Supplemental Statement of Reasons

The California Department of Public Health (Department) has instituted additional changes to these proposed regulations, and they are discussed below. These changes are either initiated by the Department or are in response to comments that were received during the 45-day public comment period that ended on August 18, 2020.

The Department will provide responses to all comments in the Final Statement of Reasons as is required.

GENERAL ACUTE CARE HOSPITALS

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 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 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 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. The 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 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 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.

ACUTE PSYCHIATRIC HOSPITALS

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 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 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.