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California Department of Public Health

GAVIN NEWSOM
Governor

NOTICE OF PROPOSED RULEMAKING
Title 22. Social Security
DPH-11-023 Adverse Events Reporting
Notice Published: July 3, 2020

Notice is hereby given that the California Department of Public Health (Department) is proposing the regulation described below. This notice of proposed rulemaking commences a rulemaking to make the regulations permanent after considering all comments, objections, and recommendations regarding the regulation.

PUBLIC PROCEEDINGS

The Department is conducting a 45-day written public proceeding during which time any interested person or such person's duly authorized representative may present statements, arguments or contentions (all of which are hereinafter referred to as comments) relevant to the action described in the Informative Digest/Policy Statement Overview section of this notice.

To request copies of the regulatory proposal in an alternate format, please write or call: Hannah Strom-Martin, Office of Regulations, 1415 L Street Suite 500, Sacramento, CA 95814, at (916) 440-7371, email to hannah.strom-martin@cdph.ca.gov or use the California Relay Service by dialing 711.

WRITTEN COMMENT PERIOD

Written comments pertaining to this proposal, regardless of the method of transmittal, must be received by Office of Regulations by 5:00 p.m. on August 18, 2020, which is hereby designated as the close of the written comment period. Comments received after this date will not be considered timely.

Written comments may be submitted as follows:

1. By email to: regulations@cdph.ca.gov. It is requested that email transmission of comments, particularly those with attachments, contain the regulation package identifier "DPH-11-023 Adverse Events Reporting" in the subject line to facilitate timely identification and review of the comment;
2. By fax transmission to: (916) 319-9821;
   By postal service or hand delivered to: California Department of Public Health, Office of Regulations, 1415 L Street, Suite 500, Sacramento, CA 95814.

All submitted comments should include the regulation package identifier, **"DPH-11-023 Adverse Events Reporting,"** along with the commentor's name and email or mailing address.

PUBLIC HEARING

The Department has not scheduled a public hearing on this proposed action. However, the Department will hold a hearing if it receives a written request for a public hearing from any interested person, or his or her authorized representative, no later than 15 days prior to the close of the written comment period

ASSISTIVE SERVICES

For individuals with disabilities, the Department will provide assistive services such as the conversion of written materials into Braille, large print, audiocassette, and compute disk. For public hearings, assistive services can include sign-language interpretation, real-time captioning, note takes, and reading or writing assistance. To request these assistive services, please call (916) 558-1710 or (California Relay at 711 or 1-800-735-2929), email regulations@cdph.ca.gov, or write to the Office of Regulations at the address noted above. Note: The range of assistive services available may be limited if requests are made less than 10 business days prior to a public hearing.

AUTHORITY AND REFERENCE

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. 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.

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.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW:

Summary of Proposal

Adverse Events (AEs) are serious reportable events that often result in patient deaths or serious disabilities. Health and Safety Code section 1279.1requires that AEs occurring in general acute care hospitals (GACHs), acute psychiatric hospitals (APHs), and special hospitals (SHs) (collectively, the hospitals), be reported to 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

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.

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), S*erious Reportable Events in Healthcare* – 2006 *Update: A Consensus Report*

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[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.

be used to define terms in these proposed regulations (Document relied upon, NQF *2006 Update)*.[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.

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 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.

Objectives (Goals) of the Regulation
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:

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[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 (cont.) (cont.) 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.

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

- 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.

Anticipated Benefits
Anticipated benefits from the proposed regulations are to provide transparency and consistency for reporting of AEs. The proposed regulations are intended to 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.

EVALUATION AS TO WHETHER THE PROPOSED REGULATION ARE INCONSISTENT OR INCOMPATIBLE WITH EXISTING STATE AND FEDERAL REGULATIONS

The Department evaluated whether the proposed regulations are inconsistent or incompatible with existing state and federal regulations. This evaluation included a review of the Department's laws, as well as those statutes and regulations related to AEs. The Department has determined that no other state regulation addresses the same subject matter, and there are no existing state or federal regulations with which the proposed regulations conflict or with which they are incompatible.

FORMS INCORPORATED BY REFERENCE

None.

MANDATED BY FEDERAL LAW OR REGULATIONS

Not applicable.

OTHER STATUTORY REQUIREMENTS

Not applicable.

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 Section 17500) of division 4 of the Government Code

DISCLOSURES REGARDING THE PROPOSED ACTION

FISCAL IMPACT ESTIMATES

A) Cost to any local agencies or school districts that must be reimbursed pursuant to Section 17561 of Government Code:
The proposed regulations do not impose costs on any local agency or school district for which reimbursement would be required pursuant to part 7 (commencing with section 17500) of division 4 of the Government Code.

B) The cost or savings to any state agency:
The Department has determined there may be a nominal cost benefit to the Department as a result of Department staff no longer needing to contact hospitals to request additional information on AEs.

C) Impact on any cost or savings in federal funding of the program:
There is no federal funding affected by the proposed regulatory action.

D) Other nondiscretionary costs or savings imposed on local agencies:
The proposed regulations do not impose other nondiscretionary costs or savings on any local agencies.

HOUSING COSTS

The Department has determined that the regulations will not have an impact on housing costs.

SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS, INCLUDING ABILITY TO COMPETE

The Department has made an initial determination that these regulations would not have a significant statewide adverse economic impact directly affecting businesses, and individuals, including the ability of California businesses to compete with businesses in other states.

STATEMENT OF THE RESULTS OF THE ECONOMIC IMPACT ASSESSMENT

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, 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]."

A review of AE data for California hospitals between state fiscal year (FY) 2007-08 through FY 2014-15 annually report between 611 and 1282 events. Implementation of a patient safety plan incorporating a culture of safety demonstrates the potential to improve patient safety and reduce health care costs.

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;
B) The creation of new businesses or the elimination of existing businesses within the State of California; or
C) The expansion of businesses currently doing business within the State of California.

COST IMPACTS ON REPRESENTATIVE PERSON OR BUSINESS

The Department 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.

REPORTING REQUIREMENT

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

The Department finds that it is necessary for the health, safety, or welfare of the people of this state that proposed sections 70970, 70972, 71565, and 71567, which require a report, apply to businesses.

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 included 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 Safecty 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.[6]

MANDATED USE OF SPECIFIC TECHNOLOGIES, EQUIPMENT, ACTIONS, OR PROCEDURES

The Department developed an electronic web-based portal (portal) for reporting of AEs, which is available on the Department's website and 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, improvement in hospital patient safety.

In considering the use of a performance-based standard 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.

ALTERNATIVES CONSIDERED

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.

[6] Health and Safety Code §124840.

TECHNICAL, THERETICAL, AND/OR EMPIRICAL STUDIES, REPORTS OR DOCUMENTS RELIED UPON

1. ADA Amendments Act of 2008 (ADAAA). Retrieved from: http://www.eeoc.gov/laws/statutes/adaaa_notice.cfm.

2. AHRQ Agency for Healthcare Research and Quality, *Patient Safety Primers Root Cause Analysis, (Pages 1-3)*. Retrieved from: http://psnet.ahrq.gov/primer.aspx?primerID=10.

3. 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/

4. *ASA Physical Status (PS) Classification System from the American Society of Anesthesiologists*. Retrieved from: http://my.clevelandclinic.org/health/treatments_and_procedures/hic_ASA_Physical_Classification_System.

5. Business and Professions Code, §2216.3.

6. California Hospital Association (2012). *Hospitals called on to participate in event and reporting project*. Retrieved from: http://www.calhospital.org/general-information/hospitals-called-participate-event-and-reporting-project.

7. The Centers for Disease Control and Prevention. *Preventing Sexual Violence 2019*. Retrieved from: https://www.cdc.gov/violenceprevention/pdf/SV-Factsheet.pdf

8. New Online California Healthcare Event and Reporting Tool (CalHEART) Retrieved from: https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/AFL-13-12.aspx

9. *Outpatient Settings Adverse Event Reporting Requirements and Adverse Events.* Retrieved from: https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/AFL-12-26.aspx https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/AFL-12-26-Attachment-01.aspx

10. Medical Board of California, Rev. 2019. *Form: Adverse Event Reporting Form for Accredited Outpatient Surgery Settings.* Retrieved from: http://www.mbc.ca.gov/Consumers/Outpatient_Surgery/outpatient_adverse_event_form.pdf

11. Health-Associated Infections Advisory Committee Meeting (August 9, 2018). Meeting Summary. Retrieved from: https://www.cdph.ca.gov/Programs/CHCQ/HAI/CDPH%20Document%20Library/HAIACMtgSummary080918_ApprovedFinalADA.pdf

12. Health Insurance Portability and Accountability Act, HIPAA. Retrieved from: https://www.dhcs.ca.gov/formsandpubs/laws/hipaa/Pages/1.10HIPAATitleInformation.aspx

13. Hyacinthe v. United States, 2009 U.S. Dist. LEXIS 108192 (E.D.N.Y. Nov. 19, 2009). Page 6-13 Retrieved from: https://www.govinfo.gov/content/pkg/USCOURTS-nynd-1_08-cv-00744/pdf/USCOURTS-nynd-1_08-cv-00744-0.pdf

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15. Kohn, L.T., Corrigan, J.M., Donaldson, M.S. (Institute of Medicine) *To Err is Human: building a safer health system*. Washington, D.C.: National Academy Press, 2000. Retrieved from: https://www.ncbi.nlm.nih.gov/pubmed/25077248

16. Levinson, D.R. Department of Health and Human Services, Office of Inspector General (2008). Retrieved from: Adverse Events in Hospitals: State Reporting Systems (OEI-06-07=00471).

17. Levinson, D.R. Department of Health and Human Services, Office of Inspector General (2010). *Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries* (OEI-06-09-00090). Retrieved from: https://oig.hhs.gov/oei/reports/oei-06-09-00090.pdf

18. National Association for Healthcare Quality, *Call to Action Safeguarding the Integrity of Healthcare Quality and Safety Systems.* October 2012. Retrieved from: http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.592.4637&rep=rep1&type=pdf

19. National Association for Healthcare Quality, *Call to Action Enhancing Health Care Quality and Patient Safety*. October 6, 2012. Retrieved from: https://www.prnewswire.com/news-releases/national-association-for-healthcare-quality-nahq-issues-call-to-action-for-enhancing-health-care-quality-and-patient-safety-174423331.html.

20. National Coordinating Council for Medication Error Reporting and Prevention (2011). Retrieved from: http://www.ihi.org/resources/Pages/OtherWebsites/NCCMERP.aspx.

21. California Penal Code Sections 240, 243(f)(4), and 277. Retrieved from: http://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?lawCode=PEN&sectionNum=240. http://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?lawCode=PEN&sectionNum=243. http://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?lawCode=PEN&sectionNum=277.

22. The National Institutes of Health-Center for Complementary and Alternative Medicine. (2009). *Spinal Manipulation*. Retrieved from: http://nccam.nih.gov/health/pain/spinemanipulation.htm.

23. The National Pressure Ulcer Advisory Panel (2016). *Updated-staging system: Pressure Injury stages revised by NPUA*. Retrieved from: http://www.npuap.org/resources/educational-and-clinical-resources/npuap-pressure-injury-stages/.

24. *The National Quality Forum Serious Reportable Events in Healthcare 2006 Update: A Consensus Report*, Washington, DC, 2007 Page 4. Retrieved from: http://www.qualityforum.org/Publications/2007/03/Serious_Reportable_Events_in_Healthcare–2006_Update.aspx

25. *National Quality Forum Serious Reportable Events in Healthcare-2011 Update: A Consensus Report*, Washington, DC: NQF; 2011 Page B2-B4. Retrieved from: https://www.qualityforum.org/Publications/2011/12/Serious_Reportable_Events_in_Healthcare_2011.aspx

26. Pre-Notice Meeting to Discuss Administrative Penalty and Adverse Events Regulations. November 24, 2010. (Comments attached). Retrieved from: http://www.cdph.ca.gov/programs/LnC/Pages/AP-Pre-Notice-Meeting.aspx.

27. The Patient Safety and Quality Improvement Act of 2005 (Public Law [P.L.] 109-41). Retrieved from: https://www.hhs.gov/hipaa/for-professionals/patient-safety/statute-and-rule/index.html

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30. Zhani, E.E. (2013, October 17). Joint commission alert: Preventing unintended retained foreign objects. *The Joint Commission*. Retrieved from: http://www.marketwired.com/press-release/joint-commission-alert-preventing-retained-surgical-items-1842315.htm

CONTACT PERSON

Inquiries regarding the substance of the proposed regulations described in this notice may be directed to Krisheidy Guerrero, email krisheidy.guerrero@cdph.ca.gov, phone (916) 327-0643. All other inquiries concerning the action described in this notice may be directed to Hannah Strom-Martin, Office of Regulations, phone (916) 440-7371, email hannah.strom-martin@cdph.ca.gov, or to the designated backup contact, Christy Correa, phone (916) 440-7764, email christy.correa@cdph.ca.gov.

AVAILABILITY STATEMENTS

The Department has prepared and has available for public review an initial statement of reasons for the proposed regulations, all the information upon which the proposed regulations are based, and the text of the proposed regulations. The Office of Regulations, at the address previously noted, will be the location of public records, including reports, documentation, and other material related to the proposed regulations.

In order to request that a copy of this public notice, the regulation text, and the initial statement of reasons or alternate formats for these documents be mailed to you, please call (916) 440-7371 (or the California Relay Service at 711), or send an email to regulations@cdph.ca.gov, or write to the Office of Regulations at the address previously noted. Upon specific request, these documents will be made available in Braille, large print, audiocassette, or computer disk.

The full text of any regulation which is changed or modified from the express terms of the proposed action will be made available by the Department's Office of Regulations at least 15 days prior to the date on which the Department adopts, amends, or repeals the resulting regulation.

A copy of the final statement of reasons when prepared will be available upon request from the Office of Regulations.

INTERNET ACCESS

Materials regarding the action described in this notice (including this public notice, the text of the proposed regulations, and the initial statement of reasons) that are available

via the Internet may be accessed at www.cdph.ca.gov and by clicking on the following: Programs, Office of Regulations, and the Proposed Regulations link.