



RON CHAPMAN, MD, MPH
Director

State of California—Health and Human Services Agency
California Department of Public Health



EDMUND G. BROWN JR.
Governor

ACTION: Notice of Proposed Rulemaking
Title 22, California Code of Regulations

SUBJECT: Administrative Penalties – General Acute Care Hospitals, Acute
Psychiatric Hospitals, and Special Hospitals, DPH-09-012

PUBLIC PROCEEDINGS: Notice is hereby given that the California Department of Public Health will conduct written public proceedings 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 this notice.

HEARING: No hearing has been scheduled; however, any interested person or his or her duly authorized representative may request in writing, no later than 15 days prior to the close of the written comment period, a public hearing pursuant to Government Code Section 11346.8. For individuals with disabilities, should a public hearing be scheduled, the Department will provide assistive services such as sign-language interpretation, real-time captioning, note takers, reading or writing assistance, and conversion of written public hearing materials into Braille, large print, audiocassette, or computer disk. Note: The range of assistive services available may be limited if requests are received less than ten business days prior to a public hearing.

To request such services or copies of materials in an alternate format, please write to Coleen Keelan, Office of Regulations, MS 0507, P.O. Box 997377, Sacramento, CA 95899-7377, or call (916) 440-7439, or use the California Relay Service by dialing 711.

WRITTEN COMMENT PERIOD: Any written comments pertaining to these regulations, regardless of the method of transmittal, must be received by the Office of Regulations by 5 p.m. on December 10, 2012, which is hereby designated as the close of the written comment period. Comments received after this date will not be considered timely. Persons wishing to use the California Relay Service may do so at no cost by dialing 711.

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-09-012" in the subject line to facilitate timely identification and review of the comment; or

2. By fax transmission: (916) 440-5747; or
3. By mail to: Office of Regulations, California Department of Public Health, MS 0507, P.O. Box 997377, Sacramento, CA 95899-7377; or hand-delivered to: 1616 Capitol Avenue, Sacramento, CA 95814. It is requested but not required that written comments sent by mail or hand-delivered be submitted in triplicate.

All comments, including email or fax transmissions, should include the author's name and U.S. Postal Service mailing address in order for the Department to provide copies of any notices for proposed changes to the regulation text on which additional comments may be solicited.

AUTHORITY AND REFERENCE CITATIONS: The Department is proposing to adopt the regulations sections identified under the authority provided in sections 1280.1, 1280.3, 131050, 131051, 131052, and 131200, Health and Safety Code. This proposal implements, interprets, or makes specific section 1280.3, Health and Safety Code.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW: In 2006, in response to concerns that the administrative penalties for hospitals were too low to effectively compel compliance, the Legislature enacted Senate Bill (SB) 1312 (Alquist, Chapter 895, Statutes of 2006) that provided CDPH with a greatly enhanced civil money penalty enforcement system for all acute care settings. The bill allowed CDPH to issue monetary penalties to hospitals for violations of state law requirements, which the Legislature believed would provide incentives for hospitals to attain and maintain regulatory compliance. The original penalties were for violations that were considered to meet the standard for immediate jeopardy as defined in H&SC Section 1280.1. An administrative penalty could have been issued to a hospital for deficiencies constituting immediate jeopardy to the health or safety of a patient in an amount not to exceed \$25,000 per violation. Immediate jeopardy is defined as a situation in which the licensee's noncompliance with one or more requirements of licensure has caused, or is likely to cause, serious injury or death to the patient. Additionally, SB 1312 allowed CDPH, upon the adoption of regulations, to administer an administrative penalty for violations that do not constitute IJ in an amount up to \$17,500 per violation. The bill required CDPH to include the following when developing regulations to establish criteria to assess administrative penalties against hospitals:

- Patient's physical and mental condition.
- Probability and severity of the risk that the violation presents to the patient.
- Actual financial harm to patients, if any.
- Nature, scope, and severity of the violation.
- Facility's history of compliance with related state and federal statutes and regulations.

- Factors beyond the facility's control that restrict the facility's ability to comply with Chapter 2 or the rules and regulations promulgated thereunder.
- Demonstrated willfulness of the violation.
- Extent to which the facility detected the violation and took steps to immediately correct the violation and prevent the violation from occurring.

In 2008, SB 541 (Alquist, Chapter 605, Statutes of 2008) raised the immediate jeopardy penalty for general acute care hospitals (GACHs), acute psychiatric hospitals (APHs), and specialty hospitals (SHs) from a maximum of \$25,000 per violation to a maximum of \$50,000 for the first penalty, a maximum of \$75,000 for the second and up to \$100,000 for the third and subsequent penalty. Hospitals that receive a penalty and then are in substantial compliance with all licensing laws and do not receive any additional penalties for a period of three years will reset fines back to the lowest amount. These new penalties took effect for violations occurring after January 1, 2009. In addition, CDPH must consider all factors and the special circumstances of small and rural hospitals in order to protect access to care in those hospitals.

Following the promulgation and enactment of regulations, SB 541 authorized the increase of administrative penalty amounts levied against GACHs, APHs, and SHs for IJ violations up to \$75,000 for a first IJ violation, up to \$100,000 for a second IJ violation, and up to \$125,000 for the third and every subsequent violation. The provision in Section 1280.3 of the Health and Safety Code also stipulates that any violation that occurs after three years of a previous violation shall be considered the first violation, given that the facility has demonstrated substantial compliance with all state and federal licensing laws and regulations. Accordingly, CDPH must consider all factors and the special circumstances of small and rural hospitals in order to protect access to care in those hospitals.

SB 541 also increased administrative penalties levied against GACHs, APHs, and SHs for non-IJ violations from \$17,500 to up to \$25,000 per violation provided regulations were adopted.

Policy Statement Overview

Problem Statement: The Department cannot assess the increased maximum administrative penalties against a licensee of a general acute care hospital, an acute psychiatric hospital, or a special hospital until regulations are adopted. Health and Safety Code Section 1280.3 authorizes the director of the Department of Public Health (Department) to assess an administrative penalty against a licensee of a general acute care hospital, an acute psychiatric hospital, or a special hospital for a violation of any requirement of licensure. H&SC § 1280.3 (b) also requires the Department to adopt regulations establishing criteria for assessing an administrative penalty against a

hospital and specifically provides eight criteria that must be included in the regulations. The Department is currently authorized to assess administrative penalties for violations that constitute immediate jeopardy under H&SC § 1280.1. When these regulations become effective, the maximum penalties for immediate jeopardy violations will increase and the Department will also be authorized to assess administrative penalties for violations that do not constitute immediate jeopardy.

Objectives (Goal): Broad objectives of this proposed regulatory action are to:

- Implement H&SC Section 1280.3.
- Adopt criteria for assessment of administrative penalties against hospitals for deficiencies that constitute immediate jeopardy, as well as less serious violations that do not constitute immediate jeopardy.
- Establish a procedure for penalty calculation that accounts for all criteria required by law.
- Enforce compliance with the full scope of hospital licensure requirements by assessing civil money penalties for failure to comply with the law.
- Protect the health and safety of hospital patients.

Benefits: Anticipated benefits including non-monetary benefits as a result of this proposed regulatory action will be:

- Improving the health, safety and welfare of California residents while within acute care hospitals by applying stiffer penalties and applying penalties to the less serious violations that affect a patient's health, welfare and or safety.
- More effectively enforce compliance with licensure requirements by increasing the maximum penalties against hospitals for the most serious deficiencies that constitute immediate jeopardy.
- Deter less serious violations that do not constitute immediate jeopardy.
- Promote statewide consistency in assessment of administrative penalties by applying specific criteria to calculate the amount of the penalty.

The Department is prohibited from assessing administrative penalties for minor violations.

Summary of Proposal

The purpose of this regulation is to implement Health & Safety Code Section 1280.3 by introducing the proposed regulation. The standards in these proposed regulations are limited to general acute care hospitals, acute psychiatric hospitals, and specialty hospitals. Existing Department regulations do not address the provisions specified in Health & Safety Code Section 1280.3.

Evaluation as to whether the proposed regulations are inconsistent or incompatible with existing state regulations

The Department evaluated this proposal as to whether the regulations are inconsistent or incompatible with existing state regulations. This evaluation included a review of the Department's existing general regulations and those regulations specific to general acute care hospitals, acute psychiatric hospitals and specialty hospitals. An internet search of other state agency regulations was also performed and it was determined that there were other state regulations that addressed similar subject matter within Health and Safety Code Section's 1278.5, 1280.4, 1280.15, 1317.4 and 1317.6, however this regulation has been specified to identify the guidelines followed within the regulation are in accordance with Health and Safety Code Section 1280.3 in order to avoid any potential conflict in law.

Therefore, the Department has determined that this proposal, if adopted, would not be inconsistent or incompatible with existing state regulations.

This regulation package proposes the adoption of:

Section 70951, to describe the applicability of Article 10 as it pertains to the assessment of hospital administrative penalties. Subdivision (a) states that Article 10 of Chapter 1 of Division 5 of Title 22 CCR applies only to the assessment of administrative penalties issued to general acute care hospitals pursuant to H&SC Section 1280.3. Additional provisions are not necessary for special hospitals because these hospitals are regulated under the general acute care standards in Article 10.

Section 70952, to define terms used in H&SC Section 1280.3 and Article 10. These definitions are necessary to clarify and to ensure consistency in the terminology used in these regulations.

Section 70953, to state that administrative penalties issued pursuant to H&SC Section 1280.3 will be assessed following the procedures set forth in Article 10. It also states that the penalty calculated under Article 10 for any single deficiency will not exceed the penalties specified in statute. This section is necessary to establish procedures for penalty calculation and to make clear that penalties are subject to any applicable statutory maximum.

Section 70954, to specify the criteria for determining an initial penalty. The matrix presented in this section is the tool the penalty assessors will use to arrive at the appropriate initial penalty for a deficiency.

Section 70955, to specify the factors to be considered when adjusting the initial penalty to determine the base penalty. This provision is necessary to specify the factors for adjusting an initial penalty and to provide a consistent basis for raising or lowering the initial penalty.

Section 70956, to define the term “base penalty” as the cumulative adjusted initial penalty as determined under Sections 70954 and 70955. This section is necessary to define the term “base penalty” for further penalty adjustments in Section 70957, and to make clear that the base penalty may exceed the statutory maximum for the purpose of penalty calculation, so long as the final penalty does not exceed the statutory maximum.

Section 70957, to describe two of the eight criteria used to adjust the base penalty in the last step of the penalty calculation leading to the final penalty.

Each adjustment factor is discussed below in related Subdivisions (a) and (b).

Subdivision (a): Immediate correction of the violation. This regulation is necessary to address the statutory mandate of H&SC Section 1280.3 (b)(8) to take into account, among other criteria, the “extent to which the facility detected the violation and took steps to immediately correct the violation and prevent the violation from recurring.”

Subdivision (b)(1) states that the base penalty is adjusted downward by five percent if hospital inspections within the last three years prior to the date of violation indicated no state or federal deficiencies that resulted in patient harm or immediate jeopardy.

Section 70958, to specify how the final penalty is reached and with applied adjustments pursuant to Section 70957, including that the final penalties are never more than the statutory maximums. This section is necessary to make clear how a final penalty is calculated.

Section 70959, to specify how administrative penalties are assessed for a violation of Hospital Fair Pricing Policies Requirements. The laws regulating hospital fair pricing policies for discount payment and charity care (“discount and charity care policy laws”) were enacted in 2006 to protect the financial interests of uninsured and underinsured consumers of healthcare, and are enforced by the Department as conditions of hospital licensure. H&SC Section 1280.3 was amended in 2007 to authorize the Department to assess administrative penalties for these violations.

Section 70960, to specify the considerations made for small and rural hospitals that are assessed an administrative penalty under HSC 1280.3. This section provides an option for a small and rural hospital (as defined in H&SC § 124840) that has been assessed an

administrative penalty to request an extended payment plan, if immediate, full payment of the penalty would cause extreme financial hardship to the hospital. The small and rural hospital may also request reduction of the penalty, if extending the payment over a period of time would cause extreme financial hardship to the hospital. This regulation is necessary to address the statutory mandate of H&SC Section 1280.3 (h) that the Department “take into consideration the special circumstances of small and rural hospitals . . . in order to protect access to quality care in those hospitals,” and to describe a process for the Department to review these special circumstances.

FORMS INCORPORATED BY REFERENCE: N/A

MANDATED BY FEDERAL LAW OR REGULATIONS: N/A

OTHER STATUTORY REQUIREMENTS: N/A

LOCAL MANDATE: The Department has determined that the regulations 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.

FISCAL IMPACT ESTIMATE:

A. Fiscal Effect on Local Government: The Department has determined that there will be local government hospitals affected by this mandate, a total of 32 county hospitals and two city hospitals fall under local government. However, there is no negative fiscal impact to be noted and no related reimbursable cost associated with this requirement as outlined in part 7 (commencing with Section 17500) of division 4 of the Government Code and therefore all costs related to this regulation have been taken into consideration with no change or impact to be reported at this time.

B. Fiscal Effect on State Government: The Department has determined there will not be an increase in costs to State government to implement the regulations. The regulations provide the Department with guidelines and criteria for assessing administrative penalties for both immediate jeopardy and non-immediate jeopardy violations to be levied against General Acute Care Hospitals (GACH's), Acute Psychiatric Hospitals (APH's), and Specialty Hospitals (SH's). The Department has established an electronic standardized working tool that will automatically calculate the appropriate amount of an administrative penalty based on the findings of a facility survey or complaint investigation using the criteria in the regulations. Use of the tool diminishes the increased workload that might have been associated with manually calculating and issuing APs in accordance with the guidelines of the proposed regulations.

In order to reach this conclusion the Department had existing staff to test the tool for impact to workload, using historical data from previously issued violations that would fall within the category of being issued an administrative penalty under the proposed regulations.

Increased administrative penalties will be issued and potentially collected by the proposed regulations as a result of the issuance of monetary penalties for violations that are at a severity level of less than an immediate jeopardy to patients.

C. Other Nondiscretionary Cost or Savings Imposed on Local Agencies: There are no known nondiscretionary costs or savings imposed on local agencies related to this regulation.

D. Fiscal Effect on Federal Funding of State Programs: There is no known impact on federally funded programs related to the promulgation of this regulation.

HOUSING COSTS: The Department has determined that the regulations will have no impact on housing costs.

SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS, INCLUDING ABILITY TO COMPETE: CDPH has determined that the proposed regulatory action would have an adverse economic impact on California business enterprises. However, it should be noted that only in the event that a GACH, APH or SH is in violation of the licensing standards, where the violation resulted in more than the potential for minimal harm to a patient(s) will they be subject to receiving an administrative penalty for an immediate jeopardy or a non-immediate jeopardy type violation. Therefore, only hospitals that are in noncompliance with licensure requirements stand to be negatively impacted by a proposed administrative penalty. Hospitals who maintain the required licensure standards and are in good standing with both state and federal requirements will not be negatively affected by this mandate and not be subject to financial penalties.

The final amount of the penalty levied against a hospital will be dependent on the number of occurrences and the scope and severity of their actions. The greater degree of harm and number of times a penalty has been repeated would yield a higher penalty amount.

It is not anticipated that this mandate will affect the ability of California businesses (hospitals) to compete with businesses in other states.

RESULTS OF ECONOMIC IMPACT ANALYSIS:

1. **The creation or elimination of jobs within the State of California.** This proposal will not result in any increase or elimination of jobs within California.
2. **The creation of new businesses or the elimination of existing businesses**

- within the State of California.** This proposal will not have any impact and/or effect on the creation or elimination of new business within the State of California.
3. **The expansion of businesses currently doing business within the State of California.** This proposal will not have any effect on how business is impacted within the State of California.
 4. **The benefits of the regulation to the health and welfare of California residents, and increases worker safety.** This proposal was introduced to effectively enforce compliance with licensure requirements by increasing the maximum penalties against hospitals for the most serious deficiencies that constitute immediate jeopardy, and to deter less serious violations that do not constitute immediate jeopardy. At the same time, the regulations promote statewide consistency in assessment of administrative penalties by applying specific criteria by which to calculate the amount of the penalty, and finally the main benefit is aimed at improving the health, safety and welfare of California residents while within acute care hospitals by applying stiffer penalties and applying penalties to the less serious violations that effect a patient's health, welfare and or safety.

COST IMPACTS ON REPRESENTATIVE PERSON OR BUSINESS: The Department estimates that approximately 435 General Acute Care Hospitals, 138 APH's, and one SH will be impacted by this mandate. The Department is unable to determine the impact on hospitals as it is impossible to speculate who will be in violation and what the resulting penalty would be. However, the Department did assess last year's administrative penalties using the new criteria and regulatory process to review the penalty outcomes and detriment to those affected. It was also noted that there would be an increase in cost related to the non-IJ administrative penalty, which prior to implementing 1280.3, hospitals did not receive an administrative penalty and will now be assessed a penalty up to the maximum amount of \$25,000. The penalty will depend on the scope and severity of the situation and can be reduced depending on the circumstances affecting the situation. It should be noted that only in the event a hospital is in violation of licensing standards where the violation is not a minor violation will they be subject to receiving an administrative penalty of any kind (except for violations of the Fair Pricing Policies requirements). Hospitals compliant with statutory and regulatory requirements will not be subject to any penalty process and there would be no financial effects associated with this regulatory process. The Legislature's goal was to increase the maximum penalty amount and subject the deficiencies to an administrative penalty in the hope that the hospitals will make additional efforts to be in compliance assuring those within their care a safer and harm free environment.

The immediate jeopardy penalty maximum will be increased by \$25,000 for first, second, third and consecutive penalties following promulgation of the regulations. The maximum penalty amounts will be assessed without consideration of other factors when an immediate jeopardy violation results in death to a patient. In other instances when a violation does not result in death to a patient, application of statutory-specific criteria

could result in a hospital's administrative penalty being issued for less than the maximum penalty amount.

The Department has determined that there will be no costs for individuals.

BUSINESS REPORT: N/A

SMALL BUSINESS: The Department has determined that there will be an effect on small business (hospital), since all GACHs, APHs & SHs fall under the regulation parameters despite their size and or location. However, the Legislature did include specific guidelines and considerations to be included within the regulation to provide appropriate consideration and exceptions for the small and rural hospital community to be used when being assessed an administrative penalty in order to prevent any possible excessive financial burden that may cause the hospital to go out of business. The guidelines include alternatives that provide the Department with the option of reducing the final penalty amount to avoid possible closure of a facility due to creating excessive financial burden, and by providing a period of time with which to make payments for any penalty that cannot be paid upon receipt.

ALTERNATIVES STATEMENT: In accordance with Government Code Section 11346.5(a)(13), the Department must determine that no reasonable alternative considered by the Department or that has otherwise been identified and brought to the attention of the Department would be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposed action or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

CONTACT PERSON: Inquiries regarding the substance of the proposed regulations described in this notice may be directed to Debby Rogers or Pam Dickfoss of the Center for Healthcare Quality, at (916) 324-6630.

All other inquiries concerning the action described in this notice may be directed to Coleen Keelan, Office of Regulations, at (916) 440-7439, or to the designated backup contact person, Alana McKinzie at (916) 440-7689.

In any inquiries or written comments, please identify the action by using the Department regulation package identifier, DPH-09-012.

AVAILABILITY OF STATEMENT OF REASONS, TEXT OF PROPOSED REGULATIONS AND RULEMAKING FILE: 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, 1616 Capitol Avenue, Sacramento, CA 95814, will be the location of public records, including reports, documentation, and other material related to the proposed regulations (rulemaking file).

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) 440-7683 (or the California Relay Service at 711), 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.

AVAILABILITY OF CHANGED OR MODIFIED TEXT: 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.

AVAILABILITY OF FINAL STATEMENT OF REASONS: A copy of the final statement of reasons (when prepared) will be available upon request from the Office of Regulations.

AVAILABILITY OF DOCUMENTS ON THE INTERNET: Materials regarding the action described in this notice (including this public notice, the regulation text, and the initial statement of reasons) that are available via the Internet may be accessed at www.cdph.ca.gov by clicking on these links, in the following order: Decisions Pending and Opportunity for Public Participation, Regulations, Proposed.

CALIFORNIA DEPARTMENT OF PUBLIC HEALTH

A handwritten signature in black ink, appearing to read "Ron Chapman", is written over a faint, circular official seal of the California Department of Public Health.

Date: 10/9/12

Ron Chapman, MD, MPH
Director