented with long-term action that is captured in a root cause analysis. This provision is necessary to eliminate burdensome and continuous reporting of incoming details regarding an adverse event.

**Subsection (c)**
In response to public comment, the Department proposes to add a provision for the submission of an adverse event by email or telephone. In the event the Department's secure electronic web-based portal is not operational, this change allows the hospital to report adverse events, and maintain regulatory compliance, in accordance with Title 22 CCR section 71567(a)(1).

**Section 71569**
**Subsection (a)(4)**
In response to public comments stating that assessing the hospital's culture of safety every 12 months is too frequent, the Department proposes to revise the requirement to assess the hospital's culture of safety to every 24 months. This Department recognizes that assessing a culture of safety every 12 months may not allow enough time to capture changes in patient safety culture. This amendment aligns with industry standards of hospitals that participate in the Agency for Healthcare Research and Quality culture of safety surveys who, on average, submit survey results every 24 months.

## Statements of Determinations

**Local Mandate**
The Department has determined that this regulatory action would not impose a mandate on local agencies or school districts, nor are there any costs for which reimbursement is required by part 7 (commencing with Government Code section 17500).

**Impact on Small Business**
The Department has determined that there is an effect on small business (hospitals), because all GACHs, APHs, and SHs fall under the regulation parameters despite size and location. However, the Legislature included specific guidelines and considerations

within the statute for small and rural hospitals if a penalty occurs relative to an AE report, pursuant to HSC section 1279.2(f). This consideration includes alternatives provided by the Department for options in reducing the penalty amount to avoid an excessive financial burden and protect the quality of patient care.

**Alternatives Considered**

The Department has determined that no reasonable alternative it considered or that has otherwise been identified and brought to the attention of the Department would be more effective in carrying out the purpose for which the regulation is proposed, would be as effective and less burdensome to affected private persons than the adopted regulation, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

# ATTACHMENTS TO THE FINAL STATEMENT OF REASONS

## ADDENDUM I
## 45-Day Public Notice

### Summary of Comments and Responses to Comments Received

The Department received comments from eight (8) commenters during the 45-day public notice period beginning July 3, 2020 and ending August 21, 2020. The comments below are aggregated and summarized or are responded to individually. No request for a public hearing was received and no hearing was held.

### List of 45 Day Commenters

| | | |
|---|---|---|
| 1. | California Hospital Association | Kiyomi Burchill |
| 2. | California Nurses Association | Saskia Kim |
| 3. | Dignity Health | Barbara Pelletreau |
| 4. | Health Services of LA County | Christina R. Ghaly, M.D. |
| 5. | John Muir Health | Stephanie R. Bailey |
| 6. | Kaiser Foundation Health Plan and Hospitals, Northern California | Robin Betts, MBA-HM, RN, CPHQ |
| 7. | Stanford Healthcare | Steven Chinn DPM, MS, MBA |
| 8. | UCLA Health | Jeff Bergen, MSN, RN |

### Section 70971: Definitions

### Comment Topic: Incorporate NQF definitions by reference

**Comment:** Commenters appreciate the Department utilizing National Quality Forum (NQF) standards as a model for the proposed regulation, however, since the definitions are not cross-referenced, they will not align with future updates. Commenters recommend that the NQF standard definitions be incorporated by reference so that the definitions are always up to date.
**Commenters:** 1, 3
**Department Response:** No change has been made to accommodate this recommendation. When incorporating by reference, the regulation must be amended through the regulatory process each time the document incorporated by reference is amended and/or has a new publication or new revision issued. Having the definition included in the regulation rather than referring to another source to determine the definition provides greater convenience for the regulated community. The Department acknowledges that there may be a substantial need to update specific definitions and will take action to do so when necessary.

**Comment Topic: Definition of "A patient death or serious disability associated with the use of restraints"**

**Comment:** There has been inconsistent interpretation of the restraints portion in this definition by the Department's Licensing and Certification program district offices. The commenter offers an example of a patient who dies of an unrelated cause, but who happens to be in restraints is at times reportable and other times not interpreted to be reportable depending on the district office. Multiple commenters recommend that the Department define "associated with the use of restraints" to clarify which events are reportable. The commenters also recommend that the Department specify that restraints are physical restraints as the NQF has noted that the there is "difficulty in defining" chemical restraints. One commenter suggests that the following definition be added: "A patient death or serious disability associated with the use of restraints" means a patient death or serious disability directly related to the use of physical restraints. The circumstance of the patient having been in physical restraints at the time of death is not sufficient to require its reporting as an adverse event."
**Commenter(s):** 1, 3, 5, 6
**Department Response:** The Department has clarified the definition of "a patient death or serious disability associated with the use of restraints" to specify that this means "physical restraints." This change aligns with HSC section 1279.1 (b)(5)(E) which states, "serious disability associated with the use of restraints or bedrails," where the context is regarding physical restraints. The authorizing statute does not define or clarify chemical restraints and the Department has not chosen to do so here.

**Comment Topic: Define "associated with"**

**Commenter:** Commenter requests that the Department define the term "associated with."
**Commenter**: 5
**Department Response**: No change has been made for this recommendation because "associated with" is being used in accordance with its common definition. As provided in Title 22 CCR section 70001, "words shall have their usual meaning unless the context or a definition clearly indicates a different meaning." According to the Merriam Webster dictionary, "associated" means (1) joined together often in a working relationship, (2) related, connected, or combined together. The word 'associated' is to be interpreted with its usual meaning where relevant in the regulations.

**Comment Topic: Definition of "detect"**

**Comment:** Commenters recommend the Department further define the word "detect." The current definition that the Department has proposed would lead to broad non-compliance by hospitals since they cannot report what they do not know. One commenter requests that the definition of detect be clarified and proposes that detection occurs when the hospital's quality/patient safety program receives and can review an

incident report. Several commenters disagree with the phrase “its personnel, or its agents” and either requested that it be removed or further defined. One commenter stated that the definition should be clarified as to whether ‘detect’ means when an adverse event is known to the hospital or when it is determined an event meets the adverse event definition. Another commenter recommended that “detect” be changed to “detected.”

**Commenter(s):** 1, 2, 3, 4, 5, 6, 7

**Department Response**: No change has been made to accommodate these recommendations. The Department is using ‘detect’ in a common context. As provided in Title 22 CCR section 70001, “words shall have their usual meaning unless the context or a definition clearly indicates a different meaning.” Here, ‘detect’ means “to discover or determine the existence, presence, or fact of,”. It is impossible to ‘detect’ an adverse event and not be aware of its existence. Further, the regulation restates the well-established doctrine of nondelegable duties which provides that licensees who operate a hospital “through employees or contractors” are responsible for their employees’ conduct in the exercise of the hospital license. Agents and those that hold themselves out to be employees of the hospital fall into this category. The California Supreme Court case, California Association of Health Facilities v. Department of Health Services (1997) 16 Cal.4th 284, applies this rule to citation penalties for long-term health care facilities licensed by the Department. The principle that a licensee will be held liable for the acts of its agents is one that has been applied whether the agent is an independent contractor or an employee. The Department believes that it is unnecessary to distinguish between the hospital’s knowledge of the adverse event and the hospital’s knowledge of whether an event rises to the level of an adverse event. The definition provides that “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.” Therefore, a hospital must exercise reasonable diligence to determine whether an event qualifies as an adverse event upon discovery.

**Comment Topic: Definition of “major life activity”**

**Comment:** The Department’s definition of “major life activity” is subjective and new. When surveyors are determining whether an adverse event has resulted in a serious disability, they must determine not what activity is substantially limited, but if a major life activity has been substantially limited. Further, the NQF does not define “major life activity” in their standards. The commenter suggests that the Department use the overarching term of “serious disability” that is already defined in state statute and "remove the proposed definition of “major life activity”.

**Commenter**: 1, 3, 6

**Department Response**: Major life activity is a term used in the definition of “serious disability” HSC section 1279.1(d) but is not further defined in the statute. The Department has defined major life activity to clarify the definition of serious disability by detailing the major life activities that could be limited. This definition of major life activity

paraphrases the Americans with Disabilities Act Amendments of 2008 definition. That definition is in the context of disabilities, so it was necessary to paraphrase rather than duplicating the definition. Alternative definitions were considered but not appropriate because they are used in the context of qualifying for services or protecting from discrimination. The ADAA definition was found to be comprehensive, descriptive, and less subject to misinterpretation of adverse event reporting requirements. Therefore, the Department has not accepted this recommendation.

**Comment Topic: Definition of "medication error"**

**Comment:** The commenter appreciates that the Department's definition of "medication error" aligns with NQF's definition. However, the proposed definition of "medication error" goes beyond the scope of the statute as it requires hospitals to report medication errors made by patients. The authorizing statute focuses on the errors that would be in the clinician's control. Another commenter believes that it is unreasonable to hold the hospital or clinician responsible for a medication error when it is not in their possession. Multiple commenters recommend revising the definition by removing the words "patient, or consumer" which will clarify that reportable medication errors are those that take place when the medication is in control of the clinician.
**Commenter:** 1, 3, 4
**Department Response:** The Department agrees with the commenter that the proposed definition goes beyond the scope of authorizing statute. The modification to remove "patient, or consumer" has been made to the definition of medication error based on public comment. This change is consistent with HSC section 1279.1 (b)(4)(A) that states "A patient death or serious disability associated with a medication error, including, but not limited to, an error involving the wrong drug, the wrong dose, the wrong patient, the wrong time, the wrong rate, the wrong preparation, or the wrong route of administration, excluding reasonable differences in clinical judgment on drug selection and dose."

**Comment:** The commenter supports the proposed definition of medication error. This accounts for other mechanisms of medication delivery such as a patient-controlled analgesia (PCA) pumps that can be controlled by the patient or a proxy (family member or caregivers). There are other instances where family members or caregivers are in control of their medications within the hospital environment. All medication errors that result in patient harm must be reported as an adverse event even if the person responsible is not a hospital employee.
**Commenter:** 2
**Department Response:** The Department recognizes that in the instances where a medication error occurs in a clinical environment, but is not the result of being directly administered by a clinician, are events that should be captured to reduce the occurrence. Further, all instances of serious medication errors should be monitored and reported by the appropriate authority. However, as the statue is currently written, the Department cannot require the reporting of medication error-related events where the

medication in not in control of a clinician, therefore, the Department modified the definition as indicated in the previous comment.

**Comment Topic: Definition of "Nationally recognized survey tool"**

**Comment:** Commenter believes that the reference to National Association for Health Care Quality (NAHQ) in the proposed regulation text is incorrect. The correct reference is to the federal Agency for Healthcare Research and Quality (AHRQ) which is an agency in the US Department of Health and Human Services.
**Commenter**: 1, 3, 4
**Department Response:** The document relied upon that is referenced in the ISOR for section 70971(a)(10) had been authored by the NAHQ and published by the Agency for Healthcare Research and Quality. To clarify this definition and provide clear direction, the Department has updated the language to "means a valid and reliable survey tool identified by the Agency for Healthcare Research and Quality…" This change references the correct organization that houses culture of safety surveys.

**Comment Topic: Definition of "retention of a foreign object"**

**Comment:** Commenter proposes to change the term "foreign object" to "surgical item" for clarity. It would exclude items that are intentionally implanted as part of a planned intervention, objects that are intentionally left in place, and objects not present prior to surgery. The definition also aligns with the definition used by Association of Operating Room Nurses. Commenter adds the Department should also add a definition for "unretrieved device fragment," which refers to specific parts or pieces of a surgical item which is an event that should be reported to the patients but is not a reportable adverse event.
**Commenter:** 3
**Department Response:** No change has been made to accommodate this recommendation because the statute describes the information that the commenter believes is excluded. Health and Safety Code section 1279.1(b)(1)(D), states "…foreign object in a patient after surgery or other procedure, excluding objects intentionally implanted as part of a planned intervention and objects present prior to surgery that are intentionally retained." The Department believes that the statute considers and accommodates the concerns of the commenter.

**Comment Topic: Definition of "root cause analysis"**

**Comment:** Multiple commenters state the Department's proposed definition of "root cause analysis" is too broad and allows for multiple approaches to conduct a root cause analysis. The definition is not prescriptive, and some commenters recommend that the definition align with The Joint Commission standard. In the proposed definition, a root cause analysis also "confirms or refutes a presumed preventable adverse event." Multiple commenters suggested that this portion of the definition be removed because

the statute does not require root cause analyses to refute a presumed preventable adverse event.
**Commenter(s):** 1, 2, 3
**Department Response:** No change has been made to accommodate these recommendations. As stated in HSC section 1279.6, health facilities shall develop, implement, and comply with a required patient safety plan that establishes a process for team or facility staff to conduct analyses which includes, but is not limited to, root cause analyses of patient safety events. The purpose of a root cause analysis is to identify the root causes of the patient safety event. In determining the root cause, this investigation may emphasize some details of a patient safety event and de-emphasize or refute other details. The definition of root cause analysis allows for flexibility in determining the full circumstances of an adverse event.

**Comment Topic: Definition of "significant injury"**

**Comment:** Multiple commenters state that the proposed definition of "significant injury" is very broad and only includes injuries that are based on physical pain. The NQF does not define "significant injury" and the commenters recommend that the Department choose not to define the term as well.
**Commenter(s):** 1, 3, 6
**Department Response:** No change has been made to accommodate this recommendation because this definition is needed to distinguish between "significant injury" and "serious disability." This enables hospitals to report adverse events and protects the health and safety of patients.

**Comment Topic: Definition of "Stage 2 Pressure Ulcer," "Stage 3 Pressure Ulcer," and "Stage 4 Pressure Ulcer"**

**Comment:** Commenters state that the current definitions of "stage 2 pressure ulcer", "stage 3 pressure ulcer", and "stage 4 pressure ulcer" adopt the National Pressure Injury Advisory Panel (NPIAP) definitions. Multiple commenters recommend that these definitions be incorporated by reference with NPIAP so that they continue to be current.
**Commenter(s**): 1, 3, 6
**Department Response:** No change has been made to accommodate this recommendation. When incorporating by reference, the regulation must be amended through the regulatory process each time the document incorporated by reference is amended and/or has a new publication or new revision issued. Having the definition included in the regulation rather than referring to another source to determine the definition provides greater convenience for the regulated community. The Department acknowledges that there may be a substantial need to update specific definitions and will take action to do so when necessary.

**Comment Topic: Define "Unstageable Pressure Ulcer"**

**Comment:** The commenter requested further defining these definitions by clarifying that an unstageable pressure ulcer is not considered to be a Stage 3 or Stage 4 until the stage can be confirmed by removing the stable eschar.
**Commenter(s):** 5
**Department Response:** No change has been made to accommodate the recommendation to modify the definition of "unstageable pressure ulcer" because the current definition is an objective description in accordance with the APA. Further defining stable eschar would go beyond the scope and merge into the practice of medicine.

**Comment Topic: Definition of "Surgery Ends"**

**Comment:** Commenter recommends that the Department update the definition of "surgery end" to include a clarification of when a vaginal birth ends. The commenter proposes the following addition, "A vaginal birth ends when the mother is in the immediate recovery period, which is defined as 1-2 hours post birth of the fetus."
**Commenter:** 3
**Department Response:** After consulting with subject matter experts, the Department has modified the definition of 'surgery end' to include when a vaginal birth ends. The department has also defined vaginal birth further to include the delivery of the placenta. The full adjustment of the definition is "A vaginal birth ends when the mother is in the immediate recovery period, which is defined as 1-2 hours post birth of the fetus and the placenta." This modification adds additional clarity to the definition of surgery end and protects and health and safety of the patient.

**Section 70972: Reporting Requirements**

**Comment topic: Electronic submission**

**Comment:** Commenter is concerned about the requirement in the proposed regulation that the hospital report adverse events electronically through the California Healthcare Event Reporting Tool (CalHEART). If there are technical difficulties or a system outage, this may cause the reporting tool to be unavailable which would prevent the prompt reporting of an adverse event. The commenter recommends additional options such as email, phone calls or faxes to be permissible ways to report adverse events if CalHEART is unavailable or inaccessible.
**Commenters**: 1, 3
Department Response: The Department agrees that there should be a viable alternative to reporting adverse events if the CalHEART systems is unavailable or offline. The following revision has been made to accommodate this recommendation: If the Department's secure electronic web-based portal is not operational, a hospital shall report an adverse event by email or phone to the Department.

**Comment topic: Reporting Sexual Assault**

**Comment:** The Department should remove Title 22 CCR section 70972 (a)(2) that requires a sexual assault to be reported within 24 hours after allegation or detection because the requirement lacks statutory authority and does not allow enough time for the hospital to gather additional information. Instead of reporting within 24 hours, some commenters recommended allowing three days or five days to report sexual assault. Another commenter states that reporting an allegation of sexual assault is too burdensome for hospitals. Several commenters request that allegations, specifically, of sexual assault be removed from the reporting requirement as well.
**Commenter(s):** 1, 3, 4, 5
**Department Response:** The statutory authority to require sexual assault be reported within 24 hours comes from HSC section 1279.1(a) where there is a requirement to report adverse events within 24 hours of detection "if that event is an ongoing urgent or emergent threat to the welfare, health, or safety of patients, personnel, or visitors." The sexual assault of a patient is an ongoing and immediate threat to the safety and welfare of the patient. The Department has amended the text to clarify that allegations of sexual assault falls under the detection of sexual assault. This means that hospitals are required to report the detection of sexual assaults, which includes allegations, within 24 hours because it is an ongoing urgent threat to the welfare, health, or safety of patients. The text will read "Sexual assault of a patient, including allegations of sexual assault of a patient, provided for under HSC section 1279.1(b)(6)(C), shall be reported within 24 hours after detection."

**Comment:** Commenter is in support of the proposed regulation requiring the reporting of sexual assault of patient within 24 hours of allegation or detection. They note that physical assault of an employee requires reporting within 24 hours pursuant to Title 8 CCR section 3342. The commenter also states that patients deserve to have the Department, in addition to the hospital, investigate an allegation or detection of sexual assault of a patient.
**Commenter:** 2
**Department Response:** The Department appreciates the support of the proposed regulation.

**Comment Topic: Required Information for Reporting**

**Comment:** The Department should amend the regulations to account for when a hospital reports an adverse event but has not gathered all of the information. Obtaining information for adverse events can take time if the information is not initially available. Commenter recommends that the Department make the following revisions to Title 22 CCR section 70972(b): (1) Name and address of the hospital.
(2) Location and service area where the adverse event occurred.
(3) Date and time the adverse event occurred and was detected, if known.
(4) Name of each individual affected by the adverse event and any patients, personnel, and visitors involved or a witness to the adverse event, if known.

(5) Description of the circumstances surrounding the adverse event, including the nature and extent of injury or harm.
(6) If an individual affected by the adverse event is a patient, the date the patient, or the party responsible for the patient, was informed of the adverse event. This date shall not be later than the date the hospital reported the adverse event to the Department.
(7) Name, title, area code, and telephone number of a hospital representative for the Department to contact for additional information.
(8) Hospital's corrective or mitigating action in response to the adverse event, if any.
(9) Any additional information as it becomes available regarding the adverse event.

Another commenter suggested removing "hospital's corrective or mitigating action in response to the adverse event" because corrective action is determined through the root cause analysis process.
**Commenter:** 1, 2, 3, 4, 5, 8
**Department Response:** The Department has made revisions that include "if known" to Title 22 CCR section 70972(b)(3) and (b)(4) to clarify that hospitals cannot report information they do not have. The word "immediate" has also been added to Title 22 CCR section 79072(b)(8) to read "Hospital's immediate corrective or mitigating action…" This distinguishes between the hospital's immediate response to the adverse event and the corrective action taken after a root cause analysis is complete. Additionally, the Department amended Title 22 CCR section 70972(b)(9) to state "Any additional information as it becomes available regarding the adverse event" to require hospitals to supplement the initial reporting of an adverse event.

The Department rejects the addition of "if any" because if an adverse event occurs, the hospital should have some measure of corrective or mitigating action in response.

**Comment Topic: Continuous reporting**

**Comment:** Commenter recommends the removal of the requirement that requires hospitals to continuously report additional information as it becomes available because it is beyond the scope of the authorizing statute.
**Commenters:** 8
**Department Response:** No changes have been made to accommodate this request. The Department has modified the text to distinguish between the hospital immediate response to the adverse and the response after a root cause analysis has been conducted. This allows the hospital to report the new information as it becomes available after additional investigation or root cause analysis takes place.

**Comment Topic: Name of each individual involved in adverse event**

**Comment:** The requirement stated in Title 22 CCR section 70972(b)(4) to report the name of each individual affected by the adverse event, including patients, personnel, and visitors, is overly burdensome for hospitals.
**Commenters:** 5, 8

**Department Response:** Hospitals are required to establish a patient safety plan and develop a process for conducting root cause analyses to investigate patient safety events (HSC section 1279.6 (b)(3)). Patient safety events includes all adverse events as described in HSC section 1279.1. The root cause analysis, as described by AHRQ, begins with data collection and reconstruction of the event by reviewing records and conducting interviews with participants. After an adverse event occurs, the hospital will be in the process of collecting the information pertaining to those involved in the adverse event. The Department has added the words "if known" at the end of Title 22 CCR section 70972(a)(4) to read, "Name of each individual affected by the adverse event and any patients, personnel, and visitors involved or a witness to the adverse event, if known," to reflect ongoing information gathering following an adverse event. The Department does not believe that it would overly burdensome for the hospital to report all the individuals involved in an adverse event if the hospital already knows that information.

## Section 70973: Investigation

### Comment Topic: Confidentiality of Root Cause Analyses

**Comment:** Commenter states it is important for the Department to educate its surveyors and other personnel to ensure the confidentiality of root cause analyses is maintained. Root cause analyses are protected from discovery by California Evidence Code 1157 and may not be made available to attorneys, even in response to a subpoena as articulated by the California Supreme court in Fox v. Kramer, 22 Cal.4th 531 (2000). The documents are also protected by the Patient Safety and Quality Improvement Act of 2005 (Pub. L. 109-41, 42 U.S.C 299b-21 through 299b-26; see also Title 42 C.F.R. part 3), which preempts any federal, state, tribal, or local law that allows or requires disclosure of patient safety work product as defined. A state may not require a patient safety work product to be disclosed, even to state surveyors (Title 42 C.F.R sections 3.204-3.212). Commenter recommends that CDPH clarify in the proposed regulation that root cause analyses remain confidential and hospitals not be required to produce these documents.
**Commenters:** 1, 3, 4
**Department Response**: The Department objects to the comment that a root cause analysis is analogous to a hospital's peer review committee process. Health and Safety Code section 1279.6 requires health facilities to develop and implement a patient safety plan that monitor and make corrective actions to prevent future adverse events, which is part of the root cause analysis. The purpose of a root cause analysis is to identify the root causes of the patient safety event. A root cause analysis is different from peer review records, which are created by an internal committee to assess quality of care issues. The Department understands that peer review documents and subsequent remediation measures are privileged and inadmissible in court. For these reasons, Evidence Code section 1157 and *Fox v. Kramer, 93 Cal.Rptr.2d 497*, are inapplicable to the Department's requirement for a root cause analysis. Since root cause analysis and peer review are separate processes, any change to the regulation is unnecessary and redundant with current law.

## Section 70974: Policies and Procedures

### Comment Topic: Annual Culture of Safety Survey Requirement

**Comment**: Commenters state that the requirement to conduct an annual culture of safety assessment is not substantiated in statute. Additional commenters state that requiring a culture of safety assessment every 12 months is over burdensome for hospitals. Commenters recommend the removal of the time-bound requirement to assess a culture of safety. Another commenter notes that's that staff members in hospital experience "survey fatigue" and this can affect the overall results of a survey if it is conducted too often. Many commenters note that the reference to NAHQ was incorrect and that the federal agency, AHRQ creates the tools for hospitals to assess their culture of safety.
**Commenter:** 1, 3, 4, 5, 8
**Department Response:** The department recognizes that in order to accurately assess changes in the culture of safety in hospitals, enough time must pass to allow for the changes to take place. In line with hospitals that use AHRQ tools to assess their culture of safety, the Department has determined that the culture of safety should be assessed every 24 months. The following change has been made: "Assessing the hospital's culture of safety every 24 months using a nationally recognized safety culture assessment and survey tool."

## Section 71565: Applicability (Psychiatric Hospitals)

### Comment Topic: Applicability for Acute Psychiatric Hospitals

**Comment:** Commenter requests that the same proposed changes for general acute care hospitals be made to the corresponding sections of the acute psychiatric hospital adverse event proposed regulations.
**Commenter:** 4
**Department Response:** The recommended changes that were accepted by the Department for Title 22 CCR sections 70971 – section 70974 of the regulation text will be applied to the applicable sections regarding psychiatric hospitals.

## Section 71567: Reporting Requirements (Psychiatric Hospitals)

### Comment Topic: Time-bound Reporting Requirement

**Comment:** The requirement to report an adverse event within 24 hours will lead to incomplete or inaccurate reports of the adverse event. These inaccurate or incomplete reports may create additional work for the Department's District Offices. Reporting adverse events within 24 hours for large organizations is challenging as the hospital may not be aware of it for several days or need time to investigate the event.
**Commenter:** 7
**Department Response**: No changes have been made to accommodate this recommendation. As defined in Title 22 CCR section 71567(b)(9), the hospital can

provide any additional information as it becomes available regarding the adverse event through additional submission or through the completion of a root cause analysis.

**Comment Topic: Reporting Requirements for Acute Psychiatric Hospitals**

**Comment:** Commenter recommends that the Department adopt the same adverse event reporting requirements for acute psychiatric hospitals as was recommended for general acute care hospitals. The contents of Title 22 CCR section 71567 should be replaced with: The provisions in Chapter 1, Article 11, section 70972 shall apply to reportable adverse events in acute psychiatric hospitals.
**Commenter:** 1
**Department Response:** The Department has adopted very similar regulations for acute care psychiatric hospitals. The changes made to accommodate recommendations in the adverse event reporting regulations for general acute care hospitals will also be made in the adverse events regulations for acute psychiatric hospitals. The Department chose to establish separate regulations for acute psychiatric hospitals for reporting adverse events because they are a separate license type from general acute care hospitals. Each facility type has unique regulations applicable to the specific care setting. It is more convenient for the regulated community to have the requirements applicable to their facility type in one location.

## Section 71568: Adverse Event Investigation

**Comment Topic: Adverse Event Investigation Requirements for Acute Psychiatric Hospitals**

**Comment:** Commenter recommends that the Department adopt the same adverse event investigation requirements for acute psychiatric hospitals. The contents of Title 22 CCR section 71567 should be replaced with: The provisions in Chapter 1, Article 11, section 70973 shall apply to reportable adverse events in acute psychiatric hospitals.
**Commenter:** 1, 3
**Department Response:** The Department has adopted very similar regulations for acute care psychiatric hospitals. The changes made to accommodate recommendations in the adverse event reporting regulations for general acute care hospitals will also be echoed in the adverse events regulations for acute psychiatric hospitals. The Department chose to establish separate regulations for acute psychiatric hospitals for reporting adverse events because they are a separate license type from general acute care hospitals. Each facility type has unique regulations applicable to specific care setting. It is more convenient for the regulated community to have the requirements applicable to their facility type in one location.

## Section 71569: Policies and Procedures (Psychiatric Hospitals)

### Comment Topic: Policies and Procedures Requirements for Acute Psychiatric Hospital

**Comment:** Commenter recommends that the Department adopt the same adverse event policies and procedure requirements for acute psychiatric hospitals. The contents of Title 22 CCR section 71567 should be replaced with: The provisions in Chapter 1, Article 11, section 70974 shall apply to reportable adverse events in acute psychiatric hospitals.
**Commenter:** 1, 3, 7
**Department Response:** The regulations in this section are very similar to the regulations in Title 22 CCR section 70974. The Department chose to establish separate regulations for acute psychiatric hospitals for reporting adverse events because they are a separate license type from general acute care hospitals. Each facility type has unique regulations applicable to specific care setting. It is more convenient for the regulated community to have the requirements applicable to their facility type in one location.

### Comment Topic: Annual Culture of Safety Survey Requirement

**Comment:** Conducting an organization assessment every 12 months is overly burdensome for hospitals and doesn't allow enough time for hospitals to implement and evaluate any patient safety improvements.
**Commenter:** 7
**Department Response:** See Department response to corresponding topic in Title 22 CCR section 70974.

# ATTACHMENTS TO THE FINAL STATEMENT OF REASONS

## ADDENDUM II
## First 15 Day Notice of Public Availablity

### Summary of Comments and Responses to Comments Received

The Department received one new comment from one commenter during the notice of public availability beginning March 23, 2021, through April 6, 2021. The comments below are summarized and the responses follow.

| List of Commenters | | |
|---|---|---|
| 1. | California Hospital Association | Kiyomi Burchill |

### Section 70971: Definitions

#### Comment Topic: Definition of "A patient death or serious disability associated with the use of restraints"

**Comment:** Commenter recommended further modifying "a patient death or serious disability associated with the use of restraints" to mean "a patient death or serious disability directly related to the use of physical restraints." Commenter stated that "associated with" is overly broad.
**Commenter:** 1
**Department Response:** No change has been made for this recommendation because "associated with" is being used in accordance with its common definition. The Department did choose to define the phrase to clarify that restraints means physical restraints. However, the Department declines to change "associated with" to "directly related to" because it is to be interpreted with its usual meaning where relevant in the regulations. As provided in Title 22 CCR section 70001, "words shall have their usual meaning unless the context or a definition clearly indicates a different meaning." According to the Merriam Webster dictionary, "associated" means (1) joined together often in a working relationship, (2) related, connected, or combined together. The phrase "associated with" is used throughout the authorizing statute HSC section 1279.1 which defines adverse events without confusion.

#### Comment Topic: Definition of "detect"

**Comment:** Commenter states that the proposed definition of "detect" would lead to broad non-compliance by hospitals since they cannot report what they do not know. The Department does not define term "agent." Commenter states that the definition specifies that an adverse event would have been known by a hospital exercising reasonable diligence, however, it does not consider that a hospital still may not have knowledge and would be unable to report an adverse event.

**Commenter:** 1
**Department Response:** See response to corresponding topic in the 45-day Addendum.

**Comment Topic: Definition of "major life activity"**

**Comment:** The Department's definition of "major life activity" is subjective and new. When surveyors are determining whether an adverse event has resulted in a serious disability, they must determine not what activity is substantially limited, but if a major life activity has been substantially limited. Further, the NQF does not define "major life activity" in their standards. The commenter suggests that the Department use the overarching term of "serious disability" that is already defined in state statute and "remove the proposed definition of "major life activity."
**Commenter:** 1
**Department Response:** See response to corresponding topic in 45-day Addendum.

**Comment Topic: Definition of "root cause analysis"**

**Comment:** Commenter states the Department's proposed definition of "root cause analysis" is too broad and recommends that the definition align with The Joint Commission standard. In the proposed definition, a root cause analysis also "confirms or refutes a presumed preventable adverse event," but the commenter suggests that this portion of the definition be removed because the statute does not require root cause analyses to refute a presumed preventable adverse event.
**Commenter:** 1
**Department Response:** See response to corresponding topic in 45-day Addendum

**Comment Topic: Definitions of "stage 2 pressure ulcer," "stage 3 pressure ulcer," and "stage 4 pressure ulcer"**

**Comment:** Commenter recommends that these definitions be removed and replaced with references to the NPIAP definitions so that the regulations continues to be current with these definitions.
**Commenters:** 1
**Department Response:** See response to corresponding topic in 45-day Addendum.

**Comment Topic: Definition of "significant injury"**

**Comment:** Commenter states that the proposed definition of "significant injury" is very broad including an injury on the basis that it causes physical pain. The NQF does not define "significant injury" and the commenters recommend that the Department choose not to define the term as well.
**Commenter:** 1
**Department Response:** See response to corresponding topic in 45-day Addendum.

## Section 70972: Reporting Requirements

### Comment topic: Reporting Sexual Assault

**Comment:** The Department should remove Title 22 CCR section 70972 (a)(2) that requires a sexual assault to be reported within 24 hours after allegation or detection because the requirement lacks statutory authority. The statute requires that adverse events that are "ongoing urgent or emergent threat to the welfare, health, or safety of patients, personnel, or visitors" must be reported no later than 24 hours, the commenter states that this is contrary to the framework of the statute. The commenter disagrees with the inclusion of allegations of sexual assault in the definition of the adverse event of sexual assault. The removal of Title 22 CCR section 70972 (a)(2) would result in hospitals reporting sexual assault of a patient within five days, or 24 hours if it is an urgent or emergent threat.
**Commenter:** 1
**Department Response:** See response to corresponding topic in 45-day Addendum.

## Section 70973: Adverse Event Investigation

### Comment Topic: Confidentiality of root cause analyses

**Comment:** Commenter states it is important for the Department to educate its surveyors and other personnel to ensure the confidentiality of root cause analyses is maintained. Hospital's root cause analyses are protected from discovery by California Evidence Code 1157 and may not be made available to attorneys, even in response to a subpoena as articulated by the California Supreme court in Fox v. Kramer, 22 Cal.4$^{th}$ 531 (2000). The documents are also protected by the Patient Safety and Quality Improvement Act of 2005 (Pub. L. 109-41, 42 U.S.C 299b-21 through 299b-26; see also Title 42 C.F.R. part 3), which preempts any federal, state, tribal, or local law that allows or requires disclosure of patient safety work product as defined. A state may not require a patient safety work product to be disclosed, even to state surveyors (Title 42 C.F.R sections 3.204-3.212). Commenter recommends that CDPH clarify in the proposed regulation that root cause analyses remain confidential and hospitals not be required to produce these documents.
**Commenter:** 1
**Department Response:** See Department response to corresponding topic in 45-day Addendum.

## Section 71567: Adverse Event Reporting Requirements

### Comment Topic: Apply same requirements for acute psychiatric hospitals

**Comment:** Commenter recommends adopting the same adverse event reporting requirements for acute psychiatric hospitals by reference. The contents of Title 22 CCR section 71567 should be replaced with: The provisions in Chapter 1, Article 11, section 70973 shall apply to reportable adverse events in acute psychiatric hospitals.
**Commenter:** 1

**Department Response:** See Department response to corresponding topic in 45-day Addendum.

## Section 71568: Adverse Event Investigation

### Comment Topic: Adverse Event Investigation Requirements for Acute Psychiatric Hospitals

**Comment:** Commenter recommends that the Department adopt the same adverse event investigation requirements for acute psychiatric hospitals. The contents of Title 22 CCR section 71567 should be replaced with: The provisions in Chapter 1, Article 11, section 70973 shall apply to reportable adverse events in acute psychiatric hospitals.
**Commenter:** 1
**Department Response:** See Department response to corresponding topic in 45-day Addendum.

## Section 71569: Policies and Procedures (Psychiatric Hospitals)

### Comment Topic: Policies and Procedures Requirements for Acute Psychiatric Hospital

**Comment:** Commenter recommends that the Department adopt the same adverse event policies and procedure requirements for acute psychiatric hospitals. The contents of Title 22 CCR section 71567 should be replaced with: The provisions in Chapter 1, Article 11, Section 70974 shall apply to reportable adverse events in acute psychiatric hospitals.
**Commenter:** 1
**Department Response:** See Department response to corresponding topic in 45-day Addendum.

# ATTACHMENTS TO THE FINAL STATEMENT OF REASONS

## ADDENDUM III
## Second 15 Day Public Notice

**Summary of Comments and Responses to Comments Received**

The Department received one new comment from one commenter during the notice of public availability beginning September 10, 2021, through September 24, 2021. The comments below are summarized and the responses follow.

| List of Commenters | | |
|---|---|---|
| 1. | California Hospital Association | Kiyomi Burchill |

## Section 70971: Definitions

**Comment Topic: Assessment of Culture of Safety**

**Comment:** Commenter recommends that the Department revise the term “patient safety culture” to “culture of safety.” The change from “culture of safety” to “patient safety culture” removes common awareness of a term that is being used by many nationally recognized surveys tools and will create confusion on how to comply.
**Commenter:** 1
**Department Response:** The Department has revised this term in the proposed regulations back to “culture of safety.” The change from “culture of safety” to “patient safety culture,” was made to increase understanding and create clarity, however, based on CHA’s comment, the change has the opposite effect. All mentions of “patient safety culture have been revised to “culture of safety” for clarity and to align with industry understanding.

## Section 70972: Reporting Requirements

**Comment Topic: Online Submission of Adverse Events**

**Comment:** The commenter is concerned about the removal of the word “secure” from the description of the website that the hospital will submit adverse events to. Will the system no longer be secure?
**Commenter:** 1
**Department Response:** The initial change to the text was made to specify that the website is being maintained by the Department. In response to this comment however, the removal of the word “secure” is concerning to the regulated community. To assure the regulated community that the website the hospital will submit adverse events to is secure, the Department has added the term “secure” to describe the website maintained by the Department where adverse events are submitted.