

**Methodology to Indicate changes to
DPH-11-023 – Adverse Event Reporting Requirements**

The proposed changes for comment that are the subject of this second 15-day public comment period are indicated as follows:

- Deleted text is indicated by single strike-through (~~strike-through~~) and highlighted gray.
- Additions to the regulation text are indicated by single underline (underline) and highlighted gray.

**California Code of Regulations
Title 22. Social Security
Division 5. Licensing and Certification of Health Facilities, Home Health Agencies,
Clinics, and Referral Agencies
Chapter 1. General Acute Care Hospital
Adopt Article 11. Adverse Event Reporting Requirements**

Adopt Article 11 to read as follows:

Adopt Section 70970 to read as follows:

Section 70970. Applicability.

No change to text.

Adopt Section 70971 to read as follows:

Section 70971. Definitions.

(a) and (a)(1) through (a)(6) *No change to text.*

(7) “Device” means a medical instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related medical product or device, including a component part or accessory, that is recognized in the United States Pharmacopeia and the National Formulary (USP-NF) or any supplement, intended for use in the diagnosis of disease or other conditions, or in the care, mitigation, treatment, or prevention of disease, in humans or other animals; or intended to affect the structure or any function of the body of humans or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of humans or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.

(a)(8) through (a)(11) *No change to text.*

(a)(12) “Nationally recognized survey tool” means a valid and reliable survey tool identified by the Agency for Healthcare Research and Quality (AHRQ), or equivalent another survey tool which raises awareness of patient safety, assesses status

of patient safety culture, evaluates impact of patient safety interventions, and identifies strengths and areas for patient safety culture improvement.

(a)(13) and (a)(14) *No change to text.*

(a)(15) "Patient safety culture" means the actions and behaviors in the hospital that are rewarded, supported, expected, and accepted in the hospital as it relates to patient safety.

(a)(15) renumbered to (a)(16)

(a)(16) renumbered to (a)(17)

(a)(17) renumbered to (a)(18)

(a)(18) renumbered to (a)(19)

(a)(19) renumbered to (a)(20)

(a)(21) renumbered to (a)(22)

(a)(22) renumbered to (a)(23)

(a)(23) renumbered to (a)(24)

(a)(24) renumbered to (a)(25)

(a)(25) renumbered to (a)(26)

(a)(26) renumbered to (a)(27)

(a)(27) renumbered to (a)(28)

(a)(28) renumbered to (a)(29)

(a)(29) renumbered to (a)(30)

(a)(30) renumbered to (a)(31)

Note: Authority cited: Sections 1275, 131050, 131051, 131052 and 131200, Health and Safety Code. Reference: Sections 277 and 278, California Penal Code; Division 12, Part 3 (commencing with Section 7600), Family Code; Sections 1250, 1279.1, 1279.2 and 1279.6, Health and Safety Code; and Sections 15610.17(a) and 15610.67, Welfare and Institutions Code.

Adopt Section 70972 to read as follows:

Section 70972. Adverse Event Reporting Requirements.

(a) Pursuant to Health and Safety Code sections 1279.1 and 1279.3, adverse events shall be reported by the hospital through an internet website maintained by the Department's ~~secure electronic web-based portal~~ pursuant to the following timelines:

(a)(1) through (b)(9) *No change to text.*

(c) In the event the Department's internet website~~secure electronic web-based portal~~ is not operational, the hospital shall report an adverse event to the Department by email or telephone.

Note: Authority cited: Sections 1275, 131050, 131051, 131052 and 131200, Health and Safety Code. Reference: Sections 1279.1, 1279.2, 1279.3 and 1279.6, Health and Safety Code.

Adopt Section 70973 to read as follows:

Section 70973 Adverse Event Investigation.

(a) The hospital shall provide the requisite information, as outlined in section 70972, necessary for the Department to determine if an adverse event is substantiated or unsubstantiated, pursuant to the following process:

(a)(1) through (a)(2)(A) *No change to text.*

(a)(2)(B) An offsite investigation that includes but is not limited to interviews, and records reviews, ~~or other investigatory means the Department determines necessary.~~

Note: Authority cited: Sections 1275, 131050, 131051, 131052 and 131200, Health and Safety Code. Reference: Sections 1279.1, 1279.2, 1279.3 and 1279.6, Health and Safety Code.

Adopt Section 70974 to read as follows:

Section 70974. Adverse Events - Policies and Procedures.

(a)(1) – (a)(3) *No changes to text*

(4) Assessing the hospital's ~~culture of safety~~ patient safety culture at least every 24 months using a nationally recognized survey tool.

Note: Authority cited: Sections 1275, 131050, 131051, 131052 and 131200, Health and Safety Code. Reference: Sections 1279.1 and 1279.6, Health and Safety Code.

Title 22. Social Security
Division 5. Licensing and Certification of Health Facilities, Home Health Agencies,
Clinics, and Referral Agencies
Chapter 2. Acute Psychiatric Hospital
Adopt Article 6.5. Adverse Event Reporting Requirements

Adopt Article 6.5 to read as follows:

Adopt Section 71565 to read as follows:

Section 71565. Applicability.

No change to text.

Adopt Section 71566 to read as follows:

Section 71566. Definitions.

No change to text.

Adopt Section 71567 to read as follows:

Section 71567. Adverse Event Reporting Requirements.

(a) Pursuant to Health and Safety Code sections 1279.1 and 1279.3, adverse events shall be reported by the hospital through an internet website maintained by the Department's ~~secure electronic web-based portal~~ pursuant to the following timelines:

(a)(1) through (b)(9) *No change to text.*

(c) In the event the Department's internet website~~secure electronic web-based portal~~ is not operational, the hospital shall report an adverse event to the Department by email or telephone.

Note: Authority cited: Sections 1275, 131050, 131051, 131052 and 131200, Health and Safety Code. Reference: Sections 1279.1, 1279.2, 1279.3 and 1279.6, Health and Safety Code.

Adopt Section 71568 to read as follows:

Section 71568 Adverse Event Investigation.

(a) The hospital shall provide the requisite information, as outlined in section 71567, necessary for the Department to determine if an adverse event is substantiated or unsubstantiated, pursuant to the following process:

(a)(1) through (a)(2)(A) *No change to text.*

(a)(2)(B) An offsite investigation that includes but is not limited to interviews, and records reviews, or other investigatory means the Department determines necessary.

Note: Authority cited: Sections 1275, 131050, 131051, 131052 and 131200, Health and Safety Code. Reference: Sections 1279.1, 1279.2, 1279.3 and 1279.6, Health and Safety Code.

Adopt Section 71569 to read as follows:

Section 71569. Adverse Events - Policies and Procedures.

(a)(1) – (a)(3) *No changes to text*

(4) Assessing the hospital's culture of safetypatient safety culture at least every 24 months using a nationally recognized survey toolfor patient safety culture assessment.

Note: Authority cited: Sections 1275, 131050, 131051, 131052 and 131200, Health and Safety Code. Reference: Sections 1279.1, 1279.2 and 1279.6, Health and Safety Code.