

INITIAL STATEMENT OF REASONS

Summary of Proposal

Adverse Events (AEs) are serious reportable events that often result in patient deaths or serious disabilities. Health and Safety Code section 1279.1 requires that AEs occurring in general acute care hospitals (GACHs), acute psychiatric hospitals (APHs), and special hospitals (SHs) (collectively, the hospitals), be reported to the California Department of Public Health (the Department). Under Health and Safety Code section 1279.2, the Department is required to investigate AE reports and complaints regarding patient safety. The proposed regulations would clarify the categories, define terms within each AE category reportable by hospitals to the Department, and prescribes the use of the Department's electronic web-based portal for reporting AEs.

Background and Summary of Existing Laws and Regulations

The California State Legislature enacted Senate Bill (SB) 1301 (Chapter 647, Statutes of 2006),¹ in part, to require the Department, successor to the Department of Health Services,² to implement a statewide system for reporting AEs to the Department. SB 1301 enacted, in part, Health and Safety Code section 1279.1, which specifies the seven categories of AEs required to be reported by hospitals to the Department within prescribed timelines.

SB 1301 also enacted Health and Safety Code section 1279.2, prescribing the Department's responsibility to investigate AE reports and complaints. Consequently, the proposed regulations specify Department actions and timelines prescribed within the statute for onsite inspection of reports for ongoing threats of imminent danger of death or serious bodily harm, or an investigation of a report absent the above-mentioned ongoing threat.

The Legislature also enacted SB 158 (Chapter 294, Statutes of 2008) requiring, in part, that hospitals develop, implement, and comply with a patient safety plan to improve the health and safety of patients and reduce preventable patient safety events.³ The patient safety plan must include a reporting system for patient safety events, pursuant to Health and Safety Code section 1279.6.

¹ SB 1301 enacted Health and Safety Code §1279.1, §1279.2, §1279.3 and §1280.4.

² Pursuant to SB 162 (Chapter 241, Statutes of 2006), which reorganized the former Department of Health Services into the Department of Public Health and the Department of Health Care Services.

³ Health and Safety Code §1279.6(a) also applies to skilled nursing facilities (SNF), licensed pursuant to Health and Safety Code §1250(c) and defined as a long-term facility pursuant to Health and Safety Code §1418(a)(1). A separate regulatory action for SNF patient safety is planned because patient safety issues in long-term care differ from acute care.

Enforcement of the proposed AE regulations is the responsibility of the Department's Center for Health Care Quality (CHCQ), Licensing and Certification Program (L&C), pursuant to Health and Safety Code section 131051(b)(1) through (b)(3). L&C's mission includes promoting the highest quality of health care in licensed hospitals. L&C's goals include consistent oversight of hospitals to ensure compliance with state and federal standards while promoting patient safety.

In response to the Department's pre-notice hearing on November 24, 2010, the regulated community recommended the AE definitions by the National Quality Forum (NQF), *Serious Reportable Events in Healthcare – 2006 Update: A Consensus Report* be used to define terms in these proposed regulations.⁴

Given NQF's expertise and the unique role the organization has in improving the quality of health care, the Department determined that using these industry-wide accepted definitions would be beneficial, as they would likely be familiar to hospitals. The NQF released a 2011 Update. Consequently, the proposed definitions are modeled after the NQF 2011 Update, when compatible with Health and Safety Code section 1279.1 AE categories and terms.

Policy Statement Overview

1. Problem Statement: Health and Safety Code sections 1279.1, 1279.2, and 1279.6 applicable to AEs are ambiguous and subject to interpretation. Health and Safety Code section 1279.1 includes medical terminology requiring definition for clarity and consistency in reporting and investigating AEs. Health and Safety Code section 1279.2 prescribes, in part, the Department's responsibility for investigating AE reports and complaints, but does not specify the hospital's responsibility to provide information to the Department. Health and Safety Code section 1279.6 requires the hospital to implement a culture of safety by developing, implementing, and complying with a patient safety plan, but does not prescribe how the plan is to be developed, or how the culture of safety is to be assessed.

To implement Health and Safety Code sections 1279.1, 1279.2, and 1279.6, the proposed regulations establish a consistent statewide system requiring hospitals to identify, report, and correct systemic problems contributing to preventable patient safety

⁴ The NQF is a nonprofit, nonpartisan, public service organization, created in 1999 in response to recommendations from the *President's Advisory Commission on Consumer Protection and Health Care Industry*. The NQF developed into a collaborative organization at the forefront of quality improvement efforts in health care. The NQF builds consensus on national priorities and performance improvement goals by endorsing national standards for measurement and public reporting of performance and promotes national goals through education and outreach programs. The NQF is a nationally recognized authority on events associated with patient death or serious disabilities that continue to recur in health care.

events, including AEs.⁵ Additionally, hospitals are required to establish systemic processes to support a culture of safety, including internal reporting and documentation of preventable patient safety events, conducting a root cause analysis to prevent recurrence, and performing annual assessments of the hospital's culture of safety.

2. Objectives (Goals): The proposed regulations clarify and specify statutory requirements for the purpose of improving patient safety in hospitals and encouraging a culture of safety in hospitals by:

- Establishing AE definitions in Title 22 to provide clarity and consistency in applying medical terms to reporting requirements.
- Defining and clarifying the reporting requirements and the situational circumstances regarding AEs.
- Requiring a hospital to use the Department's secure electronic web-based portal for transmitting AE reports to the Department, preserving patient confidentiality.
- Specifying reporting, investigation, or inspection timelines for AEs.
- Requiring hospitals to conduct a root cause analysis to identify systemic problems and implement corrective actions to prevent future occurrence of AEs.
- Requiring hospitals to annually assess the hospital's culture of safety.

Benefits

Anticipated benefits from the proposed regulations are to:

- Facilitate uniform and comparable data for public reporting of AEs.
- Facilitate the use of evidence-based solutions elicited from a root cause analysis of the AE to prevent future occurrences, thereby promoting patient safety.
- Provide comparable electronic data for systematic analysis, comparison, and sharing of information between hospitals to improve patient safety.
- Improve accountability of hospitals to the public.

Evaluation as to Whether the Proposed Regulations Are Inconsistent or Incompatible with Existing State and Federal Regulations

The Department reviewed existing state and federal regulations, concluding the proposed regulations are consistent and compatible with existing state or federal regulations.

Authority and Reference Citations

The following are proposed for adoption: Health and Safety Code section 1275 requires the Department to adopt, amend, or repeal regulations to carry out the purposes and intent of Chapter 2 (Licensing Provision) of the Health and Safety Code; and Health and Safety Code sections 131000, 131050, 131051, 131052 and 131200 specify the Department's authority vested by the California Public Health Act of 2006, SB 162 (Chapter 241, Statutes of 2006), effective July 1, 2007.

⁵ Preventative patient safety events are defined at Health and Safety Code §1279.6(c).

Health and Safety Code section 1250 defines the licensure categories for GACH, APH, and SH. The proposed regulations implement, interpret and make specific Health and Safety Code sections 1279.1, 1279.2, 1279.3, and 1279.6, which require AE reporting, Departmental investigation, and public posting of information regarding substantiated AE, and the preparation and implementation of patient safety plans by hospitals.

Detailed Discussion of Each Regulatory Provision Proposed to be Amended

The Department proposes to adopt the following articles and sections to implement the regulations needed to address AEs.

Title 22, Division 5, Chapter 1, General Acute Care Hospitals, Article 11 – Adverse Event Reporting Requirements

Section 70970. Applicability.

Adopt section 70970 to clarify AE reporting requirements under proposed Article 11 relating only to GACHs and SHs for consistency with the organization of Title 22 CCR, which regulates GACHs and SHs in Chapter 1.

Subsection (a) specifies subdivision (a) of Health and Safety Code section 1279.1, so the regulated community can readily locate the provision that requires GACHs and SHs to report AEs.

Subsection (b) introduces paragraphs (b)(1) and (2) to clarify applicability.

Paragraph (b)(1) uses “hospital” for consistency with the definition of GACH and SH at 22 CCR sections 70003 and 70062.

Paragraph (b)(2) is necessary to clarify that a distinct part of intermediate care facilities (DP ICF) or a distinct part skilled nursing facilities (DP SNF) are not subject to the AE reporting requirements. DP ICF and DP SNF provide long-term care rather than acute care and are regulated under different chapters than hospitals, pursuant to 22 CCR sections 70503 and 70627.

Section 70971. Definitions.

Adopt section 70971 to provide operational definitions of terms used in the body of the regulation, thereby providing uniform interpretation of the terms in Health and Safety Code section 1279.1, 1279.2, and 1279.6. The definitions in proposed subsections (a)(1) through (29) clarify the terms associated with each category of AEs and with the Department’s investigative determinations. Without clarification, the meaning of the terms would be subject to interpretation, resulting in inaccurate and inconsistent reporting or misinterpretation of the outcome of the Department’s investigation.

It is necessary to define medical and public health phrases used in Health and Safety Code sections 1279.1, 1279.2, and 1279.6. The NQF 2011 Update is the basis of some definitions, specifically for “decision-making capacity,” “device,” “infant,” “low-risk

pregnancy,” “medication error,” “retention of a foreign object,” “surgery,” “surgery begins,” and “surgery ends.”⁶ Other terms included are not defined by the NQF. The Department discusses these terms below.

“Adverse event” is defined to provide clarity to the reader that the term is used as defined under the Health and Safety Code.

“Biologic” and “countershock” are defined as they are necessary to provide operational definitions for the regulations. These definitions are consistent with the U.S. Food and Drug Administration (FDA) definitions. Alternative definitions at Health and Safety Code §1600.1, California Food and Agricultural Code section 9203 and CCR, Title 22, section 72017 for the term “biologic” were considered. These definitions are not used because they are not applicable to hospital setting reportable AEs.

“Detect” is defined to bring clarity to the reporting requirements of hospitals. The definition provides that the detection of an adverse event includes not only the discovery of the adverse event, but the reasonable belief that an adverse event occurred. In considering how to define this term, the Department considered how the federal government requires the reporting of medical information breaches under HIPAA (Part 164.404(a)(2) of Title 45 of the Code of Federal Regulations). The Department has determined that hospitals are to report adverse events not only when there is certainty of an adverse event, but when the hospital is reasonably certain that an adverse event may have occurred. Under this definition, detection by the hospital’s personnel or agents is attributable to the hospital.

“Major life activity” is necessary to clarify the ambiguous term “major life activities” as it relates to an individual’s loss of bodily function or capability resulting from serious bodily injury or harm. The proposed definition paraphrases the definition of “major life activities” in the Americans with Disabilities Act Amendments Act of 2008 (ADAAA) enacted pursuant to Public Law 110-325 (S 3406), on September 25, 2008, and effective January 1, 2009 (see Title 42, United States Code (42 USC), Chapter 126, section 12102(2)(A) and (B)).

The ADAAA section 3(2)(A) and (B) defines “major life activities” within the context of the definition of “disabilities” at section 3(1), while the context of these proposed regulations is adverse event reporting. Therefore, it is necessary for clarity to paraphrase the proposed definition of “major life activities” rather than duplicate the ADAAA definition.

Alternative definitions in 22 CCR by other California state departments were considered but determined not to be appropriate for adverse event reporting because the purpose of those departments’ definitions was to qualify a person for services, or protect a person from discrimination when State funding is used (22 CCR section 98100, General

⁶ *NQF 2011 – Update*, Appendix B – Glossary, B-4 and page A-4.

Prohibition). The ADAAA definition is comprehensive, descriptive, and less subject to misinterpretation of adverse event reporting requirements.

“Nationally recognized survey tool” is defined to clarify the requirement in proposed section 70974(a)(4), which requires hospitals to assess their culture of safety using a nationally recognized tool. The Department’s research determined that the National Association for Healthcare Quality (NAHQ) identifies a number of survey tools available for hospitals.⁷ Specifying NAHQ as one example gives hospitals a point of entry for encouraging a culture of safety using nationally recognized tools.

“Normal, healthy patient” is necessary to define a medical and public health term used in Health and Safety Code section 1279.1(b)(1)(E). The definition used by the Department is consistent with the NQF as well as the American Society of Anesthesiologists (ASA). The NQF recognizes the ASA’s established system for ranking patient health status as a prediction of anesthetic or surgical risk, which is a nationally recognized standard.⁸

“Party responsible for the patient” is defined to provide clarity and specificity to Health and Safety Code section 1279.1(c), in defining an authorized representative or “responsible party” to the patient. This ensures the patient is represented in accordance with his or her wishes and as prescribed by law, ensuring appropriate patient protection.

“Patient safety event” is defined to provide clarity to the reader that the term is used as defined under the Health and Safety Code.

“Root cause analysis” provides an operational definition for the term that provides contextual methods for analysis in reported AEs to reduce misinterpretation of data. The use and rationale of root cause analysis is examined in more detail under the discussion of section 70974(a)(3), below.

“Serious bodily harm” is defined to provide clarity to a term used in Health and Safety Code section 1279.2(a)(1) and (2)(b). A definition of the term “serious bodily harm” is necessary to explain what triggers the Department to make an onsite inspection or investigation.

“Significant injury” is defined to provide clarity to a term used in Health and Safety Code section 1279.1(b)(6)(D). A definition of the term “significant injury” is necessary to distinguish it from the term “serious disability”⁹ and to enable facilities to report adverse events.

⁷ National Association for Healthcare Quality, *Call to Action, Safeguarding the Integrity of Healthcare Quality and Safety Systems*, 2012.

⁸ The Cleveland Clinic Foundation, *ASA Physical Classification System*, 2013.

⁹ Defined at Health and Safety Code §1279.1(d).

“Stage 2 pressure ulcer” is necessary to define because it may be exempted as a reportable AE if recognized on admission to the hospital, pursuant to Health and Safety Code section 1279.1(b)(4)(F). In defining the term, the Department references the 2016 pressure injury categories as set forth by the National Pressure Ulcer Advisory Panel.¹⁰

“Stage 3 pressure ulcer” and “Stage 4 pressure ulcer” are defined to clarify Health and Safety Code section 1279.1(b)(4)(F). In defining the terms, the Department references the 2016 pressure injury categories as set forth by the National Pressure Ulcer Advisory Panel.¹¹

“Substantiated” and “unsubstantiated” definitions are necessary to implement and make specific Health and Safety Code section 1279.2(d), which requires the Department to notify the licensee and complainant of its determination.

“Suspected deep tissue pressure ulcer” is defined to clarify the proposed definitions of “Unstageable pressure ulcer,” “Stage 3 pressure ulcer,” and “Stage 4 pressure ulcer,” all of which contain guidance on verifying the stage of an ulcer. “Suspected deep tissue pressure ulcer” is needed to differentiate from the verified ulcers. In defining the term, the Department references the 2016 pressure injury categories as set forth by the National Pressure Ulcer Advisory Panel.¹²

“Unstageable pressure ulcer” is defined to clarify its use in the proposed definitions for “Stage 3 pressure injury” and “Stage 4 pressure injury.” In defining the term, the Department references the 2016 pressure injury categories as set forth by the National Pressure Ulcer Advisory Panel.¹³

“Wrong person” is defined to provide an operational definition for the term and was created to be consistent with California Penal Code section 277 and Division 12, Part 3 (commencing with section 7600) of the Family Code.

Section 70972. Adverse Event Reporting Requirements.

Adopt section 70972, which provides a new regulatory section for placement of terms and conditions for reporting AEs. Under subsection (a), the Department provides the manner in which AEs are reported to the Department. The Department chose the electronic web-based portal because it is convenient for hospitals, best ensures the security of the data, and is consistent with other reporting requirements for hospitals.

Paragraphs (a)(1) through (3) clarify the timeline for reporting AEs to the Department for consistency with Health and Safety Code section 1279.1(a), which specifies the criteria

¹⁰ National Pressure Ulcer Advisor Panel. <http://www.npuap.org/resources/educational-and-clinical-resources/npuap-pressure-injury-stages/>. Last accessed June 6, 2016.

¹¹ National Pressure Ulcer Advisor Panel, *supra*.

¹² National Pressure Ulcer Advisor Panel, *supra*.

¹³ National Pressure Ulcer Advisor Panel, *supra*.

related to reporting within 24 hours or 5 days for AEs. Proposed paragraph (a)(2) requires reporting of a sexual assault within 24 hours of allegation or detection because the sexual assault may come to the attention of the hospital based on an allegation by the victim, or may be detected by the hospital based on injuries suffered by the victim or by the assault being witnessed by personnel or others. 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.

Section 70972(b) implements, clarifies, and makes specific the reporting requirements pursuant to Health and Safety Code sections 1279.1 and 1279.3 regarding information disclosures by hospitals. As required by Health and Safety Code sections 1279.1 and 1279.3, the Department collects, organizes and analyzes hospital-related AE data. The electronic web-based portal provides hospital access to the Department's secure database, thereby facilitating the investigative process, reporting of results, and ultimately improvement in hospital patient safety. The Department requires hospitals to provide basic information to assist in the Department's investigation.

Section 70972(b)(1) through (7) provide pertinent information so the Department can determine the district office with jurisdiction and the urgency of the investigation or inspection to protect patients and initiate an AE investigation within the timeframes proposed in section 70973.

Section 70972(b)(8) is necessary for the Department:

- To review, agree to, and monitor a hospital's plan of correction (POC) pursuant to Health and Safety Code section 1280, which prescribes the actions the Department may take when a hospital fails to implement the POC, or the AE poses an immediate and substantial hazard to the health or safety of patients; and
- To be apprised of mitigating actions taken by the hospital to immediately reduce further injury or risk to the patient.

Section 70972(b)(9) enables the Department to have the most current information regarding the AE in order to fulfill investigation requirements at proposed sections 70973 (GACH Article 11) and 71568 (APH Article 6.5).

Section 70973. Adverse Event Investigation.

Adopt section 70973 creating a new regulatory section describing investigations of AE reports and complaints.

Section 70973(a) specifies the hospital's responsibility to enable the Department to determine if the adverse event occurred pursuant to Health and Safety Code section 1279.2.

Section 70973(a)(1) provides that, in the event of an ongoing threat of imminent danger

of death or serious bodily harm, the hospital will be subject to an onsite inspection within 48 hours or 2 business days, whichever is greater, consistent with Health and Safety Code section 1279.2(a)(1). This provision is included as an indication of the serious nature of these specific AEs and the Department's recognition of the need to address these events in a timely manner.

Section 70973(a)(2) is included to distinguish between those AEs that are ongoing threats of imminent danger situations and those AEs that do not meet this threshold. The Department has determined that in situations in which there is not an ongoing threat of imminent danger of death or serious bodily harm, hospitals shall be subject to Department action, either in the form of an onsite inspection per paragraph (a)(2)(A) or an offsite investigation per paragraph (a)(2)(B). Given the wide variety of AE reports received by the Department, the Department has concluded it is best to determine the appropriate action on a case-by-case basis. Some AEs that are not ongoing threats of imminent danger of death or serious bodily harm are still serious enough to warrant an onsite inspection. Others are important but may not warrant the use of these resources and are sufficiently handled by an offsite investigation. The Department has concluded it should use discretion based on the facts of each instance as they present themselves.

Section 70973(a)(2)(B) specifies the documents and processes included in an offsite investigation to clarify how an investigation can be conducted without going to the hospital. The phrase "other investigatory means" is purposely broad so the Department's investigative avenues are not limited, and the circumstances of the AE can guide the Department's investigative strategies.

Section 70974. Adverse Events – Policies and Procedures.

Adopt section 70974 to introduce a new regulatory section to implement Health and Safety Code section 1279.6 by specifying the components for policies and procedures for patient safety plans that hospitals develop, implement and maintain, pursuant to proposed subsection (a).

Section 70974(a) prescribes components to implement statutory requirements for hospitals to maintain an overall patient safety plan. This requirement creates system-wide accountability, establishes expectations of hospital staff, and may decrease the risk of patient injury by promoting decisive action consistent with the hospital's safety plan.

Section 70974(a)(1) is added to describe and specify development of a culture of safety in hospitals by establishing a blame-free environment, thereby encouraging personnel to report adverse events. A culture of safety encourages prevention of future errors by facilitating an environment where individuals learn from mistakes and avoid similar mistakes in the future. Section 70974(a)(1) uses the term "internally" to distinguish the reporting of patient safety events from the hospitals' reporting of AEs to the Department's secure, electronic web-based portal.

Section 70974(a)(2) is added to specify hospitals' responsibility to develop policies and

procedures for documenting reportable patient safety events and provides the basis for a root cause analysis (RCA) as described in the proposed section 70974(a)(3).

Section 70974(a)(3) clarifies hospitals' responsibility to conduct an RCA, while maintaining compliance with section 70737 so the protection afforded the public by timely reporting of reportable diseases or unusual occurrence is not compromised. RCA is a structured method of analyzing patient safety events. Developed to analyze industrial accidents, RCA is a method for analysis of errors in health care. The Joint Commission, which is an independent, nonprofit organization that accredits and certifies nearly 21,000 health care organizations and programs throughout the United States and is recognized as a leader in establishing industry performance standards, mandated the use of RCA to analyze sentinel events. Since 2007, twenty-six states have mandated reporting of serious AEs using the NQF list of "Never Events." The goal of RCA is to identify patterns of error and point the way toward solutions. Applied to the health care industry, RCA is a highly effective tool for improving patient care and reducing the occurrence of patient safety events. When RCA yields findings directly related to system-wide failure (e.g., staffing, equipment, devices, medication, effective communication), a plan implementing systemic change must occur for the benefit of patient health, safety, and welfare.

Section 70974(a)(4) interprets and makes specific Health and Safety Code section 1279.6(b)(1)(E)(4), which is necessary to encourage a culture of safety and reporting of patient safety events in hospitals. The annual survey of the hospital's culture of safety supports the review and update of patient safety plans, which are required to be conducted annually or more frequently as needed [Health and Safety Code section 1279.6(b)(1)(E)]. Patient safety plans are required to include AEs pursuant to Health and Safety Code section 1279.6(c). A hospital could choose to survey more frequently, if deemed necessary. The NQF and comments from the pre-notice public hearing recommend using a nationally recognized culture of safety survey tool.

The Department's research determined that the National Association for Healthcare Quality (NAHQ) identifies a number of survey tools available for hospitals.¹⁴ Specifying NAHQ as one example gives hospitals a point of entry for encouraging a culture of safety using nationally recognized tools. Although the Department does not require use of a specific survey tool to assess a hospital's culture of safety, nationally recognized tools as defined in section 70971(a)(11) provide a number of survey tools available for hospitals. Periodic review and analysis of data collected for patient safety events provide a basis on which to form a plan to prevent future recurrence of preventable patient safety events.

¹⁴ National Association for Healthcare Quality, *Call to Action, Safeguarding the Integrity of Healthcare Quality and Safety Systems*, 2012.

Title 22, Division 5, Chapter 2. Acute Psychiatric Hospital, Article 6.5. Adverse Event Reporting Requirements

Section 71565. Applicability.

Adopt section 71565 to clarify AE reporting requirements under proposed Article 6.5 relating to acute psychiatric hospitals (APHs) for consistency with the organization of Title 22 CCR, which regulates APHs in Chapter 2. The section specifies subdivision (a) of Health and Safety Code section 1279.1, so the regulated community can readily locate the provision that requires APHs to report AEs.

Section 71566. Definitions.

Adopt section 71566 for the reasons provided for under section 70971, above.

Section 71567. Adverse Event Reporting Requirements.

Adopt section 71567 for the reasons provided for under section 70972, above.

Section 71568. Adverse Event Investigation.

Adopt section 71568 for the reasons provided for under section 70973, above.

Section 71569. Adverse Events – Policies and Procedures.

Adopt section 71569 for the reasons provided for under section 70974, above.

Documents Relied Upon

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Statement of Determinations

1. Reasonable Alternatives

The Department has made an initial determination that no reasonable alternative considered by the Department, or otherwise identified and brought to the attention of the Department, would be (a) more effective in carrying out the purpose of the proposed regulations, (b) would be as effective and less burdensome to affected private persons than the proposed regulations, or (c) would be more cost-effective to affected private persons and equally effective for implementing Health and Safety Code section 1279.1, 1279.2, and 1279.6.

Based on a petition, the Department considered but ultimately decided against whether healthcare-associated infections (HAI) fit into the broad language of an adverse event under Health and Safety Code section 1279.1(b)(7). Provision (b)(7) states, “(b) For purposes of this section, ‘adverse event’ includes any of the following: (7) An adverse event or series of adverse events that cause the death or serious disability of a patient, personnel, or visitor.” The Department decided against interpreting that HAI fit into provision (b)(7) after a HAI Advisory Committee Meeting in which stakeholders expressed concern that such an action would add needless complexity and confusion.

2. Local Mandate

The Department has made an initial determination that these proposed regulations do not impose a mandate on local agencies or school districts that requires reimbursement as it expands the definition of a crime under Health and Safety Code section 1279.1.

3. Economic Impact Assessment

The Department has made an initial determination that these proposed regulations would have no significant direct economic impact on California business enterprises and individuals, including the ability of California businesses to compete with businesses in other states because the proposed regulations would not significantly affect:

- a. **The creation or elimination of jobs within the State of California.** The proposal clarifies and specifies reporting of AEs and the implementation of patient safety plans that hospitals are currently required to do. The proposal does not create or eliminate jobs within the State of California.
- b. **The creation of new businesses or the elimination of existing businesses within the State of California.** The proposal will not have any impact upon the creation or elimination of new businesses within the State of California. The regulations are designed to clarify existing statutory reporting requirements.
- c. **The expansion of businesses currently doing business within the State of California.** This proposal does not create the need for expansion of businesses currently doing business within the State of California. The regulations are designed to clarify existing statutory reporting requirements.
- d. **The benefits of the regulation to the health and welfare of California residents, worker safety, and the state's environment.** The proposal provides transparency and consistency for reporting of AEs. The proposed regulations improve reporting, accountability, and patient safety by establishing clear and consistent statewide reporting standards, endorsed by the NQF, for detection and response to systemic problems and/or AEs, thereby promoting a culture of safety, and improved public accountability and trust. The proposed regulation does not contribute negatively to the state's environment because it does not affect the environment.

The benefits of the regulations to the health and safety of California residents far outweigh the costs associated with hospitals reporting of AEs and the development and implementation of patient safety plans, as the following demonstrates:

An abstract of a medical journal article, A comprehensive patient safety program can significantly reduce preventable harm, associated costs, and hospital

mortality,¹⁵ reported on the evaluation of “the effectiveness of a hospital-wide initiative to improve patient safety by implementing high-reliability practices as part of a quality improvement (QI) program aimed at reducing all preventable harm.” The evaluation concluded, “Substantial reductions in serious safety event rate, preventable harm, hospital mortality, and cost were seen after implementation . . . Measurable improvements in the safety culture were noted as well.”

The New Jersey Hospital Association (NJHA) reported “that the three-year Partnership for Patients-New Jersey, part of the nationwide Partnership for Patients project spearheaded by the [CMS], led to 13,730 instances where patient harm was averted and a total savings of \$120 million in healthcare costs, based on data from the Agency for Healthcare Research and Quality (AHRQ).”¹⁶

A review of AE data for California hospitals between state fiscal year (FY) 2007-08¹⁷ through FY 2014-15 annually report between 611 and 1282 events.¹⁸ Implementation of a patient safety plan incorporating a culture of safety demonstrates the potential to improve patient safety and reduce health care costs.

4. Effect on Small Business

The Department has made an initial determination 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 did include specific guidelines and considerations within the statute for small and rural hospitals if a penalty occurs relative to an AE report, pursuant to Health and Safety Code 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.¹⁹

5. Housing Costs

The Department has made an initial determination that the proposed regulations would have no impact on housing costs.

¹⁵ J Pediatr. 2013 Dec; 163(6):1638-45. Doi: 10.1016/j.jpeds.2013.06.031. Epub 2013 July 30, Copyright © 2013 Mosby, Inc. All rights reserved. Accessed May 21, 2016 at <https://www.ncbi.nlm.nih.gov/pubmed/23910978>.

¹⁶ N.J. Hospital Quality Initiative Averts 13,730 Cases of Harm, \$120 Million in Costs, Page 2. Retrieved from: <http://www.njha.com/pressroom/2015-press-releases/sept-25-2015-nj-hospital-quality-initiative-averts-13730-cases-of-harm-120-million-in-costs/>

¹⁷ FY 2007-08 was the first year hospitals were required to report AEs, pursuant to SB 1301, operative July 1, 2007 (Statutes of 2006, Chapter 647).

¹⁸ FY 2014-15 is the latest year available because FY 2015-16 ends June 30, 2016.

¹⁹ Health and Safety Code §124840.

6. Cost Impacts on Representative Person or Business

The agency is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action. Hospitals must already report AEs to the Department, and the purpose of these proposed regulations is to clarify terms, reporting requirements, and investigation parameters.

7. Reporting Requirements

While hospitals are required to report AEs under existing statute, this regulation would make specific the details of this requirement and prescribe the use of the Department's electronic web-based portal for reporting AEs. The Department has found that reporting AEs via the web-based portal protects data integrity and is in line with current industry practices designed to safeguard public health.

8. Mandated Use of Specific Technologies, Equipment, Actions, or Procedures

The Department has developed an electronic web-based portal (portal) for reporting of AEs, which is available on the Department's website and which does not require a fee to use or enroll. Hospitals must register to use the portal and redacted database information is then available for use by hospitals for the purpose of analysis. The Department determined that use of the portal is convenient for hospitals, best ensures the security of the data, and is consistent with other reporting requirements for hospitals. The portal provides hospitals access to the Department's secure database, thereby facilitating the investigative process, reporting of results, and, ultimately, the improvement of hospital patient safety.

In considering the use of performance-based standards over the prescription of specific technologies and procedures, the Department determined that performance-based standards would be inadequate to address its duties as prescribed in statute.