SUPPLEMENTAL STATEMENT OF REASONS

The California Department of Public Health (Department) has instituted additional changes to these proposed regulations which are discussed below. These changes are either initiated by the Department or in response to comments that were received during the Office of Administrative Law's (OAL's) review and approval period which ended on August 13, 2021. Additional discussion to the Initial Statement of Reasons (ISOR) and documents relied upon, identified below, are added to the rulemaking file.

Regulation Text Changes:

Section 70971: Except for the following, no additional changes to this section are proposed:

- **Subsection (a)(7):** The text was revised to add a comma after "component part or accessory" because the previously proposed regulation text did not meet the clarity standard. The addition of the comma clarifies that the definition of "device" as recognized in the United States Pharmacopeia and the National Formulary (USP-NF) applies to the entire definition and not just a component part or accessory.

- **Subsection (a)(12):** The Department proposes to revise the definition of "nationally recognized survey tool" by deleting the word "equivalent" because it is vague and may require the regulated community to determine what an equivalent survey tool is, leading to confusion. The revised definition now states specifically that which constitutes a valid and reliable survey tool, as defined by the Agency for Healthcare Research and Quality (AHRQ[1]).

- **Subsection (a)(15):** The Department proposes to add a definition for "patient safety culture." This definition is necessary to clarify and specify elements that make up the hospital's patient safety culture. This definition is informed by the AHRQ which publishes tools that assess patient safety culture in health care settings.[2]

- **Subsections (a)(15) – (a)(30):** The Department proposes to renumber existing subsections (a)(15) – (a)(30) to (a)(16) – (a)(31) as indicated due to the definition added as new subsection (a)(15). Except for renumbering, no additional changes are proposed to the text for these subsections.
    - Renumber existing subsection (a)(15) to subsection (a)(16)
    - Renumber existing subsection (a)(16) to subsection (a)(17)

[1] About SOPS. Content last reviewed April 2021. Agency for Healthcare Research and Quality, Rockville, MD. https://www.ahrq.gov/sops/about/index.html
[2] *Ibid*

- Renumber existing subsection (a)(17) to subsection (a)(18)
- Renumber existing subsection (a)(18) to subsection (a)(19)
- Renumber existing subsection (a)(19) to subsection (a)(20)
- Renumber existing subsection (a)(20) to subsection (a)(21)
- Renumber existing subsection (a)(21) to subsection (a)(22)
- Renumber existing subsection (a)(22) to subsection (a)(23)
- Renumber existing subsection (a)(23) to subsection (a)(24)
- Renumber existing subsection (a)(24) to subsection (a)(25)
- Renumber existing subsection (a)(25) to subsection (a)(26)
- Renumber existing subsection (a)(26) to subsection (a)(27)
- Renumber existing subsection (a)(27) to subsection (a)(28)
- Renumber existing subsection (a)(28) to subsection (a)(29)
- Renumber existing subsection (a)(29) to subsection (a)(30)
- Renumber existing subsection (a)(30) to subsection (a)(31)

Section 70972: Except for the following, no additional changes to this section are proposed:

- As initially noticed, **subsections (a) and (c)** required adverse events be reported via a secure electronic web-based portal. This wording was revised for clarity to specify that reports are to be made through an internet website maintained by the Department.

Section 70973: Except for the following, no additional changes to this section are proposed:

- **Subsection (a)** has been revised to provide a cross reference to section 70972. This revision clarifies what requisite information is when reporting an adverse event.

- **Subsection (a)(2)(B)** has been revised to remove “or other investigatory means the Department determines necessary” because the provision did not meet clarity standards. Furthermore, the subsection was revised to clarify that off-site investigations include but are not limited to interviews and records reviews.

Section 70974: Except for the following, no additional changes to this section are proposed:

- **Subsection (a)(4)** has been amended to correct the term “culture of safety” to “patient safety culture” for consistency with the proposed definition in subsection 70971(a)(15) and the definition in subdivision 70971(a)(12).

Section 71567: Except for the following, no additional changes to this section are proposed:

- As initially noticed, **subsections (a) and (c)** required adverse events be reported via a secure electronic web-based portal. This wording was revised for clarity to specify that reports are to be made through an internet website maintained by the Department.

Section 71568: Except for the following, no additional changes to this section are proposed:

- **Subsection (a)** has been revised to provide a cross reference to section 71567. This revision clarifies what requisite information is when reporting an adverse event.

- **Subsection (a)(2)(B)** has been revised to remove "or other investigatory means the Department determines necessary" because the provision did not meet clarity standards. Furthermore, the subsection was revised to clarify that off-site investigations include but are not limited to interviews and records reviews.

Section 71569: Except for the following, no additional changes to this section are proposed:

- **Subsection (a)(4)** has been revised to correct the term "culture of safety" to "patient safety culture" for consistency with the proposed definition in subsection 70971(a)(15) and the definition in subdivision 70971(a)(12). The Department has also updated the regulation to be consistent with the applicable General Acute Care Hospital chapter of these regulations.

<u>Additional Clarifications:</u>

Section 70971(a)(1): No changes have been made to the regulation text; however, the following clarification addresses concerns regarding potential duplication of statute within the proposed regulations.

- The requirement to report adverse events that are ongoing urgent or emergent, threatening the welfare, health, or safety of patients, personnel, or visitors within 24 hours as prescribed in proposed 22 CCR section 70971(a)(1) is necessary for clarity even though the 24-hour report window is duplicative of Health & Safety Code section 1291.1(a). Placing the 24-hour reporting timeframe in regulations provides clarity for industry and staff and is necessary to clearly inform facilities and individuals of the law.

The noticed ISOR included a reference to a petition at the beginning of the last paragraph on page 14. The Department would like to clarify this was not a formal regulation petition but rather was feedback provided by stakeholders in a stakeholder engagement meeting.