FINAL STATEMENT OF REASONS

The information contained in the Initial Statement of Reasons (ISOR) at the time of Public Notice remains unchanged with the exception of the following modifications.

Section 70952. Definitions.

Paragraph (a)(5).
In response to a suggestion received during the 45-day comment period, a nonsubstantative change has been made by removing the second use of the word "violations" within this subsection as it was determined to be superfluous and is deleted for clarity reasons.

Section 70954. Determining the Initial Penalty for Each Violation.

Subsection (c).
The California Department of Public Health (Department) received and considered many comments during the initial 45-day comment period that suggested the "extent" of a noncompliance within the original matrix was too vague. Commenters were concerned that the original regulation text would not be conducive to consistent application within the acute care environment.

In revising subsection (c), the Department considered the concerns of the commenters and replaced the extent of noncompliance matrix and criteria originally proposed with the Scope and Severity Matrix and the respective criteria as set forth in the revised regulation text. As part of the revision, the Department proposes eliminating the categories for extent of noncompliance – major, moderate, and minimal – and integrating the scope of the noncompliance. The scope of noncompliance matrix focuses primarily on whether the noncompliance is isolated, part of a pattern, or a widespread occurrence. Whereas the original regulation proposed would assess the extent to which a hospital deviated from hospital licensure requirements, the revised regulation is based on measuring the scope to which the patients have been affected by, or the number of staff or locations involved in the noncompliance.

The Department believes that assessing the scope of the noncompliance ensures a more objective determination of the seriousness of violations. Furthermore, the

underlying elements of the Scope and Severity Matrix are modeled on the federal long-term care assessment matrix used by the Centers for Medicare and Medicaid Services (CMS), which is familiar to many in the healthcare industry, including all California hospitals that operate distinct part skilled nursing facilities on their hospital license. The CMS assessment matrix is found in the CMS State Operations Manual (SOM), which applies nationwide to all long-term care facilities that participate in Medicare. The scope of noncompliance is comprised of three levels within the assessment matrix that are to be taken into consideration in determining if a violation is "isolated," a "pattern," or is "widespread."

To promote more consistent application of civil money penalties as a federal enforcement remedy, CMS developed a Civil Money Penalty (CMP) Analytic Tool that provides a logic structure, and defined factors for mandatory consideration in the determination of CMPs. The tool includes a worksheet with CMP grids based on the CMS scope and severity matrix. To calculate a penalty, the tool starts with a base amount based on the CMS scope and severity matrix, but it also includes additional amounts that are added to the base amount for repeat deficiencies, culpability, and history of noncompliance.

In subparagraph (c)(2)(A), the revised proposed regulations detail what constitutes an isolated noncompliance. The criteria include the extent to which a patient has been affected, whether such violation impacts "one or a very limited number of patients," or "one or a very limited number of staff involved," or the violation "occurred only occasionally," or the violation "occurred in a very limited number of locations." Similarly, subparagraph (c)(2)(B) defines a pattern of noncompliance as situations in which either: "more than a very limited number of patients" have been affected, "more than a very limited number of staff" are involved, the violation "occurred in several locations," or the "same patients had been affected by repeat occurrences" of the noncompliance. As provided in subparagraph (c)(2)(C), a violation shall be deemed widespread if it is either "pervasive throughout the hospital," or it represents a "systemic failure that affected or had the potential to affect a large portion or all of the hospital's patients."

In determining the appropriate scope level, the Department will evaluate, on a case-by-case basis, a violation in a manner similar to the federal guidelines. For example, if the hospital lacks a system or policy (or has an inadequate system) in place to meet the requirements and this failure has the potential to affect a large number of patients in the hospital, then the deficient practice is likely to be widespread. Similarly, if an adequate system or policy is in place but is being inadequately implemented in certain instances, or if there is an inadequate system with the potential to impact only a subset of the hospital's patients, then the violation is likely to be pattern. Furthermore, if the deficiency

affects or has the potential to affect one or a very limited number of patients, then the scope is to be considered isolated.

In developing these criteria, the Department modeled the Scope and Severity Matrix extensively on the federal CMS assessment matrix, which evaluates each violation on a case-by-case basis. The CMS assessment matrix provides guidance on scope levels and defines the concepts of isolated, pattern and widespread in essentially the same manner. In part, the Department has incorporated these scope levels in this way so that they will be familiar to the Department's surveyors.

The CMS SOM, which is applied nationally, includes the three scope levels proposed in the Department's regulations – isolated, pattern, and widespread. As provided in the SOM, the "scope levels are defined" as follows:

- "Scope is isolated when one or a very limited number of residents are affected and/or one or a very limited number of staff are involved, and/or the situation has occurred only occasionally or in a very limited number of locations."

- "Scope is a pattern when more than a very limited number of residents are affected, and/or more than a very limited number of staff are involved, and/or the situation has occurred in several locations, and/or the same resident(s) have been affected by repeated occurrences of the same deficient practice. The effect of the deficient practice is not found to be pervasive throughout the facility."

- "Scope is widespread when the problems causing the deficiencies are pervasive in the facility and/or represent a systemic failure that affected or has the potential to affect a large portion or all of the facility's residents. Widespread scope refers to the entire facility population, not a subset of residents or one unit of a facility. In addition, widespread scope may be identified if a systemic failure in the facility (e.g., failure to maintain food at safe temperatures) would be likely to affect a large number of residents and is, therefore, pervasive in the facility."

The Department's intent is to assess the scope level of a noncompliance in a manner that is consistent with the federal assessment process, articulated above. It is the Department's belief that using this model will improve the understanding of the regulation, as well as providing for a uniform penalty assessment process.

Many commenters expressed concern that the scope levels within the scope of noncompliance are vague or subjective. However, the Department believes that the definitions provided in the revised regulation are appropriately detailed. Because the

severity levels are applied to a wide range of violations—patient care, medication management, infection control, physical environment (life safety), patient rights, hospital administration, medical recordkeeping—further definition of this standard could cause confusion and reduce the utility of the Scope and Severity Matrix. The scope of noncompliance has been designed to be used on a case by case basis, in a variety of settings and circumstances and providing more specificity would likely make the Scope and Severity Matrix ineffective and overly complex.

In the assessment of a violation, Department surveyors must take into consideration the specific facts of each case. These variables must be examined in the larger context of each noncompliance, which is a crucial component in determining the appropriate scope level. For example, when assessing an infection control issue, the surveyor will take into consideration the size of the unit under review and the degree to which the infection control issue is prevalent. The surveyor would then check to see if there were similar problems on other units within the hospital in an effort to determine the degree that the problem has been noted throughout the hospital. If infection control issues were noted in one unit in a large hospital, this could be classified as an isolated occurrence. However, further assessment would need to be done before reaching the final scope level. For example, the infection control occurrences may be considered to be isolated to one unit, however, if this situation is an ongoing infection control issue, or consistently happened over a period of time within the one unit, this may be assessed as a pattern instead of an isolated scope level. Department surveyors are well versed in the use of this assessment process, and in fact, provide similar case-by-case assessments under the CMS federal assessment process.

Subparagraphs (A) and (B) include the phrase “a very limited number” as part of the assessment process, which some commenters considered too vague. The Department considered alternative means to more precisely quantify this concept. However, the Department believes that the phrasing of this part of the Scope and Severity Matrix is appropriate in this context. First, as noted previously, these concepts are based on a similar assessment processes used for decades at the federal level. Secondly, “a very limited number” will also vary depending upon the size of the hospital or area in question, and providing an exact numerical threshold in this instance would likely prove counterproductive and ineffectual. For example, a “limited number” would not be the same for a large teaching hospital as it would be for a small or rural hospital with fewer bed and patients. Furthermore, 10 occurrences of an incident may not appear to be widespread in the larger hospital, but could be considered to be widespread within the small or rural hospital. Therefore the Department has determined to leave the isolated, pattern or widespread and the term “a very limited number” as unspecified with no set numerical value. The Department has also determined within the three levels of scope

as defined that there will be enough specificity to apply the penalty assessments consistently and fairly across the board on a case-by-case basis. Each noncompliance scenario will be based upon its individual supporting facts, which will be taken into consideration in order to determine the final level of scope. This is modeled on the federal civil penalty assessment method, which to the Department's knowledge is the only established standardized assessment tool that is used successfully to assess monetary penalties within the healthcare environment.

Similarly, commenters have expressed concern about the vagueness of the terms "pervasive" and "several" as provided in this subsection. As provided in 22 CCR § 70001, "words shall have their usual meaning unless the context or a definition clearly indicates a different meaning." Here, "several" means "being more than two but fewer than many in number or kind." [Dictionary.com <http://dictionary.reference.com/browse/several> [as of Sept. 12, 2013]]. Similarly, "pervasive" is to be understood in the context of its common meaning.

Subsection (d).
A nonsubstantative change has been made and the word "extent" is stricken and replaced with the term "scope" in the first sentence within section (d) to be consistent with the use of "scope" throughout the Scope and Severity Matrix. The word "extent" has also been replaced with the word "scope" throughout the Scope and Severity Matrix, to be consistent with changes made within subsection (c).

Scope and Severity Matrix.

The Department received many comments on the extent of noncompliance matrix originally proposed by the Department. As detailed above, the Department revised the manner in which it proposes to assess penalties, incorporating the scope and severity matrix model. These changes are reflected in the proposed Scope and Severity Matrix. While the various severity levels the Department proposed have not changed, the original matrix's extent model (which included "minimal," "moderate," and "major" violations) has been replaced in the Scope and Severity Matrix with the scope of the noncompliance.

Many commenters offered insights on the Department's penalty percentages for the original matrix. Several suggested that the penalty percentages for the "moderate" and "major" categories were too low for Severity Level 2. Upon review of the allocated percentages for the Scope and Severity Matrix, it was determined that a noncompliance with a Severity Level 2 in what is now proposed to be the "pattern" or a "widespread" degree of scope would result in insufficient penalties. Under the previous proposed

regulations, penalties were being assessed at 35% of $25,000 and 50% of $25,000, respectively, resulting in initial penalties of $8,750 and $12,500.

The Department has reviewed these comments and considered them in the context of the revised Scope and Severity Matrix. In doing so, the Department determined that when there are violations that are considered pattern or widespread, it demonstrates an ongoing and widespread system failure, and thus these levels needed to be assessed at a higher percentage amount to create a more balanced matrix. Another example of this rationale can be found when assessing staffing levels. If a staffing violation occurred and was initially assessed at a Severity Level 2, consideration would be given as to the scope of the violation. Violations found to be a pattern or widespread in scope should be assessed at a higher penalty than initially assigned, as they demonstrate multiple or repeated occurrences of the deficient practice. Therefore, the Department increased both Severity Level 2 violations that fall into either a pattern of scope from 35% to 50%, and the widespread level of scope from 50% to 70%, respectively. This change results in the following increases: From $8,750 to $12,500 and from $12,500 to $17,500. The Department believes these amounts are appropriately higher when there is a pattern or widespread noncompliance by a hospital, given the number of patients that are potentially affected.

Additionally, the Scope and Severity Matrix penalty for Severity Level 1 has been changed. Under the initial matrix, the Department classified the penalty for Severity Level 1 as “minor violation,” which cannot be assessed a penalty. Based on comments, the Department has concluded that this part of the original matrix was confusing and unclear, even though both a Severity Level 1 violation and a “minor violation” were intended to have no penalty assessed under the Scope and Severity Matrix. To remedy this, the Department has simply changed the penalty listed under Severity Level 1 as “no penalty” and added to the bottom of the Scope and Severity Matrix “minor violations” and expressly stated that this level of violation will result in no penalty, as provided by the statute.

Section 70958.1. Penalties Imposed by Department of Managed Health Care.

The Department has added this section of the regulation text based on comments received requesting that the Department make a substantive change to accommodate Health and Safety Code section 1280.6 within this regulation text. This section has been added taking into account this specific Health and Safety Code section, and it requires the Department to take into consideration any provider that may be assessed an administrative penalty for a noncompliance of licensure by the Department of Managed Health Care (DMHC) if at the same time that provider is under investigation by the

Department for the same noncompliance. Under Health and Safety Code section 1280.6, the Department is required to limit a penalty assessment to take into consideration an assessed penalty of DMHC for a similar deficiency. The Department added this section for consistency between Health and Safety Code sections 1280.3 and 1280.6. However, the Department is unaware of a situation arising as contemplated by section 1280.6, and the comments did not describe any scenarios in which the proposed regulation section 70958.1 would be invoked. However, the Department proposes this regulation text should such a situation ever occur.

Section 70959. Penalties for Violations of Hospital Fair Pricing Policies Requirements.

Paragraph (b).
Many comments were received during the 45-day comment period, in strong opposition to the initial penalty amounts set for the Hospital Fair Pricing violations. Many commenters indicated that the proposed penalty of $2,000 for a “major” noncompliance and $1,000 for a “moderate” noncompliance of licensing requirements was insufficient. Those opposed to these amounts provided strong supporting information and examples requesting a significant increase of the penalty amounts outlining the nature and extent of hospitals continuing to violate the hospital fair pricing and charity care laws.

Commenters indicated that some facilities employ harsh practices while seeking to claim reimbursements for hospital billing, including wage garnishments and imperiling a patient’s residence. It was felt that the initial penalty amounts in this section were not high enough to be an effective deterrent as initially implied by the Legislature. Hospital fair pricing and charity care laws have been in place since 2006 to protect the consumer. Violations of these laws can cause considerable harm in the event a patient is unable to take care of their primary needs as a result of being placed into a financial hardship situation. The Department received comments following its 15-day comment period in opposition to the revised amounts, suggesting that such predatory practices are extremely rare in the wake of the 2006 patient protection efforts. However, the Department believes that if such practices are in fact rare, the healthcare providers as an industry would not be negatively impacted by the increased penalties.

Therefore, a substantive change has been made to this subsection. The Department has determined that due to the degree that patients can be, and are being financially harmed when a violation of the fair pricing and charity care laws occur, a significant increase was appropriate. The Department has increased a “major,” initial penalty amount of $2,000 to $25,000 and in section 70959(b)(2) a “moderate” initial penalty amount of $1,000 is increased to $12,500 for a noncompliance of the Hospital Fair

Pricing requirements. The Department believes these amounts are appropriate as the comments detailed the hardships many patients endure in the face of aggressive and improper collection efforts on the part of some hospitals. These increased amounts are intended to be a strong incentive against predatory practices.

An additional nonsubstantive change is made in paragraph (b)(3) which deletes the first use of the word “penalty” in the second sentence, and replaces it with “violation.” The Department had used this word in error and has corrected it with the appropriate word.

Section 70960. Small and Rural Hospitals.

Paragraph (a)
Following comments received during the 45-day comment period, a minor change has been made to delete the word “extreme” in the phrase “extreme financial hardship.” Using the word “extreme” when referring to financial hardship suggests that the hospital would be required to prove that they were experiencing an extreme financial hardship situation and thus setting a higher standard to meet than may be necessary, therefore, the word “extreme” has been removed throughout this section. The Department also believes that differences between an “extreme financial hardship” and simply a “financial hardship” would be difficult to quantify, and such efforts would undermine the intended purpose of offering relief to small and rural hospitals which often operate at a financial disadvantage. Additionally, Subsections (a)(1) and (a)(2) include an additional phrase “or a significant danger of reducing the provision of needed health care services,” based on similar language in Welfare and Institution Code Section 14168.32 (n), relating to fee waivers. This phrase was added to the penalty modification request provisions for clarity reasons, and to allow small and rural hospitals to present evidence of any actual or potential impact to the community in the event the hospital is forced to shut down or reduce essential health care services due to high, unaffordable administrative penalties.

Paragraph (b)
Two nonsubstantive changes are made to paragraph (b). First, in the opening sentence of the paragraph, the word “subdivision” is deleted and replaced with “subsection,” which is done for internal consistency. Secondly, the word “extreme” is deleted from the second sentence for reasons detailed above.

Paragraph (c)
A nonsubstantive change is made to paragraph (c) in which the word “extreme” is deleted from the first sentence. This is done for reasons detailed above.

STATEMENT OF DETERMINATIONS

ALTERNATIVES CONSIDERED

The California Department of Public Health (the Department) has determined 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.

LOCAL MANDATE DETERMINATION

The Department has determined that the proposed regulation amendments will 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.

IMPACT ON BUSINESS

The Department has determined that the proposed regulations would not have any impact and or effect on the creation or elimination of new business within the state of California.

ATTACHMENTS TO THE FINAL STATEMENT OF REASONS

ATTACHMENT 1

Document Relied Upon

The following document was provided in the 15-Day Notice of Public Availability:

State Operations Manual
Appendix P - Survey Protocol for Long Term Care Facilities - Part I (Rev. 42, 04-24-09)
http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_p_ltcf.pdf
Pages 91 – 93: IV. Deficiency Categorization – A, B, C, D; accessed on July 18, 2013.

ADDENDUM II
45-Day Public Notice
Summary of Comments and Responses to Comments Received

Section 1: Definitions Comments

1-1. Comment: Definition of "Actual Financial Harm," Lacks Statutory Authority
"Actual financial harm" is defined in 70952(a)(1) as a "concrete financial loss for medical costs incurred by patient, where the loss was not covered or reimbursed by the health insurance." This definition fails to take into account those individuals who have health insurance but who face high medical costs due to high deductibles, lack of a cap on out of pocket maximum, lack of an annual or lifetime limit on costs, or other exposure to high out of pockets. The definition also fails to take into consideration the collection practices of hospitals, which are precluded under CA law, including garnishing wages, liens on primary residence and interest on hospital debt. These are instances of actual financial harm that are concrete financial loss arising from medical debt. For these reasons, we suggest an alternative definition: Section 70952 (a) (1) "Actual financial harm" means concrete financial loss ~~for medical costs~~ for costs arising from health care incurred by a patient where the loss was not covered or reimbursed by health insurance. Such financial harm shall include costs due to wage garnishment and lien on primary residence that arises from debt to a hospital.
Commenter(s): 48
Department Response: No change is made to accommodate the recommendation for the reason that the California Department of Public Health (Department) does take into consideration concrete financial loss for medical costs incurred by a patient, where the loss was not covered or reimbursed by health insurance. For example, situations such as a high deductible would be taken into consideration in the event the patient is not reimbursed at any time. However, the financial loss is limited to actual medical costs and does not include lost wages or other costs usually recovered under tort law. Under Section 70959 relating to hospital fair pricing policy requirements, variables such as garnishing wages, liens on primary residence, and interest on hospital debt, may be considered in assessment of administrative penalties for violations of collection practice standards (Health and Safety Code Section 127425 (f)(1) and (g)), but not as actual financial harm as defined in Section 70952(a)(1).

1-2. Comment: Proposed §70952(a)(5) defines "repeat deficiencies" as follows: "(5) "Repeat deficiencies" means violations of hospital licensing requirements or federal certification standards in the same or substantially similar regulatory grouping of requirements, which violations are found during an inspection, subsequently corrected, and found again at a subsequent inspection." For the purposes of clarity, we suggest that the second use of the term "violations" be removed from the definition as follows: (5) "Repeat deficiencies" means violations of hospital licensing requirements or federal certification standards in the same or substantially similar regulatory grouping of requirements, which ~~violations~~ are found during an inspection, subsequently corrected, and found again at a subsequent inspection.

Commenter(s): 49
Department Response: The Department has considered the commenters suggestion and made the proposed revision to the regulation text. The Department deleted the second use of the word “violations” as suggested for clarity.

1-3. Comment: More than minimal harm is not defined it appears that any clinical finding could be subjectively viewed as having the potential for meeting this undefined criterion. There needs to be an expanded set of definition of terms, such as: Minimal harm or minimal relationship to patient (Is any harm to patient acceptable?).
Commenter(s): 19, 23, 24, 29, 30, 33, 35, 36, 37, 38, 50, 51, 52, 53, 54, 55, 56, 57, 58, 101
Department Response: No change is made to accommodate the recommendation for the reason that the Department has based the “more than minimal harm” standard on existing federal standards that are described, but not formally defined, under the Centers for Medicare and Medicaid (CMS) State Operations Manual (SOM), specifically Appendix P – Survey Protocol for Long Term Care. These federal standards include guidance of severity levels and are the basis for the proposed terminology. In reviewing a potential violation, State surveyors will be basing their evaluations that relate to minimal harm in the same basic manner that surveyors will be doing in review of potential federal violations. The survey process in which a deficiency has been found to exist proceeds with a determination of the outcome level (severity) and a determination of the number of patients potentially or actually impacted by, or the prevalence of, the deficient practice (scope). These determinations are based on review of evidence, deficiency statements, worksheets, and result of team discussions. The Department may consider evidence from record review, interviews, and/or observations.

1-4. Comment: The proposed regulations improperly define “minor violations” to mean a violation that has only a minimal relationship to the health or safety of hospital patients, through analogy to Health and Safety Code section 1424(i) and California Code of Regulations, Title 22, section 72701. However, the Legislature explicitly chose different language to describe minor violations in Health and Safety Code section 1280.3 than it did when it enacted Health and Safety Code section 1424(i). By doing so, it did not intend to give them the same meaning. CDPH should withdraw its narrow definition of a “minor violation.” The exception for minor violations is not properly defined in the proposed regulations.
Commenter(s): 88, 102
Department Response: No change is made to accommodate the recommendation. The Department agrees that all violations of California Code of Regulations do not lead to a determination of risk to patients. Health and Safety Code section 1280.3 provides for exception from penalty assessment those violations, which are determined to be, “minor violations.” However, Health and Safety Code section 1280.3 does not specifically define the term. For this reason, the Department decided to clarify the statutory language by defining “minor violations” within the proposed regulations. The proposed definition is similar to the standard used by the Department to issue notices of violation without a citation penalty to long-term health care facilities pursuant to Title 22

section 72701 (a)(4), which uses the term “minor violations” that is defined in Health and Safety Code section 1424(i).

1-5. Comment: CDPH should amend proposed subdivision 70951(b) to clarify that immediate jeopardy penalties pursuant to Health and Safety Code section 1280.3 will only be assessed based on incidents occurring on or after the effective date of any implementing regulations: (b) This article applies only to incidents occurring on or after [the effective date of this regulation as determined by OAL]. As to such incidents, the hospital’s compliance history prior to [the effective date of this regulation as determined by OAL], including deficiencies constituting immediate jeopardy, shall not be considered in assessing administrative penalties as provided in this article and under Health and Safety Code section 1280.3 (a) and (b).
Commenter(s): 102
Department Response: No change is made to accommodate the recommendation for the reason that the legislature fully intended for the Department to continue to maintain an ongoing penalty history following promulgation of the regulation. This history provides the department with an important background of a hospitals past adherence to licensing and certification requirements, which would otherwise be lost. Health and Safety Code section 1280.3(e) refers to a point of reference moving forward with regard to individual incidents. The Department does not believe the legislature’s intent was to disregard the hospital history of compliance in this action. Penalties will only be subject to increase upon promulgation of the regulation at which time Health and Safety Code section 1280.1 will no longer be in effect, and will be replaced with 1280.3.

1-6. Comment: *The demonstrated willfulness of the violation.* Proposed Section 70955(e)(4) permits a 10 percent increase of an initial penalty if the deficiency was the result of a willful violation. The definition of “willfulness,” “willfully,” and “willful” proposed by CDPH is based on a criminal statute, Health and Safety Code Section 1248.8, which assesses criminal liability upon an individual acting “willfully” in violation of the outpatient licensure laws. Here, CDPH attempts to assign strict liability upon licensees (hospitals) by *defining a “willful violation*” to mean that the “licensee, through its employees or contractors, willfully commits an act or makes an omission. . .” This definition is in direct conflict with Health and Safety Code Section 1280.3(b)(6), which requires that CDPH consider factors outside the hospital’s control, such as employees acting outside the scope of their employment. CDPH cites *California Association of Health Facilities v. Department of Health Services*, 16 Cal.4th 284 (1997) (*CAHF*) for the proposition that the licensee “must be responsible.” CDPH’s citation to *CAHF* is misplaced as that was a case for declaratory judgment related to the reasonable licensee defense (Health and Safety Code Section 1424) in the state nursing home licensure enforcement system, which is separate from the hospital enforcement system. Moreover, the *CAHF* court acknowledged that “there may be a limitation on the doctrine of non-delegable duties for licensees similar to that found in tort law [for “unusual circumstances” that negate the presumption that the employer had the capacity to control the employee]. . . .” The *CAHF* court declined to address the limits on the doctrine of nondelegable duties in the absence of a specific factual setting.

CHA recommends the proposed paragraph 70952(a)(8) be amended to read: (8) "Willful violation" means that the licensee, ~~through its employees or~~ ~~contractors~~, willfully commits an act or makes an omission ~~with knowledge of the facts~~, ~~which bring the act or omission within the deficiency~~ that is the basis for an administrative penalty.
Commenter(s): 102
Department Response: No change is made to accommodate the recommendation for the reason that the regulation restates the well-established doctrine of nondelegable duties which provides that licensees that operate a hospital "through employees or contractors" are responsible for their employees' conduct in the exercise of the hospital license. The cited California Supreme Court case, *California Association of Health Facilities v. Department of Health Services* (1997) 16 Cal.4th 284, applies this rule to citation penalties for long-term health care facilities licensed by the Department. There is no reason to think that that the court would not similarly apply this doctrine to hospital administrative penalties under Health and Safety Code section 1280.3.

The Court held that the licensee of a nursing home could not avoid vicarious liability for the conduct of its employees/independent contractors who engaged in the operation of the facility. The court held that the "rule of nondelegable duties of licensees" was related to the rule of *respondeat superior* in tort law and that a licensee operating a health facility through employees is responsible to the licensing agency for their employees' conduct. The court stated that if a licensee were not liable for the actions of his independent contractor, effective regulation would be impossible. The licensee could contract away the daily operations of the business to independent contractors and become immune to disciplinary action by the licensing authority. The principle that a licensee will be held liable for the acts of its agents is one that has been applied whether the agent is an independent contractor or an employee. As the Supreme Court explained:

> The rule, akin to the rule of *respondeat superior* in tort law, is that "`"[t]he licensee, if he elects to operate his business through employees[,] *must be responsible* to the licensing authority for their conduct in the exercise of his license...." By virtue of the ownership of a ... license such owner has a responsibility to see to it that the license is not used in violation of law.' " [citations] As we observed: "The settled rule that licensees can be held liable for the acts of their employees comports with the general law governing principal-agent liability. `An agent represents his principal for all purposes within the scope of his actual or ostensible authority....'" (*Id.* at p. 360, citing Civ. Code, § 2330.) . . . The essential justification for this rule is one of ensuring accountability of licensees so as to safeguard the public welfare. (16 Cal.4th 284, 295.)

This commenter's objection to the citation of this case in support of the regulation, and in particular, that a licensee "must be responsible" for employees' actions or omissions in the operation of the hospital, is baseless. The phrase "must be responsible" is a direct quote from case. Although the Court speculated that there may be a limitation on the general principle of nondelegable duties for health facility licensees in unusual circumstances, the Court declined to rule on this question in 1997 and there have been

no cases on point to date. It is beyond the scope of this regulation to establish limitations to the doctrine of nondelegable duties where the courts have declined to do so. The definition of "willful" does not conflict with Health and Safety Code section 1280.3(b)(6), which requires that CDPH consider factors outside the hospital's control, because the adjustment for factors outside the hospital's control is limited to disasters requiring emergency response. In addition to the definition's similarity to Health and Safety Code Section 1248.8 (c) (as noted in the ISOR, the definition of "willful" is also identical to the definition of this term as found in Health and Safety Code section 1290(d), applicable to all health facilities regulated under Health and Safety Code, Division 2, Chapter 2, including hospitals, further demonstrating the appropriateness of the definition in this context.

1-7. Comment: There needs to be some clarification to terms/definitions as they are vague, subjective and then would be difficult to enforce, such as: Beyond the hospital's control, potential harm, extent of noncompliance.
Commenter(s): 101
Department Response: No change is made to accommodate the recommendation for the reason that the Department does not agree that specific clarification is necessary. The term, "factors beyond the hospital's control," as used in the proposed regulatory language creates a criterion that allows for downward adjustment of the final penalty assessment in the event the hospital developed and maintained disaster and emergency programs as required by state and federal law that were appropriately implemented during a disaster (See Comment 2-25). The term "potential harm" is part of the deficiency severity level determination and is to be understood in the plain meaning of the term. Assessment of the severity level will depend on the factual and regulatory findings of the deficiency which, which will be done on a case-by-case basis. To determine the level of severity based on potential harm, CDPH considers the patient's physical and mental condition, as well as the probability and severity of the risk that the violation presents to patients, both criteria derived from Health and Safety Code section 1280.3. There should also be consideration of potential for harm to other patients by the cited deficient practice. The Department would base the final determination of potential for harm on an evaluation of the hospital's noncompliance in relation to the nature, scope and severity of the violations, the patient's physical condition and known (or could be expected to be known) risks, and the severity and probability of an adverse outcome to the patient. The term, "extent of noncompliance," has been changed to "scope of noncompliance." The term "scope of noncompliance" is used here to mirror the CMS scope standards set forth at the federal level for the survey of long-term care facilities and is used as part of the determination of prevalence of the hospital's noncompliance from the licensure requirement. For "scope of noncompliance," CDPH evaluates the deficiency to determine the number of patients potentially or actually impacted by, or the prevalence of, the deficient practice (scope).

1-8. Comment: There needs to be expanded definitions that include examples or process for how to determine if a violation has occurred, such as: Willful violation (How is that determined and by whom?)
Commenter(s): 101

Department Response: Although no change is made to the regulation to accommodate the recommendation, the Final Statement of Reasons discusses some examples showing the application of a regulatory standard to specific fact situations. Examples of "willful" violations are found in Health and Safety Code section 1424(f)(2), which defines "willful material falsification," as "any entry in the patient health care record pertaining to the administration of medication, or treatments ordered for the patient, or pertaining to services for the prevention or treatment of decubitus ulcers or contractures, or pertaining to tests and measurements of vital signs, or notations of input and output of fluids, that was made with the knowledge that the records falsely reflect the condition of the resident or the care or services provided," and Health and Safety Code section 1424(f)(3), which defines "willful material omission" as "the willful failure to record any untoward event that has affected the health, safety, or security of the specific patient, and that was omitted with the knowledge that the records falsely reflect the condition of the resident or the care or services provided."

Section 2: Penalty Matrix Process & Final Penalty Assessments Outcomes Comments

2-1. Comment: Commenter is concerned about the proposed complex process being used to assess penalties and the focus being on improving quality through penalties and not on patient care as intended. The calculations for the fines are subjective and complex, resulting in opportunities to misuse the regulations.
Commenter(s): 2, 7, 8, 9, 10, 12, 13, 16, 17, 19, 22, 23, 24, 29, 30, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 87, 89, 90, 92, 93, 94, 95, 96, 103, 106
Department Response: In response to comments that the proposed process to assess penalties was too complicated, the Department has modified the proposed matrix, creating a Scope and Severity Matrix that it believes will enable penalties to be assessed as consistently and objectively as possible, but also without excess complexity. The Department has modeled the Scope and Severity Matrix and corresponding process on the existing penalty matrix developed by CMS. By incorporating these elements into the Scope and Severity Matrix, the Department believes that the affected hospitals will be reasonably familiar with the broader concepts of the regulatory framework as these concepts and the CMS matrix has been used at the federal level for decades. The proposed regulation is a process by which the Department applies the information collected from its investigation of a violation of the licensure requirements to defined criteria to calculate the penalty assessment on a case-by-case basis. Thus, the proposed process provides a logic, structure, and defined factors for consideration in the determination of penalties that will not be too complex for hospitals. Furthermore, in setting the penalty amounts and developing the criteria, the Department followed the requirements in accordance with Health and Safety Code section 1280.3. The Department does not agree that the administrative penalty process takes away from patient safety and care. Rather, the intent of the legislature was to motivate hospitals to focus on providing quality patient care. The administrative penalty process provides a more efficient, more preventive, less draconian protective system to the system of suspending or revoking licenses.

2-2. Comment: Nursing home model assessment tool does not meet the complexity of acute care setting. We are extremely concerned with the proposed regulation's focus on very high monetary penalties to be imposed based upon a model rejected by the California State Legislature. The proposed regulations are modeled on a nursing home system, which is extremely different from the acute psychiatric setting. The California State Legislature was clear in its mandate to model its SB 1312 general acute care regulation on eight statutory criteria and specifically chose not to adopt the federal nursing home enforcement system's scope and severity grid. Therefore, the nursing home grid proposed by CDPH meets neither the letter nor the spirit of SB 1312, which mandates the criteria for assessing administrative penalties. These regulations add layers of ambiguity that will only increase penalties without augmenting quality and safety. Regulations do not meet the Legislators mandated 8 criteria for penalty assessment.
Commenter(s): 4, 5, 6, 11, 14, 15, 18, 25, 26, 27, 28, 31, 74, 78, 79, 80, 81, 82, 83, 84, 85, 86, 88, 104
Department Response: The Department believes that the proposed regulations are consistent with the statute and therefore no change is made. While it is true that an acute care setting and a nursing home setting are both unique, the broader goal of the Scope and Severity Matrix is to assess penalties for patient harms other than immediate jeopardy (IJ). The Department believes that the framework of the Scope and Severity Matrix is broad enough to be applied to most any patient care setting, including an acute care setting, and is consistent with the legislatively mandated criteria for penalty assessment. In its methodology to calculate administrative penalties, CDPH factored in the eight criteria in Health and Safety Code section 1280.3. The severity of the harm to a patient and the prevalence of a noncompliance practice are important determinants that are equally applicable across health care settings. Furthermore, the statute provides authority to assess penalties “for a deficiency constituting an IJ violation as determined by the department *up* to a maximum” penalty. (Emphasis added). The implicit meaning of this provision is that the legislature authorized the Department to develop a scale for various penalties, based on the severity of the noncompliance. Furthermore, that the legislature did not look to federal law specifically in requiring the Department to develop these regulations is irrelevant; the legislature was clear in authorizing the Department to implement a regulatory framework and provided that the Department shall “have full discretion to consider all factors when determining the amount of an administrative penalty pursuant to this section.”

2-3. Comment: Actual Financial Harm - Patient cost sharing due to preventable readmissions, hospital-acquired infections, and longer stays due to preventable complications are some examples of actual financial harm to patients due to the failure of hospitals to comply with California laws and regulations. If Medicare has reduced payment to three quarters of hospitals for such preventable errors, then surely consumers should not face actual financial harm from such errors. Yet nowhere in the regulations is actual financial harm contemplated. This is not consistent with the statute, which requires the Department to take into account actual financial harm.
Commenter(s): 99, 100

Department Response: No change is made to accommodate the recommendation for the reason that the proposed regulations do contemplate actual financial harm. Actual financial harm is defined as a concrete financial loss for medical costs incurred by a patient, where the loss was not covered or reimbursed by health insurance. Under these proposed regulations, the financial loss is limited to medical costs and does not include lost wages or other costs usually recovered under tort law, because medical costs have a more direct relationship to the violation that is the subject of the administrative penalty and are not dependent on variables, such as whether or not the patient was employed. The Department believes this is consistent with the statutory purpose of administrative penalties, which is to enforce compliance with licensing requirements. Such a definition clarifies that medical costs that are covered or reimbursed by a patient's health insurance do not result in actual financial harm to the patient, to the extent that the insurance covered the medical bills. The plain language meaning of "actual financial harm to patients" excludes financial harm to insurance companies that pay the patients' medical bills.

2-4. Comment: The proposed regulations leave several gaps in effectively implementing these fines. They should contain fair and understandable criteria for assessing penalties within the acute care setting not open to the evaluator's very broad interpretation. Fairness and objectivity are not determined in the regulations as currently drafted. Clarity is needed for these criteria as they are definitely open to the evaluator's interpretation and are very broad in nature. Given the complexity of today's healthcare system, it is imperative that the evaluator be objective in their interpretation and enforcement of the regulations. Clarity is also needed for the prevention of evaluator variance and provide assurance of fairness across all facilities in CA.

The proposed regulations give significant consideration to only one criterion enumerated in SB 1312: the nature, scope and severity of the violation. CDPH has virtually ignored the other seven criteria, all of which we believe are relevant to a determination of failure to comply. The regulations require objective, consistent, and measurable criteria to promote patient safety and quality.
Commenter(s): 7, 17, 20, 39, 82, 83, 84, 86, 91, 97
Department Response: No change is made to accommodate the recommendation for the reason that all eight criteria have been incorporated into the regulation matrix and are further explained within the Initial Statement of Reasons. Furthermore, the Department considered giving equal weight to all eight criteria in Health and Safety Code section 1280.3, but this alternative was not chosen because some criteria are given more weight than others with regards to the protection of patient health and safety. For example, the nature, scope, and severity of the violation are deemed to be generally more important to the public health than specific financial harm to patients. Thus, this criterion was weighted more than others. However, all eight criteria are considered under the proposed regulations.

The Scope and Severity Matrix has been designed by the Department to be as clear and fair as possible. While the assessing of penalties as provided for by Health and Safety Code section 1280.3 is inherently complex, the Department believes that the

proposed matrix will allow for the assessment of penalties in a transparent and consistent manner.

2-5. Comment: Concerns with regard to interdepartmental variability between offices and counties in executing this fine structure. The undefined process for CDPH inter-rater reliability does not guarantee the fair and consistent application of such criteria across the state and it is unclear whether final decisions rest with the CDPH central office (HQ) or with each DO.
Commenter(s): 17, 19, 23, 24, 29, 30, 33, 35, 36, 37, 38, 50, 51, 52, 53, 54, 55, 56, 57, 58
Department Response: No change is made to accommodate the recommendation for the reason that after the adoption of these administrative penalty regulations, the Department intends to implement a universal electronic penalty assessment tool that will be used by all District Offices and surveyor staff, on a case-by-case basis, when assessing an administrative penalty within an acute care hospital, which will provide transparency and consistency throughout the state.

2-6. Comment: The 6 level scoring index allows for administrative penalties to be assessed even when there is no finding of immediate jeopardy.
Commenter(s): 19, 23, 24, 29, 30, 33, 35, 36, 37, 38, 50, 51, 52, 53, 54, 55, 56, 57, 58
Department Response: No change is made to accommodate the recommendation for the reason that the Scope and Severity Matrix was created in accordance with the requirements set forth within Health and Safety Code section 1280.3, which authorized and requires the Department to adopt regulations establishing criteria for assessing an administrative penalty against hospital at IJ levels as well as less serious violations that do not constitute immediate jeopardy.

2-7. **Comment**: The proposed regulations allow CDPH to calculate the penalty starting at a dollar amount this is higher than the legislative mandated dollar amount as long as the final penalty does not exceed the dollar amount defined by the Legislator rather than starting with the mandated penalty amounts.
Commenter(s): 19, 23, 24, 29, 30, 33, 35, 36, 37, 38, 50, 51, 52, 53, 54, 55, 56, 57, 58
Department Response: No change is made to accommodate the recommendation for the reason that, while the administrative penalty calculation process does start with a percentage (20%-100%) of the maximum “mandated penalty amounts,” and the calculations may cause the base penalty to be adjusted upwards or downwards, under the proposed regulations the final penalty cannot exceed the statutory maximum. The proposed regulations expressly state this in section 70956 where it states that for the purpose of penalty calculation, “the base penalty may exceed the statutory maximum, so long as the final penalty does not exceed the statutory maximum.” In section 70958, the final penalty is defined as “the cumulative adjusted base penalty as determined under section 70957.”

2-8. Comment: There is no appeals process noted in the regulations (H&S Code 1280.1(b)) is not included.
Commenter(s): 19, 23, 24, 29, 30, 33, 35, 36, 37, 38, 50, 51, 52, 53, 54, 55, 56, 57, 58
Department Response: No change is made to accommodate the recommendation for the reason that the appeals process is identified within Health and Safety Code section 1280.3(f), which states that "[i]f the licensee disputes a determination by the department regarding the alleged deficiency or alleged failure to correct a deficiency, or regarding the reasonableness of the proposed deadline for correction or the amount of the penalty, the licensee may, within 10 working days, request a hearing pursuant to section 131071."

2-9. Comment: For integrated systems, the proposed regulations do not address the balancing of findings and AP against Department of Managed Care investigations and penalties (H&S Code 1280.6)
Commenter(s): 19, 23, 24, 29, 30, 33, 35, 36, 37, 38, 50, 51, 52, 53, 54, 55, 56, 57, 58
Department Response: The Department appreciates the commenter's recommendation and has amended section 70958.1, which accounts for potential penalties assessed by the Department of Managed Health Care.

2-10. Comment: We strongly recommend that Severity Levels 4, 5, and 6 be combined into one category and that the maximum penalty applied, regardless of the extent of noncompliance. We understand that HSC § 1280.3·provides for penalties "up to" $75,000, $100,000, or $125,000, and provides CDPH discretion to consider all factors when determining the penalty amount. That said, immediate jeopardy violations indicate serious noncompliance with the law and put patients' lives at risk. We believe that maximizing penalties for immediate jeopardy violations will capture the spirit of the law, which is to enhance Department enforcement and properly protect patients.
Commenter(s): 49
Department Response: No change is made to accommodate the recommendation for the reason that the various severity levels were created to capture differences in the levels of severity for a violation. While Severity Level 4 and Severity Level 6 are both IJ levels, there is a significant difference in the amount of harm to the patient. In Severity Level 4, for example, the IJ is likely to cause serious injury or death, while Severity Level 6 penalties captures when the harm to the patient leads to death. While these levels of harm are certainly significant and warrant penalties, the Department believes that these levels are distinct enough that different penalty amounts should be assessed.

2-11. Comment: Proposed § 70954(c)(3) states, in part: " ... For requirements with more than one part, the extent of the violation shall be determined based on the most significant requirement. "It is unclear how CDPH would determine which of the parts within a multi-part requirement is "the most significant." Further, situations could arise in which there is minor compliance with the part of the requirement CDPH deems "the most significant," and major noncompliance with one or more of the other parts of the multi-part requirement. Under this provision, the determination of minor noncompliance would supersede major noncompliance with any other violations of the requirement, thereby potentially triggering a lower initial penalty amount.

Commenter(s): 49
Department Response: In response to comment received, the Department has revised the proposed regulatory language by replacing the concept of "extent" with the concept of the "scope" of the deficiency. Therefore, the concern regarding determination of "the most significant" impact has been eliminated. The revised matrix uses the severity of the violation, and takes into account the scope or degree of the hospital's noncompliance with the regulatory requirement and impact on patient outcomes.

2-12. Comment: Hospitals need to understand what they are being measured against.
Commenter(s): 20
Department Response: No change is made to accommodate the recommendation for the reason that hospitals are inspected or surveyed for potential or actual patient harms, and in the event there is a noncompliance the regulation provides an assessment tool by which to calculate an administrative penalty in connection with the violation's nature, scope and severity. The administrative penalty will be based on the scope of the violation – whether it is "isolated," part of a "pattern," or "widespread." The surveyor will on a case-by-case basis, determine through an investigation the severity of the potential or actual harm to the patient. Using these elements, an administrative penalty will be determined using the scope and severity matrix.

2-13. Comment: Only providers with repeat offenses of the same nature should be considered for potential fines.
Commenter(s): 32
Department Response: No change is made to accommodate the recommendation for the reason that the law does not limit the assessment of administrative penalties to repeat offenses. Furthermore, it was the legislature's intent to increase the administrative penalty amounts in an effort to place an added emphasis on patient care and safety goals. Introducing a process that permits hospitals to violate licensing requirements resulting in administrative penalty and have no consequences until they repeat the same violation for a second time would not be in compliance with the law as written in statute.

2-14. Comment: It makes little sense to fine a provider for an error when the probability of potential harm to the safety of the patient is minimal. The potential impact and severity of the errors need to be factored into any determination and assessment of fines.
Commenter(s): 32
Department Response: No change is made to accommodate the recommendation for the reason that the regulation states that, in fact, no penalty will be given for minor violations or violations that reach Severity Level 1. Severity Level 1 violations include instances where there has been no actual harm, but with potential for no more than minimal harm. The nature, scope, and severity of the violation, as well as the probability and severity of the risk that the violation presents to patients, will be considered within the Scope and Severity Matrix.

2-15. Comment: The required self-reporting has occurred and a hospital has in good faith implemented corrective action and has demonstrated that results have been sustained; the penalties do not work to improve quality of care or patient safety.
Commenter(s): 32
Department Response: No change is made to accommodate the recommendation for the reason that the regulation does take into consideration a reduction in penalty in the event a hospital does discover and correct. As provided in section 70957(a), the base penalty is modified when factoring in an immediate correction of the violation. When the Department determines that a hospital subject to an administrative penalty promptly corrects the noncompliance for which the administrative penalty was imposed, the base penalty shall be adjusted downward by 20 percent.

2-16. Comment: A rigorous explication of all of these criteria is particularly important in the acute psychiatric environment. Patients are most often not admitted by choice, but rather, by behavioral and/or dual diagnosis (medical and behavioral). Our patient centered approach entails that we operate within a non-restraint environment.
Commenter(s): 84
Department Response: No change is made to accommodate the recommendation for the reason that the regulation will be applied to the acute psychiatric environment in the same manner as it is applied to other acute care areas, in accordance with applicable regulations, and adjusted according to the nature, scope, and severity of the deficiency on a case-by-case basis.

2-17. Comment: In addition to our need for knowing how we are to be judged when investigations are initiated by CDPH, there is the added dimension presented by the right of patients and their families to request that CDPH launch a complaint investigation. In the acute care setting, such situations are fraught with emotion and we must have a clear understanding of the factors which CDPH will consider in reviewing that complaint.
Commenter(s): 84
Department Response: No change is made to accommodate the recommendation for the reason that this comment does not fall within the scope of the regulation's purpose.

2-18. Comment: We must emphasize we are dealing with non-Immediate Jeopardy situations that are open to subjective surveyor interpretation. These regulations expand beyond immediate jeopardy, which is good, but do not address the day-to-day noncompliance/ratio violations that may not result in patient harm or possibly even immediate jeopardy, but occur with such regularity that those outcomes are very much a potential and at the very least provides poor quality of nursing care to our patients. Ratio violations increase the likely hood of the 'Never Events' healthcare is working so diligently to solve. The routine violation, history of violation, epidemic in acute care hospitals needs to have some penalty for incentive to comply with the law and regulation. The regulations need to focus on daily staffing, along with disasters as they are laid out in this language. Nurse-to-patient ratios as written in Title 22 is a black and white issue, that should be clearly defined in the regulation. If this isn't done than real enforcement will continue to be unachievable. The ambiguity in the language of these

proposed regulations will continue to allow hospitals to avoid taking responsibility for meeting legal requirements, providing adequate staffing, but more importantly protecting patients. Level 2-Does this take into consideration trends or simply individual complaints? All violations, not resulting in an IJ or serious injury, should fall into this category when staffing ratios are violated and no harm should occur when breaking the law.

Staffing Ratios: Lack of Clarity, Lack of Consistency with the statute. Under what circumstances would a violation of the nurse to patient ratios constitute actual or potential patient harm? The proposed regulation lacks clarity in how violations of staffing ratios would be penalized. The proposed regulation is not consistent with the statute since it rests solely on potential patient harm. A complaint about King-Drew medical center (before it was closed) alleged that staffing in the neonatal intensive care was one registered nurse to 18 NICU babies rather than the 1:1 or 1:2 (or 2:1) required under the regulations (as adjusted for acuity). Is that potential patient harm? Is that a major violation? Or, is that an IJ for those severely ill babies? If a hospital litigated an administrative penalty related to staffing ratios, the department might or might not be successful in asserting patient harm, even though it could easily assert "the nature, scope, and severity of the violation".
Commenter(s): 92, 99, 100, 101, 107
Department Response: The Department appreciates the commenter's concerns and has amended the Scope and Severity Matrix to address many of the issues raised. The Scope and Severity Matrix has been modified to include a scope assessment step, and is designed to focus on all related patient care issues, including staffing ratios, within the acute care environment. The Scope and Severity has been designed to be applied across multiple areas of care, on a case-by-case basis, and the Department has added an assessment component to determine whether violations are isolated, a pattern, or widespread, adjusting the penalty accordingly. The Department has developed the Scope and Severity Matrix to be applied as objectively as possible across each district and patient care setting. The application of this objective penalty assessment procedure -- in both the example the commenter provided, or any prospective situation -- will depend on all the facts in the case in determining the specific Severity Level. Furthermore, the Department has increased the penalty percentage for level 2 deficiencies that are found to be pattern and or widespread.

2-19. Comment: Implementation of these regulations should ensure that "potential patient harm" isn't relegated to the "minor violations" category and that the regulations are broad enough to cover issues such as the following examples: 1) State statutes require reporting various data and other information to the department concerning hospital-acquired infections and safety and training programs established by acute care hospitals to prevent them. These are clearly policy priorities established under state law aimed at improving provider prevention activities through public reporting. Yet a direct nexus of failure to accurately report these infections with patient harm is not clearly covered under these administrative fines. 2) Similarly, sanitation standards (e.g. janitorial and food), are meant to protect patient safety and well-being and are essential to preventing hospital-acquired infections. It is not clear what the department would

need to prove in terms of specific patient harm to levy administrative fines for violation of these sanitation standards. 3) Various staffing rules—from qualifications for certain hospital positions, board certifications and nurse-patient staffing ratios-- are embodied in licensing standards and clearly connected to prevention of medical harm. Whether the department would connect failure in these areas as "actual or potential patient harm" under these regulations is unclear.

These and other violations of the statute and regulations might or might not be construed as constituting potential patient harm if litigated: the proposed regulations should be revised so that the administrative penalty is based on the nature, scope and severity of the violation as provided in the statute.
Commenter(s): 97
Department Response: No change is made to accommodate the recommendation for the reason that the proposed regulations address administrative penalties for violation of licensure requirements and use the assessment of the nature, scope, and severity of the noncompliance in the determination of the civil money penalty. The Scope and Severity Matrix's Severity Level 2 is designed to assess penalties for noncompliance in which there is potential for harm, but no actual harm. The Scope and Severity Matrix has been designed to be applied across multiple areas of patient care. The application of this objective penalty assessment procedure -- in the examples the commenter provided, or any prospective situation -- will depend on all the facts in the case in determining the specific Severity Level.

2-20. Comment: Repeat deficiencies' violations that are found during an inspection, corrected but found again ... does this result in penalty?
Commenter(s): 101
Department Response: Repeat deficiencies that are found during an inspection corrected but found again, will result in a penalty, except for those violations that fall under the Minor Violation and Severity Level 1 categories. No change is made to accommodate the comment submitted.

2-21. Comment: Level 1-This is where many violations occur. Nursing staff may avoid immediate jeopardy and patient harm, but not potential or minimal harm, which should still not be acceptable when breaking the law.
Commenter(s): 101
Department Response: No change is made to accommodate the recommendation for the reason that in accordance with Health and Safety Code section 1280.3, the Department is prohibited from assessing administrative penalties for minor violations and the Department further believes that Level 1 violations do not warrant a monetary penalty. However, hospitals that are in noncompliance can still be issued deficiencies for specific violations at this level.

2-22. Comment: While many noncompliance is an isolated incident it is unfortunate that staffing violations come in clusters and are often complicated by other violations. If a hospital has many minor or moderate violations, the cumulative effect of those violations should be considered as a factor in the penalty structure. A hospital with a

violation here or there is likely a very different institution than a hospital with lots of moderate violations. The nature, scope, and severity of the violation depend, in part, on the number of patients affected. These factors also depend on the duration of the violation. Was the hospital in violation over a protracted period of time? The department might find its enforcement capacity enhanced if it looked to the nature, scope, and severity of the violation rather than being forced to determine actual or potential patient harm. Similarly, the definition of "major" violation seems unduly narrow in the context of adverse events and HAIs, particularly given the example the department proposes to enshrine in regulations. If a hospital has a policy in place for reducing HAIs but routinely ignores it, that action would be a "moderate" violation. Yet should routine noncompliance be a moderate violation? If a hospital immediately corrects a violation, not only is the hospital attempting to comply with the law but fewer patients are likely to be affected. If a hospital persists in violating the requirements of law or regulation, the duration of the violation should be reflected in the penalty.
Commenter(s): 99, 100
Department Response: The Department appreciates the commenter's suggestions and has addressed the concerns submitted by amending the original matrix. The revised Scope and Severity Matrix focuses on both the scope and the severity when assessing a penalty. Additionally, the Scope and Severity Matrix has been modified such that a noncompliance will be assessed on a case-by-case basis, factoring in whether the violation is isolated, a pattern or widespread types of events. Taking these and the other factors into account, a penalty will be applied accordingly.

2-23. Comment: The first 2 levels of violation discuss a "potential" for harm with 2 levels identified. That is a discussion which could never be resolved. As for actual injury, our goal as nurses is to prevent additional injury while in our care.
Commenter(s): 101
Department Response: Thank you for your comment. No change is made to accommodate the comment.

2-24. Comment: Number of patients affected, Duration of violation- We suggest that regulations be amended to take into account the number of patients affected. Traditionally it is a unit and not the # of patients that are considered.
The proposed regulations in section 70957 contemplate adjustment to the base penalty if the hospital identified and immediately corrected the noncompliance. This construction assumes that the noncompliance is an isolated event rather than a pattern and practice. Similarly the adjustment upward of five percent for repeat deficiencies seems insufficient to deal with a pattern and practice of noncompliance.
Commenter(s): 99, 100
Department Response: The Department has amended the Scope and Severity Matrix following the commenter's suggestions to include the scope of the deficiency, which has resulted in a more useful tool designed to capture the scope of the violation, whether it be an isolated event, a pattern, or widespread. The Department has also increased the penalty percentage amounts for level 2 deficiencies for pattern and or widespread penalties, which demonstrate system problems rather than isolated issues and should be assessed accordingly.

2-25. Comment: For factors beyond the hospital's control-What does that exactly mean? Does this apply to call-offs (which is often the excuse for noncompliance) as the hospital is supposed to have a staffing plan in place that includes Rapid Deployment of personnel that includes not only staffing needs but also admission and discharges.
Commenter(s): 101,
Department Response: No change has been made to accommodate the comment. The term, "factors beyond the hospital's control," as used in the proposed regulatory language is a criterion that allows for downward adjustment of the final penalty assessment. Health and Safety Code section 1280.3(b)(5) requires the Department to consider factors beyond the hospital's control that restrict the hospital's ability to comply with licensure requirements in Health and Safety Code, Division 2, Chapter 2 and regulations adopted thereunder. Under these circumstances, this regulation provides that the initial penalty shall be adjusted downward by 5 percent, if the hospital developed and maintained disaster and emergency programs as required by state and federal law that were appropriately implemented during a disaster. As stated in the ISOR, this provision is necessary to encourage disaster planning and emergency preparedness by providing a penalty reduction to hospitals that implement appropriate disaster and emergency programs during a disaster or emergency. Additionally, the administrative penalties apply to all relevant violations that fall within the Scope and Severity Matrix, including staffing issues.

2-26. Comment: The commenter has examined these regulations and found two significant overreaching challenges to them: (a) They lack clarity, which will make them difficult for hospitals to comply with; and (b) They unduly narrow the enforcement authority of the California Department of Public Health rendering it virtually impossible for the department to issue violations.
Commenter(s): 101
Department Response: No change is made to accommodate the comment for the reason that the objectives of the proposed regulations are to implement the requirements within Health and Safety Code section 1280.3 and to provide an assessment process when issuing administrative penalties for non-compliance. The regulations do not provide any additional requirements for which hospitals must comply. The Department has amended the proposed regulations to clarify further the use of scope and severity in determining, on a case-by-case basis, any penalties to be assessed. In addition, the revised original matrix has been modified to be even more closely aligned with existing federal regulations. These changes are intended to enhance the clarity of the regulations and their implementation. The Department does not believe that the regulations narrow the Department's ability to issue, after completion of an investigation, a penalty for a violation of a licensing requirement. Under these regulations, the Department does not know of any restriction impeding the issuance of violations.

2-27. Comment: The commenter does not believe that this proposal provides fair criteria for the consistent assessment of administrative penalties. The commenter

therefore requests that CDPH withdraw these regulations and convene stakeholder meetings to develop a better system for assessing administrative penalties.
Commenter(s): 102
Department Response: No change is made to accommodate the recommendation for the reason that the Department did offer many opportunities for stake holders to be involved in the development of the regulation and CHA did in fact submit their input during the open public pre-notice meeting prior to the development of the regulation. All submitted input was taken into consideration. In the course of the development of the proposed regulations the Department has amended the Scope and Severity Matrix in response to the stakeholder input and added a consideration of the scope of the hospital's noncompliance. The Department believes this makes satisfactory use of the criteria in Health and Safety Code section 1280.3.

2-28. Comment: CHA requests that CDPH broaden the perspective from a punitive penalty-based system to one focused on quality of care.
Commenter(s): 102
Department Response: No change is made to accommodate the recommendation for the reason that following the requirements set forth in Health and Safety Code section 1280.3 the Department developed a regulation that satisfied the objectives within the statute. The legislative intent was to drive improvement in health care systems through this initiative. The scope and objectives of these regulations are to adopt criteria for assessment of administrative penalties against hospitals for deficiencies that constitute an IJ as well as less serious violations that do not constitute an IJ, and enforce compliance with the full scope of hospital licensure requirements. The regulation is not intended to provide details on how to provide the necessary patient care but is an administrative penalty assessment procedure in the event of a violation of the hospital licensure requirements. In compliance with licensing requirements, the hospital system should already be focused on the provision of quality care. Pursuant to Health and Safety Code Section 1280 (a), any licensed health facility, including a hospital, may request consulting services from the Department "to assist in the identification or correction of deficiencies or the upgrading of the quality of care provided by the health facility."

2-29. Comment: The proposed regulations focus almost exclusively on financial penalties, and how they will be calculated. Equal attention should be paid to patient outcomes, and developing best practices for system improvements. The AAHSA report recommends enhanced communication among regulators, surveyors, and providers by providing joint education of providers and surveyors to ensure they are all "on the same page." CHA's members have reported that there may not be a common understanding between CDPH and hospitals as to what is expected of hospitals.

The regulations should also detail that the collected penalties will be utilized for quality improvement efforts in hospitals. Health and Safety Code section 1280.15 provides that all penalties collected pursuant to Health and Safety Code sections 1280.1, 1280.3 and 1280.4 shall be deposited into the Internal Departmental Quality Improvement Account and expended, upon appropriation, for quality improvement activities. Despite inquiries,

CHA has not yet been able to ascertain how the funds in the Internal Departmental Quality Improvement Account have been spent, if at all.
Commenter(s): 102
Department Response: No change is made to accommodate the recommendation for the reason that the scope and objectives of this regulation are to 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 an IJ and enforce compliance with the full scope of hospital licensure requirements. The Legislature was explicit in its intent for the Department to implement regulations for the assessment of financial penalties for licensure violations.

The commenter's inquiry as to how the Internal Departmental Quality Improvement Account (IDQIA) is to be utilized by the Department is outside of the scope of this regulation, however, the IDQIA was created to deposit amounts associated with administrative penalties, and the Department has received legislative spending authority for IDQIA funds on a variety of projects. For more information, the commenter may want to submit a formal request to the Department.

2-30. Comment: The proposed regulations are designed around a system and grid used to enforce deficiencies in the long-term care environment, not the acute care environment. CDPH failed to consider whether an enforcement system tailored to a SNF population is appropriate for hospitals. A general acute care hospital often provides acute care in relatively short time frames, which is different from a SNF that typically provides care to most of its patients that can span months or years. Hospitals also treat a wider array of patients, have more acute patients and are more accessible to the public (visitors and patients) than post-acute providers like nursing homes. Hospital-based SNFs typically serve higher acuity patients than freestanding nursing facilities.
Commenter(s): 102
Department Response: No change is made to accommodate the recommendation for the reason that, as provided in the Initial Statement of Reasons, this approach was chosen by the Department because of its similarity to the criteria and the procedures that CMS uses to assess the seriousness of deficiencies prior to assessment of civil money penalties to long-term health care facilities. While the Department agrees that the acute care environment is very different from the nursing home environment, the intent of the statute was to assess penalties for deficiencies and the Scope and Severity Matrix can be applied, on a case-by-case basis, to multiple environments relatively easily. For example, medication errors may occur in both acute care and long-term health care facilities, and such deficiencies can be evaluated for nature, scope and severity, and other factors utilizing the Matrix and the regulations to calculate the administrative penalty.

2-31. Comment: Initial penalty: Results in penalty if loss or impairment lasts for more than 7 days or at time of discharge. If it last 6 days, there is no resulting increase in penalty? Does financial harm include increased length of stay that may not include increased costs to patient?

Commenter(s): 101
Department Response: No change has been made to accommodate the recommendation for the reason that commenter has asked for clarification regarding the initial penalty adjustment factors and not made a comment requesting change. Under section 70955(a), the initial penalty is adjusted upward by 10 percent if certain conditions are met, including if the impairment or loss last more than seven days. If the impairment or loss lasting less than seven days, there is no adjustment to the penalty.

Actual financial harm is defined within the proposed regulation section 70952(a)(1) is limited to concrete financial loss for medical costs incurred by a patient, and does not include lost wages or other consequential financial loss. The criteria for imposing additional penalty amounts based on financial harm are in the proposed regulation section 70955 (a).

2-32. Comment: CDPH should give hospitals an opportunity to correct non-immediate jeopardy deficiencies prior to the imposition of administrative penalties. Any penalty system for non-immediate jeopardy incidents should allow an opportunity to correct or remedy the processes and be used as a learning opportunity.
Commenter(s): 102, 32,
Department Response: No change is made to accommodate the recommendation for the reason that in accordance with Health and Safety Code section 1280.3(b), the Department is required to promulgate regulations to increase Immediate Jeopardy (IJ) administrative penalty fines and introduce penalties for non-IJ administrative penalties. Section 70957(a)(1) provides an opportunity for a reduction in the initial penalty amount in the event the hospital identifies and corrects the noncompliance, including completing a sustainable corrective action within 10 days of the incident. Further, non-IJ deficiencies include actual patient harm, as well as exposure to significant potential harm. The latter, the Department believes is serious enough to warrant a penalty, even if the hospital is able to “correct” the deficiency.

2-33. Comment: In addition, in the federal system, if a facility waives its right to an appeal, any civil monetary penalty is reduced by 35 percent. (Code of Federal Regulations (CFR), Title 42, Section 488.436.)
Commenter(s): 102
Department Response: No change has been made to accommodate the recommendation for the reason that the Department has considered implementing a waiver of appeal and 35% reduction allowance but determined that allowing such an option was outside the Legislature’s intent in passing SB 541.

2-34. Comment: CHA recommends that the current proposed Section 70953 be renumbered subdivision 70953(a) and that the following subdivisions be added to the proposed as follows: Section 70593: (b) The Department shall not assess administrative penalties for deficiencies that do not constitute immediate jeopardy without first granting a hospital an opportunity to correct any deficiencies pursuant to Health and Safety Code section 1280. Hospitals receiving a deficiency of actual harm

or above (severity Level 3 or above) that have received deficiencies of actual harm or above in the past three years shall not be granted an opportunity to correct.
Commenter(s): 102
Department Response: No change is made to accommodate the recommendation for the reason that the Department has already provided an appropriate for penalty reduction in section 70957, which allows for a deduction in the amount of the final administrative penalty in the event the hospital finds and corrects the deficiency prior to the Department discovering the noncompliance. The commenter further suggests that hospitals should receive no penalty at all for non-immediate jeopardy violations at Level 3 [actual patient harm] and Level 2 [potential for more than minimal harm] permitting the appropriate penalty process has been put in place. The Department believes that some penalty assessment is warranted for deficiencies at these levels even if the hospital has maintained a relatively good compliance history.

2-35. Comment: CHA requests that CDPH withdraw the "extent of noncompliance" scale or provide additional guidance regarding how the "extent of noncompliance" scale will be applied after consultation with stakeholders. The proposed regulations also alter the federal nursing home system grid by replacing "scope" with an "extent of noncompliance" scale. The Initial Statement of Reasons provides no rationale for this change. As discussed in detail, the "extent of noncompliance" scale is too vague for consistent application.
Commenter(s): 102
Department Response: The Department partially agrees with the commenter and has amended the regulation by removing "the extent" and replacing with "the scope" of the noncompliance. The department does not agree with the commenter's comment that the "scale is too vague for consistent application." The amended regulation will provide a consistent tool for assessing administrative penalties within the acute care environment.

2-36. Comment: The Initial Statement of Reasons provides no rationale for the weightings in the proposed regulations. CDPH has given no rationale to explain why the specific amounts were chosen: e.g., why all deficiencies in severity-level 6 are marked 100 percent regardless of the extent of the hospital's noncompliance. The percentages developed for adjustment factors are similarly arbitrary.
Commenter(s): 102
Department Response: No change is made to accommodate the recommendation for the reason that the Department disagrees and believes that the percentages of the initial penalty and all adjustment factors considered in assessing the amount of a final penalty constitutes a fair allocation and assessment based on the severity and the scope criteria. The weightings that the Department has proposed use a reasonable scale in which the lowest level of potential harm to a patient results in no penalty, and gradually increases to the maximum level based on actual harm or severity of risk of harm. Actual harm is regarded as more serious than potential harm, as demonstrated by the penalty percentage in Severity Level 3 being higher than the penalty percentage in Severity Level 4. Within each Severity Level, the penalties increase based on whether the scope of the violation is isolated, a pattern, or widespread. Furthermore,

the commenter states that it is unclear why all Level 6 deficiencies (death of the patient) are 100%. It is the Department's belief that the maximum initial penalty is appropriate whenever a patient has died as a result of a hospital's noncompliance.

2-37. Comment: California law requires hospitals to have in place protocols and procedures to minimize hospital-acquired infections and adverse events, preventable medical errors - we looked at the proposed structure of the regulations, we question whether the proposed regulations give the department the enforcement tools necessary to enforce the existing law regarding hospital-acquired infections and adverse events.
Commenter(s): 99, 100
Department Response: No change is made to accommodate the recommendation, as it does not fall within the scope of this regulation. Furthermore, the Department does not agree that the proposed regulations will impact how it enforces current standards.

2-38. Comment: Because the proposed matrix does not properly take into consideration a patient's physical and mental condition, CHA recommends that CDPH withdraw the use of the matrix. However, if CDPH continues to use the matrix, CHA urges CDPH to amend proposed paragraph 70955(a)(1) to provide for an adjustment factor permitting a reduction of the base penalty amount of up to 75 percent depending on the patient's physical and mental condition.
Commenter(s): 102
Department Response: No change is made to accommodate the recommendation for the reason that the Department has thoroughly taken into consideration a patient's physical and mental condition, and believes the patient's physical and/or mental condition, as applied in the Department's survey and investigation process, is appropriately weighted in determining the severity level under Section 70954(b)(2)(A) and in the penalty adjustments of Section 70955(a). In doing so, the Department considerations include how substantial any impairment might be, the loss of bodily function, and the length of time for the impairment. Furthermore, the Department believes that an adjustment of up to 75% would be too substantial, as the assessed penalty would likely lose any relation to the Severity Level at which the penalty was assessed.

2-39. Comment: Proposed Section 70954(b)(2) also states that evaluators should consider the probability and severity of the risk that the violation presents to patients when determining the level of severity. Unfortunately, the proposed regulations similarly provide no flexibility for considering this factor in the assignment of a severity level. This is an important consideration, especially for acute psychiatric hospitals, because many medical decisions involve balancing the probability of benefits and the probability of adverse effects of a given course of action; nearly all medical decisions involve some risk.
Commenter(s): 102
Department Response: No change is made to accommodate the recommendation for the reason that these considerations are required by Health and Safety Code section 1280.3 (b)(2) and will be factored into the penalty assessment by the Department under the regulations.

2-40. Comment: The National Health Service (NHS) in the United Kingdom has recommended a risk matrix for risk managers that may serve as a model for CDPH evaluators in assessing the probability and severity of the risk of a violation. This risk matrix distinguishes between both the probability and severity of risks (i.e., the difference between a one in 100 chance of a less severe outcome and a one in a 1,000 chance of a more severe outcome). CHA recommends CDPH consider the NHS model for assessing the value given to the probability and severity of the risk the violation presents to the patient.
Commenter(s): 102
Department Response: No change is made to accommodate the recommendation for the reason that the Department did research and review the NHS risk management tool. This is not a risk management process in either the investigative process or the penalty phase. Therefore, the Department determined that the chosen penalty process was appropriate to implement Health and Safety Code section 1280.3.

2-41. Comment: Proposed subparagraph 70957(a)(2)(A) should also be amended to permit greater discounting if the violation was isolated, while permitting full assessment of an administrative penalty if the deficiency was a repeat violation, as follows: (A) "The base penalty shall be adjusted downward by 25 ~~five~~ percent if hospital inspections within the last three years noted no state or federal deficiencies that resulted in patient harm or immediate jeopardy deficiencies that resulted in patient harm or immediate jeopardy (Severity Levels 3 through 6, inclusive)"
Commenter(s): 102
Department Response: No change is made to accommodate the recommendation. While the Department agrees it is valuable to incentivize compliance with state and federal laws, it believes that affording a 25 percent adjustment downward is too steep for Severity Levels 3 through 6, as these are instances which include patients that have been severely harmed or have died as a result of hospital noncompliance. Therefore, the Department believes the 5 percent reduction in the relevant section is appropriate.

2-42. Comment: Proposed Section 70955 quizzically permits a five percent reduction of an initial penalty only "if the hospital developed and maintained disaster and emergency programs. . . that were appropriately implemented during a disaster." CDPH gives no rationale as to why this criteria appears to be limited to disaster and emergency situations. Other factors beyond the facility's control may restrict its ability to comply, including the unknown and/or unpredictable actions of third parties. Moreover, a reduction of only five percent is too low. CDPH should comply with Health and Safety Code section 1280.3 to permit a substantial reduction of penalties when a violation arises due to factors beyond the facility's control. Proposed subparagraph 70955(a)(3) should be amended to read: "For factors beyond the hospitals control that restrict the hospital's ability to comply with licensure requirements, the initial penalty may ~~shall~~ be adjusted downward by up to 75 percent.
Commenter(s): 102
Department Response: No change is made to accommodate the recommendation for the reason that the Department interprets the statute's requirement that factors beyond

the hospital's control to be limited to instances in which natural disasters or specified emergencies prevent or impair the hospital's ability to comply with its licensure requirements. Actions of third parties, in particular employees or contractors, do not, in the belief of the Department, equate to factors beyond the hospital's control. Furthermore, as noted above in a similar comment, the Department believes that an adjustment of up to 75 percent exceeds what is reasonable, given the relative severity of the noncompliance.

2-43. Comment: *The extent to which the facility detected the violation and took steps to immediately correct the violation and prevent the violation from recurring.* Proposed subdivision 70957(a) permits a 20 percent reduction of an administrative penalty when the hospital promptly corrects a non-immediate jeopardy deficiency, subject to specific requirements. Under 42 CFR Section 488.438, under analogous circumstances, a federal civil monetary penalty may be reduced by 50 percent. Moreover, this proposed section is far too narrow. Under the federal nursing home system, the state has the option not to issue a civil monetary penalty at all for non-immediate jeopardy deficiencies, except if the facility has had two "actual harm" deficiencies. As discussed above, CDPH should amend its proposed Section 70953 to allow hospitals to have the opportunity to correct violations without the assessment of administrative penalties. CDPH should also amend proposed subdivision 70957(a) to permit a 50 percent reduction in the penalty for non-immediate jeopardy violations that fall outside the exemption proposed by CHA in proposed Section 70953 as is permitted in the federal system pursuant to 42 CFR Section 488.438 as follows:
(1) Immediate correction of the violation. When the department determines that a hospital subject to an administrative penalty promptly corrects the noncompliance for which the administrative penalty was imposed, the base penalty shall be adjusted downward by ~~20~~ 50 percent, provided that all of the following apply . . . .
Commenter(s): 102
Department Response: No change is made to accommodate the recommendation for the reason that it is not consistent with the legislative intent of Health and Safety Code section 1280.3 to allow, as a rule, hospitals to correct violations without assessment of any administrative penalties. Immediate correction of a violation is just one of the eight criteria to assess an administrative penalty (Health and Safety Code section 1280.3 (b)(8)), and should not completely eliminate the penalty as an enforcement option. The Department declines to change the penalty reduction for immediate correction to 50%, because a 20% reduction is a reasonable incentive to encourage hospitals to identify and promptly remedy problems with the provision of quality patient care, and to put system improvements in place to prevent recurrence. Other comments urged elimination of any penalty reduction for immediate correction of violations, and substitution of an increased penalty for failure to immediately correct a violation. Section 70957(a) incorporates a reasonable, balanced approach while preserving the deterrent effect of a money penalty.

2-44. Comment: The proposed regulations combine the worst elements of a penalty system — a scheme that attempts to classify violations using vague elements and a prescriptive method of calculating penalties that is unreasonable, unfair and overly

vague. If CDPH moves forward with the nursing home model, CDPH must clarify these regulations before finalizing them.
Commenter(s): 102
Department Response: The Department has amended the regulations and the original matrix and believes that they provide a logical structure and defined factors for the determination of administrative penalties, on a case-by-case basis.

2-45. Comment: CDPH's proposed subdivision 70952(a)(4) defines the term "minor violation" narrowly by borrowing from the doctrine of "substantial compliance." The proposed rules define a "minor violation" based on whether the violation of law "has only a minimal relationship to the health or safety of hospital patients." The examples provided by CDPH in the Initial Statement of Reasons with respect to this definition reflect the spirit of CHA's intent in advocating for the "minor violation" exception. CDPH then circuitously alters the definition of a "minor violation" in proposed paragraph 70954(b)(1). There, severity level 1, which the Initial Statement of Reasons describes as "for minor violations," is defined as "no actual patient harm but with potential for no more than minimal harm."
Commenter(s): 102
Department Response: In response to the comment, the Department has changed the regulation to correct an inconsistency in the definition of "minor violation" in section 70952(a)(4) and subsequent use of the term in section 70954 to describe Severity Level 1. As amended, Severity Level 1, as defined in 70954(b)(1), does not include the term "minor violations." The department also amended the Scope and Severity Matrix in section 70954(d) by replacing "Minor violation" with "No penalty," and adding a category for "minor violation" at the bottom of the Scope and Severity Matrix. The amended regulation is now consistent with the original definition of "minor violation."

2-46. Comment: The concept of a "potential for no more than minimal harm" arises in the context of "substantial compliance," which uses the "potential for causing minimal harm" as a standard. Health and Safety Code section 1280.3(a) uses the term "substantial compliance" to describe when an immediate jeopardy violation will be considered a first violation for the purposes of determining the penalty amount, but does not define "substantial compliance." The proposed regulations borrow their definition of "substantial compliance" from the federal nursing home system, where "substantial compliance" is used as a standard to define when a nursing home may stay certified and for the cessation of enforcement penalties.

The legislative intent behind SB 1312 was for the term "minor violation" to mean technical violations that do not reasonably lead to a risk of actual harm to patients. Defining a "minor violation" in the context of a "potential for causing no more than minimal harm" is inappropriate because nearly any action or omission by a hospital can have a "potential for causing minimal harm." Even administering an aspirin has potential for causing "minimal harm." CHA requests that CDPH remove the description of Severity Level 1 and replace it with a category for "minor violations." CHA further requests that CDPH replace its definition of "minor violation" with the following: "Minor

violation" means any violation of law relating to the operation or maintenance of a hospital that does not reasonably lead to a risk of actual patient harm.
Commenter(s): 102
Department Response: No change is made to the definition of "minor violation" for the reason that the language proposed by the comment is vague and overbroad. The narrower definition in section 70952(a)(2), a violation that "has only a minimal relationship to the health and safety of hospital patients" is simpler and being more tailored, will direct administrative penalties at violations impacting patient care.
The Department has changed section 70954 to correct an inconsistency between the definition of "minor violation" in section 70952(a)(4) and subsequent use of the term in section 70954 to describe Severity Level 1. As amended, Severity Level 1, as defined in section 70954(b)(1), does not include "minor violations." The department also amended the Scope and Severity Matrix in section 70954(d) by replacing "Minor violation" with "No penalty," and adding a category for "minor violation" at the bottom of the Scope and Severity Matrix. The amended regulation is now consistent with the original definition of "minor violation."

2-47. Comment: The "severity" scale is vague and will lead to inconsistent results. The definition of "immediate jeopardy" is too vague for consistent application. The definition of "immediate jeopardy" in Health and Safety Code section 1280.3 mirrors the definition in federal regulations. However, that term has caused a lot of inconsistency in its application. As noted by a federal administrative law judge, ". . . the determination of whether there was immediate jeopardy requires some prognosticating, some predicting of probabilities . . . reasonable minds can and do differ on issues such as these." CHA recommends that CDPH clarify the definition of the phrase "is likely to cause" within the definition of "immediate jeopardy" to mean "presents an imminent danger or substantial probability that death or serious harm would result therefrom."
Commenter(s): 102
Department Response: No change is made to accommodate the recommendation for the reason that the language proposed by the comment would change the definition of immediate jeopardy as established by Health and Safety Code section 1280.3, which is prohibited under subdivision (d) of that section.

2-48. Comment: Severity Level 2 is described as "no actual patient harm but with potential for more than minimal patient harm, but no immediate jeopardy." Due to the nature of medicine, almost all treatment, including withholding treatment, has some potential for harm. For example, giving a patient an aspirin without a care plan may relieve pain symptoms, but also has a "potential" for causing gastrointestinal bleeding. CHA recommends that CDPH collapse Severity Level 2 into Severity Level 1, i.e., into the category for "minor violations." Deficiencies that fall into what CDPH has proposed as Severity Level 2 should not be assessed administrative penalties.
Commenter(s): 102
Department Response: No change is made to accommodate the recommendation for the reason that the severity levels are designed to cover the full range of actual or potential harm to the patient, even at the level of no more than minimal harm to the patient. Level 2 deficiencies that put patients at risk of more than minimal harm, but

have not caused, or are not likely to cause, serious injury or death, are significant violations that warrant administrative penalties to protect patient health and safety. Assessment of the severity level will depend on the factual and regulatory findings of the deficiency. To determine the level of severity, section 70954(b)(2) also requires consideration of the patient's physical and mental condition, as well as the probability and severity of the risk that the violation presents to patients, both criteria derived from Health and Safety Code section 1280.3. There should be consideration of level of harm, if any, to the affected patient and/or potential for harm to other patients by the cited deficient practice. The Department would base the final determination of potential for harm on an evaluation of the hospital's noncompliance in relation to the nature, scope and severity of the violations, the patient's physical condition and known (or reasonably expected to be known) risks, and the severity and probability of an adverse outcome to the patient.

The comment posed the hypothetical of a patient given an unnecessary drug, aspirin without a care plan. Factors that the Department could consider in evaluating the *nature* of such a deficiency include dose, duration, and adequacy of monitoring for adverse reactions. Other factors could include the extent and seriousness of the hospital's regulatory noncompliance. For example, did the hospital follow policies and procedures on safe medication practices and staff training on safe medication practices? Were the appropriate licensed staff involved in the ordering and the administration of the medication? In evaluating actual or potential patient harm, the Department would consider the physical condition of the patient. For example, did the patient have a condition where the administration of aspirin could be anticipated to cause an adverse effect such as gastrointestinal bleeding or stomach pain? Was the patient taking other drugs where giving aspirin is contraindicated? An elderly patient on an anticoagulants or an antiplatelet drug could be at risk of more than minimal harm, possibly even serious injury, if given aspirin outside of the care plan, whereas a healthy adult may well tolerate an aspirin. The totality of these considerations will be assessed on a case-by-case basis.

2-49. Comment: "Actual patient harm" is neither defined nor limited to physical harm suffered by patients. Severity Level 3 is described as "actual patient harm that is not immediate jeopardy." However, the proposed regulations provide no definition of "actual patient harm." There is no meaningful distinction between "actual patient harm" (Severity Level 3) and "serious injury" (Severity Level 5). CHA recommends that a definition be added to proposed section 70952, as follows: "Actual patient harm" means concrete physical harm incurred by a patient as a result of a deficiency. This clarification will help clarify what constitutes an immediate jeopardy deficiency and what does not. Without clarification, evaluators will be inconsistent as to how they assign severity levels.
Commenter(s): 102
Department Response: No change is made to accommodate the recommendation for the reason that definition of "actual patient harm" recommended by the comment is unnecessary. Section 70954 states that an "initial penalty shall be determined for each deficiency, considering the nature, scope and severity of the deficiency" and "severity of

actual and potential harm to patients shall be considered when using the matrix." It is clear from the context of the regulation that "actual patient harm" refers to harm to the patient as a result of a deficiency. However, "actual patient harm" is not limited to physical harm, because one of the criteria listed in Health and Safety Code section 1280.3(b)(1) is consideration of the "patient's physical and *mental* condition."

2-50. Comment: There is nothing that meaningfully distinguishes between the "potential for more than minimal harm" (Severity Level 2) and the "potential for no more than minimal harm" (Severity Level 1). The proposed regulations do not define "minimal harm." CHA recommends that CDPH withdraw proposed Severity Level 2, by collapsing it into Severity Level 1.
Commenter(s): 102
Department Response: No change is made to accommodate the recommendation for the reason that the severity levels are designed to cover the full range of actual or potential harm to the patient, even at the level of no more than minimal harm to the patient. The severity levels for potential harm range from no more than minimal harm (Level 1) and more than minimal harm (Level 2), to likely to cause serious injury or death (Level 4). Level 2 deficiencies that put patients at risk of more than minimal harm, but have not caused, or are not likely to cause, serious injury or death, are significant violations that warrant administrative penalties to protect patient health and safety. The standard of no more than minimal harm should be understood in its plain meaning using the common ordinary meaning of the words. Because the severity levels are applied to a wide range of violations—patient care, staffing, medication management, infection control, physical environment (life safety), patient rights, hospital administration, medical recordkeeping--further definition of this standard could reduce the overall utility of the Scope and Severity Matrix, without commensurate improvement in clarity.

2-51. Comment: The "scope" scale is ambiguous and will lead to inconsistent results. The proposed regulations do not give sufficient guidance as to the meanings of minor, moderate and major violations. Hospitals cannot tell what it means for an action or inaction to: (1) "deviate[s] somewhat from the requirement," "but not as well as if all provisions had been met," (2) "deviate[s] from the requirement, but. . . compl[y] to some extent, although not all of its important provisions are complied with," or (3) "deviate[s] from the requirement to such an extent that the requirement is completely ignored and none of its provisions are complied with, or the function of the requirement is rendered ineffective because some of its provisions are not complied with." These determinations are completely subjective, leaving far too much room for inconsistency.
Commenter(s): 102
Department Response: In response to comments received the Department modified the original matrix to capture whether a violation is isolated, part of a pattern,, or widespread. The Department agrees that by amending the regulations original draft addresses any ambiguities that were present under the previous draft, which included "minor," "moderate," and "major" elements in the scope and severity matrix. By incorporating a broader sense of the scope of the violation, the Department is confident

that penalties can be assessed consistently across the various districts on a case-by-case basis.

2-52. Comment: The proposed rules do not provide any guidance as to the basis upon which administrative penalties will be assessed. The methodology for calculating violations is important because the assessment of multiple violations for a single practice may have disastrous financial consequences for a hospital, especially since CDPH has proposed such high minimum penalty amounts. For example, the failure of a single nurse to document his/her assessments in three patients' medical records for a period of a month is one violation, not 30 violations for each day of the month and not 90 violations for each patient for each day of the month. [sic]
Commenter(s): 102
Department Response: In response to the commenter's suggestion, as well as other comments the Department has received, the Department has modified the original matrix to capture whether a violation is isolated, part of a pattern of violations, or widespread. Previously, the Department considered whether the violation was minor, moderate, or major. By incorporating the broader scope of the noncompliance, the Department believes assessed penalties will be distributed more fairly. Thus, in the example the commenter provided, the hospital would not be assessed a penalty for each separate violation, but would instead be assessed a single penalty based on the scope of the violation.

2-53. Comment: The proposed regulations should clarify that the counting of immediate jeopardy deficiencies to determine the maximum penalty amount is limited to state immediate jeopardy deficiencies. Health and Safety Code section 1280.3(a) and proposed Section 70954(d) establish increased administrative penalty amounts for subsequent immediate jeopardy deficiencies within a three-year penalty [sic]. However, the failure to clarify that the increased administrative penalty amounts are assessed based only on state immediate jeopardy deficiencies could lead to State evaluators going to a facility, assessing a federal immediate jeopardy deficiency in their federal certification roles, and then switching back to their licensure roles to assess a state immediate jeopardy deficiency for the same incident. In this case, even though the deficiency is a hospital's first immediate jeopardy deficiency, by using both the federal and state enforcement systems, the evaluator could assess increased penalty amounts.
Commenter(s): 102
Department Response: No change is made to accommodate the recommendation for the reason that the statute and regulations are clear that the Department is only authorized to issue penalties for state IJ deficiencies. However, if the noncompliance is a violation of federal law as well, the Department will assess the appropriate penalty as provided by the State statute's authority, irrespective of additional penalties assessed by the federal government.

2-54. Comment: Proposed subdivision 70957(a) provides for a penalty reduction when a hospital immediately corrects a violation. However, subparagraph 70957(a)(1)(C) is vague because not all deficiencies are subject to mandatory reporting requirements. It is also vague as to what it means by "it was identified by the department." CHA

recommends that subparagraph 70957(a)(1)(C) be clarified to read: "If applicable, m~~M~~et mandatory reporting requirements before the violation ~~it~~ was identified by the department during a survey or by means of a complaint lodged by a person other than an official representative of the hospital."
Commenter(s): 102
Department Response: No change is made to accommodate the recommendation for the reason that the regulation as written is sufficiently clear. As the commenter points out, not all deficiencies are subject to mandatory reporting requirements. However, some deficiencies – such as adverse events under Health and Safety Code section 1279.1 – do require reporting by the hospital. Under subparagraph 70957(a)(1)(C), if any reporting requirements are mandatory, the hospital must report the deficiency prior to the Department independently identifying the deficiency.

2-55. Comment: Proposed Section 70960 also requires that hospitals demonstrate "potential severe adverse effects on access to quality care in the hospital." CDPH provides no explanation why it has limited Health and Safety Code section 1280.3(h)'s mandate in this way. CDPH should amend proposed Section 70960 to permit relief for small and rural hospitals simply "in order to protect access to quality care in those hospitals."
Commenter(s): 102
Department Response: No change is made to accommodate the recommendation for the reason that the Department is required by the statute to "take into consideration the special circumstances of small and rural hospitals…in order to protect access to quality care in those hospitals." The implicit rationale for allowing for special considerations for these hospitals is that they provide healthcare for underserved populations without the financial resources of larger hospitals. The regulation provides a means by which small and rural hospitals can continue to provide access to quality care without undue financial hardship. In doing so, the Department reasonably requires the small and rural hospital to demonstrate its financial need. The Department has however, modified the regulation by eliminating the requirement for small and rural hospitals to show "extreme" financial hardship, determining that simply showing financial hardship is sufficient.

2-56. Comment: With these regulations, CDPH has the opportunity to compel adherence to the law by establishing penalties that are high enough to deter violations. As such, we are concerned that the upward penalty adjustments proposed in Section 70955 are too low to influence facility behavior, and do not reflect the potentially severe impact on patients that violations may have. Heightened in light of the proposed 20 percent downward adjustment a hospital may receive for immediate correction that is proposed in Section 70957(a)(1).
Commenter(s): 49
Department Response: No change is made to accommodate the recommendation for the reason that the Department believes the penalties are adequate in relation to their respective scope and severity levels. The Department believes it would be inappropriate to make these penalties excessive and reserves higher penalties only for the most severe instances. While the Department's scope and severity matrix has built in adjustment factors that are designed to encourage hospitals to emphasize patient safety

and quality of care, the Department believes that adjustment factors that are too high or low would no longer allow the penalty to be properly associated with the specific violation.

2-57. Comment: Under what statutory authority does the department propose to reduce the maximum penalty for violations that cause serious injury or are likely to cause serious injury or death? The plain language of the statute treats serious injury and jeopardy that is likely to cause serious injury or death in the same manner as violations that cause death of a patient. Yet the department proposes that a violation that is likely to cause serious injury or death have a maximum penalty of 40%-60% of the penalty for a violation that causes death. This is not consistent with Section 1280.3 (a) or (g). For purposes of penalties imposed under California law, the structure of penalties under federal law is not germane, particularly since in enacting Chapter 895 the Legislature did not look to federal law. If the department wishes to rely on the federal administrative penalty structure, it should seek legislation permitting it to do so. We note that on policy grounds, we would oppose legislation allowing lower penalties for immediate jeopardy for serious injury or lower penalties for immediate jeopardy likely to cause death or serious injury. For both policy reasons and lack of statutory authority, we oppose the proposed diminution of immediate jeopardy violations in the manner proposed by the department.
Commenter(s): 99, 100
Department Response: No change is made to accommodate the recommendation for the reason that the statute clearly provides the Department with the authority to develop these regulations and the means by which penalties are assessed. The statute provides authority to assess penalties "for a deficiency constituting an IJ violation as determined by the department *up* to a maximum" penalty. (Emphasis added). The implicit meaning of this provision is that the legislature authorized the Department to develop a scale for various penalties, based on the severity of the noncompliance. Furthermore, that the legislature did not look to federal law specifically in requiring the Department to develop these regulations is irrelevant; the legislature was clear in authorizing the Department to implement a regulatory framework and provided that the Department shall "have full discretion to consider all factors when determining the amount of an administrative penalty pursuant to this section."

2-58. Comment: We recommend that Section 70957 be deleted and replaced with new language that would solely impose an upward adjustment to the base penalty if it is found that the hospital does NOT immediately correct the noncompliance that led to the violation. Such an amendment would place the right incentive for hospitals that do not take the necessary steps to correct and prevent noncompliance, and would appropriately implement HSC §1280.3(b)(8).
Commenter(s): 49
Department Response: No change is made to accommodate the recommendation though both the commenter's suggestion and the Department's proposed text are designed to incentivize hospitals to immediately correct mistakes. Here, the Department believes that offering a hospital a possible reduction in a penalty would be

an appropriate incentive to safeguard patient safety, rather than providing for an additional penalty.

2-59. Comment: Section 70954 defines the categories for the degree of severity based on actual or potential patient harm. This is not specifically addressed in the statute and should be used with caution so the department's ability to act when patients' safety is at risk is broadened rather than narrowed. Health and Safety Code section 1280.3 directs the department to take into account not only the probability (or potential for harm) and severity of the risk to the patient [(b)(1)] but also the other categories provided for.
Commenter(s): 97
Department Response: No change is made to accommodate the recommendation for the reason that, because the overarching regulatory objective is to protect the health and safety of hospital patients, the severity levels are properly based on factors of actual or potential patient harm. In its methodology to calculate administrative penalties, the Department factored in the eight criteria spelled out in Health and Safety Code section 1280.3.

The proposed severity levels provide a tool to determine the seriousness of identified deficiencies and guide assessment of administrative penalties. Level 5 and Level 6 deficiencies reflect the most serious consequences of noncompliance with licensure requirements, where the deficiency has resulted in serious injury or death. Level 4 deficiencies are nearly as serious, but have not yet resulted in serious injury or death. Although deficiencies classified in Severity Level 4, Level 5, and Level 6 are all categorized as IJs, the result or outcome of the deficiency would determine whether the deficiency falls into one level or another.

2-60. Comment: If a hospital fails to provide adequate nursing staff and expects a surgical nurse to serve as circulating assistant for more than one operating room at a time, is that a "major" violation? This is exactly the type of violation that the department should enforce against and that the intermediate sanctions were intended to give the department the additional enforcement capacity to enforce more effectively.
Commenter(s): 99, 100
Department Response: The Department appreciates the commenter's question. Staffing ratio noncompliance is a violation of a hospital's licensure requirements, and as such may be subject to an administrative penalty under these regulations. In the determination of the appropriate Severity Level and the assessment of a penalty, the Department will consider all of the relevant facts on a case-by-case basis.

2-61. Comment: Initial Penalty Adjustment Factors: Proposed Section 70955
We agree that an initial penalty adjustment based on the patient's condition is appropriate, but believe that the proposed adjustments are unsatisfactory.

We recommend that willful violations, regardless of whether they are initial or repetitive regardless of the severity or noncompliance level, should lead to the maximum fine possible. The proposed regulations assess a mere 10% increase in fines for a willful violation, yet proposes double that - a 20% reduction - in the fine when a hospital

promptly corrects a violation. A willful violation means the hospital commits acts or makes omissions with full knowledge of the facts. When this is the culture of the hospital, it is a clearly among the most egregious of violations of patient safety.

In many instances, noncompliance is an isolated incident, but often violations come in clusters and compound each other. For example, a hospital might fail to report or may under report hospital-acquired infections, may also have severe housekeeping violations that create unsafe conditions under which infections may breed, and may have unqualified staff that are not trained in infection control procedures. These would be multiple violations. The proposed regulations fail to address how the penalty schedule would work in such instances. If a hospital has many minor or moderate violations, the cumulative effect of those violations should be considered as a factor in assessing the scope of the violation and in determining the penalty structure.

The regulations should be adjusted when multiple patients are affected. The nature, scope, and severity of the violation clearly are related to the number of patients affected. These factors also depend on the duration of the violation. Was the hospital in violation over a protracted period of time? The law speaks to “the facility’s history of compliance” and “the extent to which the facility detected the violation and took steps immediately to correct the violation and prevent the violation from recurring”. If a hospital immediately corrects a violation, not only is the hospital attempting to comply with the law but fewer patients are likely to be affected. Conversely, if a hospital persists in violating the requirements of law or regulation, the duration of the violation should be reflected in the penalty.

Section 70957 of the proposed regulations contemplates adjustment to the base penalty if the hospital identified and immediately corrected the noncompliance. This presumably is directed to situations in which noncompliance is an isolated incident, rather than a pattern and practice. But it is unclear that it would be limited to that circumstance. In addition, the adjustment upward of five percent for repeat deficiencies seems insufficient to deal with a pattern and practice of noncompliance.
Commenter(s): 49, 94, 100
Department Response: No change is made to accommodate the recommendation for the reason that the Department believes that the upward adjustment of 10 percent for a willful violation is appropriate. Central to the purpose of the statute is incentivizing hospitals to minimize potential or actual harm to patients, and the penalties are based on those specific levels of potential or actual harm. The Department does not believe that a Severity Level 2 deficiency, for example, which involved no actual harm and only the potential for more than minimal harm, should be given the maximum penalty, even if the violation was willful.

The Department appreciates the commenter’s suggestions regarding multiple violations and the number of patients impacted. As a result, the Department has modified the proposed regulations to incorporate the scope of the violation. Under the revised regulations, violations will be considered in the context of whether they are isolated, part of a pattern, or widespread.

Under the adjustment to the base penalty, if the hospital immediately corrects the violation, irrespective of the scope of the violation, the penalty will be adjusted downward, so long as the conditions of section 70957(a) are met.

2-62. Comment: Section 70954 defines the categories for the degree of severity based on actual or potential patient harm. This is substantially narrower than and not consistent with the statute. Section 1280.3 directs the department to take into account not only the probability and severity of the risk to the patient (b)(1) then lists all 8 criteria to be included. Nowhere in the proposed regulations does the department take into account "the nature, scope and severity of the violation". Instead the proposed regulations limit deficiencies to those instances of "actual or potential patient harm". Yet there are many violations where determining patient harm will be difficult. The statute is not limited to instances of actual or potential patient harm: instead it plainly contemplates that the department will impose intermediate penalties based on "the nature, scope and severity of the violation" as well "actual financial harm". Determining potential patient harm is particularly problematic. The regulations might or might not be construed as constituting potential patient harm if litigated: the proposed regulations should be revised so that the administrative penalty is based on the nature, scope and severity of the violation as provided in the statute.
Commenter(s): 99, 100
Department Response: The Department appreciates the commenter's suggestions and has amended the original matrix to incorporate the scope of the violations. The revised regulations replace the original concept of "minimal," "moderate" and "major" violations and in their place provide for the scope and severity or the noncompliance, measured in terms of whether the violation is isolated, a pattern, or widespread. However, because the overarching regulatory purpose is to protect the health and safety of hospital patients, the severity levels continue to be based on actual or potential patient harm.

2-63. Comment: We do not oppose the adjustment based on patient's condition but suggest that this adjustment alone is not sufficient to address the violations of the law and regulations that do not result in actual patient harm. Second, the proposed adjustment for actual financial harm is not consistent with the statute. A 1% increase in a penalty that is 20% of $25,000 amounts to $50. Yet, the actual financial harm to a patient from a preventable readmission or a longer hospital stay or other care that results in significant out of pocket costs for an insured patient can be significantly in excess of $50. Limiting the adjustment to "information discovered by the department during the normal course of an investigation" has no basis in statute and is contrary to the policy of this Administration enunciated in the Let's Get Healthy California Taskforce report of reducing preventable readmissions and hospital infections. Other instances of actual financial harm have come to our attention in the course of dealing with a particular hospital system that routinely fails to comply with the law on patients that have been stabilized after an emergency. If a patient is admitted to a noncontracting hospital and is exposed to out of network cost sharing, in violation of Section 1262.8, the actual financial harm to the patient may far exceed 1% of the penalty. The statute

contemplates that the penalty shall be based on actual financial harm to the patient, not a small fraction of that amount. Again, this is an example of a violation of existing law that results in patient harm but a very different kind of patient harm than that contemplated in the proposed regulations.
Commenter(s): 99, 100
Department Response: No change is made to accommodate the recommendation for the reason that while the actual financial harm to the patient is a factor the legislature requires the Department to consider, the Department believes that the primary focus for the statute involve serious patient care violations, including IJ violations that cause serious injury or death. While actual financial harm is an important consideration, protecting patients from physical and mental harm is the primary focus of the administrative penalties, particularly for IJ violations. Furthermore, the penalties assessed by the Department for violations that resulted in actual financial harm are not meant to be valued in direct dollar-for-dollar relationship to the actual financial harm experienced by the patient. Rather, these administrative penalties are meant to encourage hospitals to improve patient care and the regulations are to be applied uniformly, regardless of various levels of actual financial harm suffered by patients.

2-64. Comment: The proposed regulation and the Statement of Reasons lack clarity in how common violations of the regulations regarding patient classifications systems would be penalized. The proposed regulation is not consistent with the statute since it rests solely on actual or potential patient harm rather than the nature, scope and severity of the violation. And if a hospital litigated a penalty arising from a violation of the regulations related to patient classification systems, the department would have difficulty demonstrating that the violation of the patient classification regulations constituted potential patient harm, but no difficulty in demonstrating that the patient classification regulations were violated and that the penalty reflected the nature, scope or severity of that violation.
Commenter(s): 99, 100
Department Response: The Department appreciates the commenter's suggestions and has amended the original matrix to incorporate the scope of the violations. The revised regulations replace the original concept of "minimal," "moderate" and "major" violations and in their place provide for the scope and severity or the noncompliance, measured in terms of the whether the violation is isolated, a pattern, or "widespread. However, because the overarching regulatory purpose is to protect the health and safety of hospital patients, the severity levels continue to be based on actual or potential patient harm.

Section 3: Financial Pressure Concerns Comments

3-1. Comment: Commenter objects to the increased penalty amounts and feels this will have not only serious repercussions for the community but will be a serious and unethical proposition for persons in need of mental health treatment.
Commenter(s): 2, 3, 9
Department Response: No change is made to accommodate the recommendation for the reason that the Department is required to adopt criteria in accordance with Health

and Safety Code section 1280.3 for assessing administrative penalties to hospitals for deficiencies identified as a result of case investigation and establish a procedure for penalty calculation that accounts for all criteria required by law. The proposed regulation is a tool by which the Department will assess civil money penalties and only hospitals in noncompliance of the required licensing standards will be affected by this regulation. The commenter does not explain how or why the increased penalty amounts will impact those in need of mental health treatment. However, the assessment process was designed to be applied to a broad spectrum of treatment options, including mental health, and the Department believes these penalties will benefit all patients and quality of care.

3-2. Comment: Commenter is concerned about the fact the Orange County facilities it represents are Disproportionate Share facilities and continue to be challenged on a month to month basis in maintaining financial viability.
Commenter(s): 13
Department Response: No change is made to accommodate the recommendation for the reason that the comment does not fall within the scope of the regulation requirements. This regulation is required by law to establish criteria and create a process that will be utilized to assess administrative penalties, it is also required to increase the IJ penalty amounts, and introduce the non-IJ penalty process. This regulation will only affect hospitals that are in noncompliance of the licensing requirements.

3-3. Comment: Hospitals are facing significant financial pressures, including underpayments by Medi-Cal and Medicare, high levels of uninsured patients, and the costs of complying with the Affordable Care Act and other new laws.
Commenter(s): 2, 7, 8, 9, 10, 12, 13, 16,17, 20, 32., 34, 39, 40, 41, 42, 43, 44, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77,85, 87, 89, 90, 91, 93, 94, 96, 98, 103, 106
Department Response: No change is made to accommodate the recommendation for the reason that the comment does not fall within the scope of the regulation. As already stated, this regulation is required by law to establish criteria and create a process that will be utilized to assess administrative penalties. It is also required to increase the immediate jeopardy penalty amounts, and introduce the non-immediate jeopardy administrative penalty process. The proposed regulation is a tool by which the Department will assess civil money penalties and only hospitals in noncompliance of the required licensing standards will be affected by this regulation.

3-4. Comment: Commenter proposes that the dollars collected in fines should be used to improve patient safety in CA.
Commenter(s): 20
Department Response: No change is made to accommodate the recommendation for the reason that moneys collected by the department as a result of administrative penalties imposed under section and sections 1280.1, 1280.3 and 1280.4 of the Health and Safety Code shall be deposited into the Internal Departmental Quality Improvement Account within the Special Deposit Fund established pursuant to section 1280.15(f).

These moneys shall be tracked and available for expenditure, upon appropriation by the Legislature.

3-5. Comment: We are extremely concerned with the proposed regulation's focus on very high monetary penalties to be imposed based upon a model rejected by the California State Legislature.
Commenter(s): 82
Department Response: No change is made to accommodate the recommendation for the reason that the penalty amounts were set by the Legislature and passed into law when enacting Health and Safety Code section 1280.3. Section 1280.3 requires the Department to develop regulations, which will specifically provide the higher administrative penalty rates to be assigned for immediate jeopardy violations and introduces a non-immediate jeopardy penalty process. The Department researched all possible assessment matrix processes available to them and found that the federal process was the only viable process that could be successfully applied to an administrative penalty process within the acute care environment.

3-6. Comment: In 2011, Sharp General Hospital provided over $103 million in unreimbursed community benefit, the bulk of which was medical care services. This reflects the high rates of unemployment and severe financial strain in the region served by SGH.
Commenter(s): 86
Department Response: No change is made to accommodate the recommendation for the reason that the comment does not fall within the scope of the regulation requirements. This regulation is required by law to establish criteria and create a process that will be utilized to assess administrative penalties within the acute care environment, it is also required to increase the IJ penalty amounts, and introduce the non-IJ penalty process. This regulation will only affect hospitals that are in noncompliance of the licensing requirements.

3-7. Comment: The Hospital’s recent Bad Debt surpasses $25 Million and Charity Care routinely exceeds $3.8 Million. In addition, our hospital is facing significant financial pressures, including underpayments by Medi-Cal and Medicare, a high level of uninsured patients, and the costs of complying with the Affordable Care Act and other new laws.
Commenter(s): 92
Department Response: No change is made to accommodate the recommendation for the reason that the comment does not fall within the scope of the regulation requirements. This regulation is required by law to establish criteria and create a process that will be utilized to assess administrative penalties within the acute care environment, it is also required to increase the IJ penalty amounts, and introduce the non-IJ penalty process. This regulation will only affect hospitals that are in noncompliance of the licensing requirements.

3-8. Comment: We have grave concerns as to the regulations potential financial and regulatory impact on our private stand-alone 204 bed acute hospital and the potential for compromising Olympia's ability to survive.
Commenter(s): 92
Department Response: No change is made to accommodate the recommendation for the reason that the comment does not fall within the scope of the regulation requirements. This regulation is required by law to establish criteria and create a process that will be utilized to assess administrative penalties within the acute care environment, it is also required to increase the IJ penalty amounts, and introduce the non-IJ penalty process. This regulation will only affect hospitals that are in noncompliance with the licensing requirements.

3-9. Comment: UC provides care to the poorest and sickest of patients. Understandably, the UC hospitals face significant financial pressures, including underpayments by Medi-Cal and Medicare, an increasingly high level of uninsured and under-insured patients, and the costs of complying with the Patient Protection and Affordable Care Act, as well as a host of other new laws and regulations.
Commenter(s): 95
Department Response: No change is made to accommodate the recommendation for the reason that this comment does not fall within the scope of the regulation. This regulation is required by law to establish criteria and create a process that will be utilized to assess administrative penalties; it is also required to increase the IJ amounts, and introduce the non-IJ penalty process. This regulation will only affect hospitals that are in noncompliance with the licensing requirements.

3-10. Comment: Health and Safety Code section 1280.3 establishes a maximum penalty of $25,000 for non-immediate jeopardy deficiencies and $125,000 for immediate jeopardy deficiencies. It does not establish minimum penalty amounts. CDPH's proposed regulations have established de facto minimum penalty amounts. CHA believes that these minimum penalty amounts are too high. CHA urges CDPH to reconsider these minimum administrative penalties to establish penalty amounts in line with other similar monetary penalty systems.
Commenter(s): 102
Department Response: No change is made to accommodate the recommendation for the reason that the Department followed the requirements of Health and Safety Code section 1280.3 when developing the criteria, guidelines and setting the penalty amounts. The Department believes the amounts for assessing penalties are appropriate for the various levels of actual or potential harm. Penalties range from $0 dollars for no actual harm with the potential for no more than minimal harm through the various levels to the maximum amount, depending on the severity of the noncompliance.

Section 4: Current Reporting Process & CDPH Response Times Comments

4-1. Comment: The Departments current untimely response when violations do occur and when hospitals self-report violations is an issue. When a violation occurs, placing

patients at risk, currently waiting up to and over a year to address the problem results in leaving and or placing patients in an ongoing problematic environment. If there is a serious safety issue, timeliness is critical in protecting our patients and addressing the problem.
Commenter(s): 2, 3, 8, 9, 10, 12, 13, 16, 17, 19, 20, 21, 22, 23, 24, 29, 30, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 67, 70, 71, 72, 73, 74, 75, 76, 77, 89, 90, 93, 94, 95, 96, 98, 103, 105, 106
Department Response: No change is made to accommodate the recommendation for the reason that the comment does not fall within the scope of the regulation requirements. However, the Department is working diligently to complete the process and assess penalties in as timely a fashion as possible. The Department carefully considers all matters of patient safety brought to its attention, investigates fully each instance of noncompliance, and factors in all of these elements in determining the appropriate penalty.

4-2. Comment: Violations that are not responded to by the Department in an appropriate time frame should be assessed at a reduced fine rate due to the Departments delay in responding.
Commenter(s): 21
Department Response: No change is made to accommodate the recommendation for the reason that the comment does not fall within the scope of the regulation requirements. The time spent investigating instances of noncompliance and assessing penalties does not diminish any actual or potential harm to the patient and the Department does not believe any reduction would be appropriate.

4-3. Comment: CDPH already has in place an “Immediate Jeopardy,” penalty, which assesses the hospital noncompliance and if it is likely to cause serious injury or death to a patient, which has since enactment resulted in a total of 224 penalties to 129 hospitals and assessed a total of $7.7 million in fines.
Commenter(s): 3
Department Response: No change is made to accommodate the recommendation for the reason that the Department is required by law to write regulations to specifically increase the IJ penalty amount in accordance with Health and Safety Code section 1280.3 and at the same time develop a process using criteria to assess the higher penalty amounts, and non-IJ violations.

4-4. Comment: Of the 35 events (required by various state statutes) we have reported to the state in the past 2 calendar years, the CDPH has only responded to 5.
We had to seek an attorney for a CDPH issued Immediate Jeopardy to appeal the decision and ward off an administrative penalty. This lJ was issued more than 2 years after the event occurred, and did not result in any serious harm to the patient, did not account for the life threatening condition of the patient whom we successfully saved, did not occur because we violated policy and procedure or a condition of licensure, and has not since been repeated.
Commenter(s): 89

Department Response: No change is made to accommodate the recommendation for the reason that the comment does not fall within the scope of the regulation requirements.

4-5. Comment: We reported one surveyor to her supervisor who, after issuing a deficiency finding from a fall investigation, was not able to provide the interpretive guidelines or the associated statutes that were being violated. Current practices by the CDPH do not allow you to clarify misinformation included in a deficiency report ahead of it becoming publicly retrievable and used by plaintiffs' attorney in court.
Commenter(s): 89
Department Response: No change is made to accommodate the recommendation for the reason that the comment does not fall within the scope of the regulation requirements.

4-6. Comment: Some of these reports contain inaccuracies or omissions and hospitals are made to correct and monitor things that are not out of compliance.
Commenter(s): 89
Department Response: No change is made to accommodate the recommendation for the reason that the comment does not fall within the scope of the regulation requirements.

4-7. Comment: Immediate identification and resolution of issues supports professional decision-oriented behaviors and patient safety. The current practice is often more than a year after the event. With the current proposal, the timeline will exceed the current practice.
Commenter(s): 90
Department Response: No change is made to accommodate the recommendation for the reason that the comment does not fall within the scope of the regulation requirements.

4-8. Comment: The proposed rules focus solely on the assessment of administrative penalties without any consideration of how deficiencies will be investigated, assessed, and appealed. For example, a fundamental problem with the “scope” and “severity” matrix is the failure to recognize that hospitals may appeal the classifications of deficiencies that lead to the imposition of penalties. When this happens, the proposed rules do not establish how administrative penalties may be re-calculated. Moreover, although Health and Safety Code section 1280.3(f) establishes procedures for appeals of administrative penalties, the proposed regulations do not establish a formalized appeal process that includes required time frames. Under the current system, hospitals have filed many appeals. CDPH needs to fully address and include required time frames for CDPH to levy a deficiency, an administrative penalty, and timely process to final determination of an appeal. The regulations should include a deemed process for CDPH’s failure to provide a timely response.
Commenter(s): 102
Department Response: No change is made to accommodate the recommendation. As the commenter notes, Health and Safety Code section 1280.3(f) establishes

procedures for appeals and a formalized appeal process, including the timeliness required to assess a penalty. Appeals will continue to be addressed using the same process in the event an administrative penalty is assessed. Should a penalty be successfully appealed, the penalty will be reassessed at the appropriate level as determined within the appeal process.

Section 5: Current Regulations & Survey Process Concerns Comments

5-1. Comment: Current Title 22 regulations are counterproductive and outdated resulting in ineffective and counterproductive regulations that surveyors use as the basis for determining a deficiency. As currently drafted the regulations lack consistency, which evaluators in different counties will interpret differently. Hospital leaders witness surveyor's variance in the interpretation on a daily basis. The current morass of outdated, conflicting, and confusing regulations for acute care hospitals is a real and serious impediment to implementing the regulations as proposed.
Commenter(s): 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 18, 19, 20, 20, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38., 39, 40, 41, 42, 43, 44, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 81, 82, 83, 84, 85, 87, 88, 89, 90, 92, 93, 94, 95, 96, 98, 102,103, 104, 105, 106
Department Response: No change is made to accommodate the recommendation for the reason that the Department is in the process of updating the California Code of Regulations, Title 22, which is a lengthy process. Both the Legislature and the Department have prioritized the proposed regulations for regulation development. The Department believes that the proposed regulations will help clarify the administrative penalty assessment process.

5-2. Comment: Surveyors are using outdated regulations to assess penalties, which further complicates the regulation compliance for hospitals and results in inconsistency in interpretation including classification of an IJ.
Commenter(s): 2, 3, 4, 5, 8, 9, 10, 11, 12, 13, 14, 15, 16, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 33, 34, 35, 36, 37, 38, 40, 41, 42, 43, 44, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 81, 90, 93, 96, 98, 103, 104, 105, 106
Department Response: No change is made to accommodate the recommendation for the reason that the Department is in the process of updating the California Code of Regulations, Title 22, which is a lengthy process. Both the Legislature and the Department have prioritized the proposed regulations for regulation development. The Department also intends to implement a standardized electronic penalty assessment tool that will be used by all District Offices and surveyor staff to provide consistent application of the regulation throughout California. The Department believes that the proposed regulations will help clarify administrative penalty assessment process.

5-3. Comment: In 2011, Sharp Mary Birch Hospital for Women and Newborns (MBHWN) worked with several hospitals with Neonatal Intensive Care Units (NICUs) and CHA to propose changes to those provisions of Title 22 of the California Code of

Regulations (CCR) that were outdated and in conflict with current standards for neonates. These recommendations were submitted in August 2011.
Commenter(s): 85
Department Response: The Department appreciates all contributions and input received during regulation updates and rewrites, any information submitted will continue to be used and considered during the regulation writing process, however, this particular comment does not fall within the scope of this regulation package.

5-4. Comment: During the Legislature's deliberation of SB 1312, the state Senate Subcommittee on Health, Aging and Long-Term Care specifically heard statements related to CDPH's responses to nursing home complaints and how cuts to CDPH's staffing had affected its ability to respond in a timely manner. This was a primary consideration by the Legislature when it enacted SB 1312.
Commenter(s): 102
Department Response: No change is made to accommodate the recommendation for the reason that the comment does not fall within the scope of the regulation requirements.

5-5. Comment: As a regional trauma center and a facility severely impacted by major wildfires, SMH reiterates the concerns provided by CHA to DPH in its August 2011 letter regarding the need for Title 22 Disaster and Mass Casualty program regulations to include flexibility without administrative burdens to initiate rapid response to disaster scenarios in circumstances that result in limited or no ability for real-time communication with CDPH.
Commenter(s): 87
Department Response: No change is made to accommodate the recommendation for the reason that the comment does not fall within the scope of the regulation requirements.

5-6. Comment: As CDPH surveyors often point out, there is a wealth of information and theories on what will work, however, it is important that we focus our efforts on proven, evidence based interventions. It is indeed distressing to think that the former could influence decisions on penalties and this flawed regulation's lack of specificity would lead to that unfortunate outcome.
Commenter(s): 88
Department Response: No change is made to accommodate the recommendation for the reason that the comment does not fall within the scope of the regulation requirements. The Department believes the proposed regulations are clear and specific as drafted.

Section 6: Patient Care and Safety Comments

6-1. Comment: Commenter feels that the regulation will create a more negative environment and divert the necessary staff away from patient care to focus on possible negative AP related outcomes occurring. To impose an increase in such penalties that may or may not impact patient safety will create a further gap in our healthcare system,

and divert resources from patient care and safety, not create the intended outcome, which should be patient safety.
Commenter(s): 12, 13, 19, 23, 24, 29, 30, 32, 33, 34, 37, 38, 39, 40, 41, 50, 87, 88, 90, 92, 93, 94, 95, 98, 102, 103, 106
Department Response: No change is made to accommodate the recommendation for the reason that the Department does not agree that the administrative penalty process takes away from patient safety and care. The proposed regulation is a process by which the Department applies the information collected from its investigation of a violation of the licensure requirements to defined criteria to calculate the final penalty amount. The intent of the legislature was to create administrative penalties that would encourage hospitals to focus on quality patient care and limit the patient's exposure to actual or potential harm.

6-2. Comment: If hospitals in California were to keep the focus on patient safety, there should be no need to add an additional monetary penalty to hospitals.
Commenter(s): 3
Department Response: No change is made to accommodate the recommendation for the reason that the comment does not fall within the scope of the regulation requirements.

6-3. Comment: Imposing draconian penalties for all but the most minor regulatory violations diverts scarce hospital resources and threatens patient safety and quality of care by diverting scarce resources away from the patient bedside and necessary patient care. Commenters feel that imposing penalties for all but the minor level violations would do nothing to improve patient care or safety.
Commenter(s): 2, 3, 7, 8, 9, 10, 12, 13, 16, 19, 21, 22, 23, 24, 29, 30, 32, 33, 34, 35, 36, 37, 38, 39, 41, 42, 43, 44, 85, 87, 88, 89, 90, 92, 93, 94, 96, 98,103,105, 106
Department Response: No change is made to accommodate the recommendation for the reason that the objective of this regulation is to adopt criteria for assessment of administrative penalties against hospitals for deficiencies that constitute immediate jeopardy, as well as less serious violations. The Legislature intended to provide incentives for hospitals to attain and maintain regulatory compliance, which directly impacts patient safety and quality of care. Thus, hospitals will only be affected by this new regulation in the event they do not maintain the required licensing requirements and will only affect those who do not continue to maintain the required standards of care.

6-4. Comment: We believe patient safety is enhanced by focusing on why clinical errors occur and how they are handled.
Commenter(s): 84, 87
Department Response: No change is made to accommodate the recommendation for the reason that the comment does not fall within the scope of the regulation requirements. The Department believes the intent of the legislature was in part to encourage hospitals to focus on quality patient care through the administrative penalty process. However, the Department appreciates the support in recognizing that patient

safety will also be enhanced by focusing on practices that result in clinical error and putting in place steps to prevent further occurrences.

6-5. Comment: It is possible to accomplish this in a pro-active manner with respect to safety and quality. Even though we are not yet required to report data on Perinatal Core Measures, Sharp Mary Birch Hospital for Women and Newborns (SMBHWN) has been collecting the data and implementing improvements to enhance patient safety for women and newborns.
Commenter(s): 85
Department Response: No change is made to accommodate the recommendation for the reason that the comment does not fall within the scope of the regulation requirements. However, the Department appreciates the commenter sharing their pro-active approach to providing safe and quality patient health care.

6-6. Comment: The California Department of Public Health should develop criteria that will focus its surveyors on priority issues related to patient care outcomes.
Commenter(s): 86
Department Response: No change is made to accommodate the recommendation for the reason that the Department has focused the criteria as required by law on patient related outcomes. The surveyors will all use the same electronic penalty assessment procedure to reach their final administrative penalty amount, which will create a more transparent, and consistent administrative penalty assessment process and outcome.

6-7. Comment: The proposed regulations with penalties raise issues of timeliness, objective criteria, and concern that subjectivity may put quality and patient safety at risk. Timeliness is imperative when addressing quality and safety issues. We feel that the proposed regulations' singular focus is on improving quality through penalties. Instead, such efforts actually threaten to undermine the goal of improving patient safety and quality by diverting scarce hospital resources away from patient care and quality improvement efforts and toward penalties that may: 1) Be imposed years after the actual non-Immediate Jeopardy violation; 2) Be imposed inconsistently; and 3) Stem from noncompliance with outdated regulations.
Commenter(s): 91, 95
Department Response: No change is made to accommodate the recommendation for the reason that "timeliness of penalty application" does not fall within the scope of this regulation. However, the Department is aware of and is addressing the back-log of penalties issued. With regards to penalties being "imposed inconsistently," following promulgation of the regulations, all District Office staff and surveyors will utilize the same electronic penalty assessment tool to assess the criteria and develop the final penalty amount. This will provide a standardized universal process to be used by all District Office staff and surveyors when assessing administrative penalty amounts.

6-8. Comment: The ambiguity in the language of these proposed regulations will continue to allow hospitals to avoid taking responsibility for meeting legal requirements, providing adequate staffing, but more importantly, protecting patients.
Commenter(s): 101

Department Response: The Department has made changes to the regulations that will effectively enable its surveyors to measure staffing violations using the scope and severity matrix. These changes will enable the Department to properly assess the scope of the staffing violations to determine if this is an isolated, pattern, or widespread staffing problem.

Section 7: Hospital Fair Pricing Comments

7-1. Comment: We oppose in the strongest possible terms the proposed regulations for violation of hospital fair pricing policies requirements because the current penalty rate is nowhere near the amount it should be to hospitals that violate Hospital Fair Pricing Act. Research has shown that: (a) the full billed charges from a hospital are typically three to four times what an insurer would pay for the same services; (b) uninsured patients on average pay more than what Medicare pays; (c) Californians who are uninsured or underinsured face hospital bills of literally hundreds of thousands of dollars; (d) hospital bills of tens of thousands of dollars are frequent; (e) hospitals charge uninsured or underinsured consumers three or four times what health insurers pay for the same care; and (f) hospital collection practices included wage garnishment and liens on primary residences.

Enforcement and resources are needed for activities devoted to ensure that hospitals are complying with their charity care duties under the law. If no one is actively monitoring hospital compliance, fines will not be levied, and, it is our experience that without meaningful oversight, hospitals have been able to under-enforce their own policies in several ways. The proposed fines of $1,000 for a “moderate violation” and $2,000 for a “major violation” of the law are much too low to have any deterrent value. The proposed penalties are unacceptable and too low to induce hospitals to comply with the law regarding discount and charity care policies and practices.

Financial harm caused by illegal hospital practices can be just as devastating as physical harm to consumers and can lead to physical harm as well. A fine of $1,000 or $2,000 is not commensurate with the financial benefit to a hospital collecting tens of thousands or hundreds of thousands of dollars from the uninsured. Initial penalty upward adjustments are too low to incent compliance; upward adjustments for violations resulting in financial harm to patients are *de minimis*; and proposed penalties for violations of hospital fair pricing are set too low to serve as an effective deterrent
Commenter(s): 45, 46, 47, 48, 49
Department Response: In response to many similar comments opposing the initial Hospital Fair Pricing penalty amounts of $2,000 for a major deviation from the requirements and $1,000 for a moderate level deviation, the Department further identified that the original valuation within this section was too low compared to the amounts proposed when assessing other administrative penalties within the Scope and Severity Matrix in the event a penalty was the result of a patient related harm scenario. Subsequently, the Department increased a “major,” initial penalty amount from $2,000 to $25,000, the maximum amount permitted by law at Health and Safety Code section 1280.3, and 70959(b)(2); a “moderate,” initial penalty amount is increased from $1,000

to $12,500 when the action or inaction deviates from the Hospital Fair Pricing policy requirements, but complies to some extent. This change was made to reflect the potentially devastating impact that illegal hospital practices can have on patients, and to increase the incentives for hospitals to comply with the law.

7-2 Comment: Proposed §70959(b) would provide that initial penalties for each deficiency would be determined in consideration of the extent of noncompliance by the hospital. The proposed regulations would establish three categories of noncompliance, each with its own accompanying penalty amount, as follows: 1) Major noncompliance - $2000, 2) Moderate noncompliance - $1000, and 3) Minimal noncompliance - No Penalty. HSC §1280.3(b) provides that a penalty for a violation not constituting immediate jeopardy may be set at an amount up to $25,000. By providing that subdivision (b) also applies to a violation of the hospital fair pricing policies (HSC Division 107, Part 2, Chapter 2, Article 3), penalty amounts for such violations may also be set at an amount up to $25,000. As such, we do not agree with CDPH's assertion that because violations of fair pricing laws do not involve physical injury or risk of physical harm, penalty amounts should be substantially lower than those proposed in the penalty matrix.
Commenter(s): 45, 46, 47, 48, 49
Department Response: The Department appreciates the commenter's suggested language, and while it has not adopted this specific language, the Department has increased the administrative penalties as provided in our response above.

7-3 Comment: We strongly recommend complete elimination of §70959(e)(1) pertaining to the 20 percent downward adjustment based on immediate correction of the violation, and recommend an increase in the upward adjustment for previous facility noncompliance.
Commenter(s): 45, 46, 47, 48, 49
Department Response: No change is made to accommodate this recommendation for the reason that the Department believes that it is valuable to incentivize immediate correction and self-reporting. However, as the commenter's proposed language is intended to limit the downward adjustment of what he or she believed was an insufficient penalty, and the Department has revised its penalty levels for Violations of Hospital Fair Pricing Policy Requirements, the Department believes the underlying concern of the commenter has been addressed.

7-4 Comment: We believe that the upward adjustments set forth in §70959(c) should be increased in order to compel compliance with the law. Further, proposed §70959(d) provides that "for the purpose of penalty calculation, the base penalty may exceed the statutory maximum, so long as the final penalty does not exceed the statutory maximum." This provision provides CDPH with additional leeway to increase proposed adjustment levels.
Commenter(s): 45, 46, 47, 48, 49
Department Response: In response to many similar comments opposing the initial Hospital Fair Pricing penalty amounts of $2,000 for a major deviation from the requirements and $1,000 for a moderate level deviation, the Department further

identified that the original valuation within this section was too low compared to the amounts proposed when assessing other administrative penalties within the Scope and Severity Matrix in the event a penalty was the result of a patient related harm scenario. Subsequently, the Department increased a “major,” initial penalty amount of $2,000 to $25,000 the maximum amount permitted by law at Health and Safety Code section 1280.3, and 70959(b)(2) a “moderate,” initial penalty amount is increased from $1,000 to $12,500 when the action or inaction deviates from the Hospital Fair Pricing Policy Requirements, but complies to some extent. This change was made to reflect the potentially devastating impact that illegal hospital practices can have on patients, and to increase the incentives for hospitals to comply with the law.

7-5. Comment: CDPH has presented no rationale as to how it established the penalties for violations of the hospital fair pricing policies requirements. The overly prescriptive method of defining penalty amounts is out of line with other fines.
Commenter(s): 102
Department Response: As the result of comments received and following further investigation the Department has rectified the Hospital Fair Pricing policy requirements by applying methodology similar valuation used to create the Scope and Severity Matrix as applied in sections 70954 through 70958 resulting in a systematic process utilizing the same valuation across the board for all administrative penalties.

Section 8: Miscellaneous Comments

8-1. Comment: The proposed fines are not in keeping with other state agencies oversight of acute care hospitals who also receive CMS funding.
Commenter(s): 20
Department Response: No change is made to accommodate the recommendation for the reason that this comment does not fall within the scope of this regulations mandate.

8-2. Comment: The enforcement of these new regulations is troublesome due to the fact they are being superimposed on an exciting [sic] fragile infrastructure.
Commenter(s): 20, 39
Department Response: No change is made to accommodate the recommendation for the reason that this comment does not fall within the scope of this regulation.

8-3. Comment: Joint Commission requests hospitals assess multiple factors when assessing system failure and determine whether or not the event has a contributing factor of noncompliance with a process/system within the facility that contributed to the reportable event.
Commenter(s): 3
Department Response: No change is made to accommodate the recommendation for the reason that Joint Commission requirements are separate from state licensing requirements. However, the proposed regulations also take into consideration multiple factors when assessing a system failure by applying the various criteria that may lead to further adjustments to the initial penalty that may ultimately increase or decrease the final penalty amount.

8-4. Comment: The limited resources of the state could be better spent in identifying and focusing on errors that are of immediate jeopardy in nature. The California Department of Public Health should focus scarce resources on solving the right problems accurately.
Commenter(s): 32, 88
Department Response: No change is made to accommodate the recommendation for the reason that the comment does not fall within the scope of the regulation requirements.

8-5. Comment: A penalty-based system for deficient compliance stifles a collaborative system of reporting problems and seeking assistance. In contrast the "just culture" embraced by Sharp, other healthcare providers, and high-consequence industries such as aviation, rail, and nuclear energy creates a strong safety culture that heightens the likelihood that mistakes are not made in the first place. A “just culture” is foundational to quality improvement and better patient outcomes, which is the goal of all hospitals.
Commenter(s): 82, 83, 85, 103
Department Response: No change is made to accommodate the recommendation for the reason that the regulation is written to serve as a penalty assessment procedure in the event a hospital is found to be in noncompliance with licensing requirements. The Department agrees with the commenter that is important for hospitals to have systems in place for assessing, reporting, and responding to patient safety issues in hospitals for the purpose of quality improvement and improved patient outcomes. However, the Legislature has mandated that the Department develop a penalty-based system in the event that hospitals endanger the health and safety of their patients. Furthermore, the Department does not believe quality improvement and assessing penalties for patient harms have to be mutually exclusive.

8-6. Comment: We would like to see processes and procedures that are closely examined in a culture that promotes safety and openness without the fear of reporting due to hefty fines being attached.
Commenter(s): 86
Department Response: No change is made to accommodate the recommendation for the reason that the scope of this regulation has no bearing on a hospital’s responsibility to report adverse events to the Department under Health and Safety Code Section 1279.1. This regulation provides a tool for assessing noncompliance with state licensing laws incorporating the penalty assessment criteria required under Health and Safety Code Section 1280.3.

8-7. Comment: Under a pro-active, just culture paradigm CDPH would use its authority to advise hospitals on its expectations with respect to licensure requirements and to develop and assume a more consultative role during surveys. By acting as a coach and disseminator of best practices, CDPH would assist hospitals in achieving the mutual goal of delivery of the highest quality care to each and every patient in each and every instance.
Commenter(s): 87, 88

Department Response: No change is made to accommodate the recommendation for the reason that the scope and objectives of this regulation is to adopt criteria for assessment of administrative penalties in the event a hospital is found to be in noncompliance of the hospital licensure requirements. However, the Department agrees with the commenter that is important for hospitals to have systems in place for assessing, reporting, and responding to patient safety issues in hospitals for the purpose of quality improvement and improved patient outcomes. Under existing law, the Department may provide consulting services upon request to any health facility to assist in the identification or correction of deficiencies or the upgrading of the quality of care provided by the health facility.

8-8. Comment: The proposed regulation's singular focus on improving quality through penalties. A penalty-based system for deficient compliance stifles a collaborative system of reporting problems and seeking assistance. An enforcement penalty system that over-values punitive factors and under-values mitigating factors is not a safe and just culture. Solutions to advance patient safety and care will stall if the fear of huge financial penalties outweighs or chills the willingness to report problems and seek assistance. We believe patient safety is enhanced by focusing on why clinical errors occur and how they are handled. It is critical that when mistakes occur, everyone feels safe in reporting them.
Commenter(s): 93, 88, 103
Department Response: No change is made to accommodate the recommendation for the reason the scope and the objectives of this regulation are to adopt criteria for assessment of administrative penalties in the event a hospital is found to be in noncompliance of the hospital licensure requirements. The regulation has no bearing on the hospital’s daily operations or its ability to promote a collaborative reporting process.

8-9. Comment: In this collaborative spirit, it would be most appropriate for CDPH to issue Administrative Penalty (AP) announcements after the penalty has been paid or the appeal process completed.
Commenter(s): 88
Department Response: No change is made to accommodate the recommendation for the reason that the comment does not fall within the scope of the regulation requirements.

8-10. Comment: A distinction should be made between physician responsibilities versus that of the hospital.
Commenter(s): 88
Department Response: No change is made to accommodate the recommendation for the reason that the comment does not fall within the scope of the regulation requirements.

8-11. Comment: California's hospitals are moving to price and quality transparency, recognizing that patients have a choice of where to receive care. Patients should have the full story and sound, current information.

Commenter(s): 88
Department Response: No change is made to accommodate the recommendation for the reason that the comment does not fall within the scope of the regulation requirements.

8-12. Comment: According to the legislative history of SB 1312, the Legislative Analyst's analysis of the Governor's Licensing Reform proposal determined that civil penalties are a central step in enforcing compliance with regulations, reflecting the consequences for failure to comply with licensing regulations. Unfortunately, the proposed regulation's method of operationalizing SB 1312 to arrive at this goal is flawed in several, fundamental ways: 1) It imposes an improper, inadequate model on acute care; 2) It imposes penalties based upon a regulatory structure that is outdated and rife with internal conflicts; 3) It fails to address and appropriately value important evaluation criteria mandated by the legislature; and 4) It fails to mitigate penalties for good faith correction, isolated incidence, factors beyond a facility's control such as actions of a third party, and waiver of right to appeal.
Commenter(s): 88
Department Response: Changes have been made to the regulation following input received during the open comment period and following further assessment of the regulation methodology and process initially proposed. The Department has amended the original by replacing the extent of a violation with the scope of a violation. The revised matrix mirrors the federal scope and severity matrix and translates well into the acute care environment. Instead of measuring the extent of noncompliance, the Department will measure the scope of noncompliance with licensure requirements and impact on patient outcomes.

The Department continues to update and promulgate regulations within Title 22. The Department adopted all the required criteria, as provided in the statute. The criteria are used to further assess an initial penalty and depending upon the hospital's compliance increases or decreases the final penalty amount. The Department agrees with the commenter's comment regarding addressing isolated incidents. Isolated incidences will now be addressed using the scope or degree of noncompliance, which is further broken down into isolated, pattern and or widespread. Finally, section 70955(a)(B)(3), which states, "For factors beyond the hospital's control that restrict the hospital's ability to comply with licensure requirements, the initial penalty shall be adjusted downward by 5 percent." Therefore, this step addresses incidents beyond the hospitals control and considers them.

8-13. Comment: These regulations seek to apply sanctions retroactively and fail to meet the principles of due process and fundamental fairness that will promote the outcomes sought by the legislature. The proposed regulations unlawfully seek to impose retroactive effects. CDPH's decision to attach new legal consequences to immediate jeopardy deficiencies preceding the effective date of these regulations is inappropriate. Providers did not have the benefit of the definitions and guidance in the regulations, and did not have the expectation that the regulations would have a retroactive effect. SB 1312 does not authorize or even consider retroactive application

of the regulations. A statute or regulation is applied retroactively "if it attaches new legal consequences to, or increases a party's liability for, an event, transaction, or conduct that was completed before the law's effective date. There exists a strong presumption against applying statutes retroactively. This strong presumption is deeply rooted in constitutional principles and specific provisions, including the Due Process Clause, where fairness dictates that "settled expectations should not be lightly disrupted." Typically, unless the Legislature expressly declares, statutes do not operate retroactively. Here, Health and Safety Code section 1280.3 does not contain express retroactive language. Section 1280.3(e), in fact, states "[t]he regulations shall apply only to incidents occurring on or after the effective date of the regulations[,]" demonstrating the statute's prospective-only application. There is also no "clear and unavoidable implication from the California Legislature" that Section 1280.3 is to have a retroactive application such that pre-enactment penalties can be used to raise the penalty level for post-enactment incidents. Therefore, CDPH's proposal to increase the penalty level based on incidents that occurred before the effective date of Health and Safety Code section 1280.3 violates due process. CDPH should amend these regulations so that they are only effective prospectively.
Commenter(s): 88, 102
Department Response: No change is made to accommodate the recommendation for the reason that section 70951(b) states that this article applies to incidents occurring on or after (the effective date of this regulation as determined by Office of Administrative Law (OAL). However, the regulation further states that the hospitals compliance history prior to (the effective date of this regulation as determined by OAL), including deficiencies constituting immediate jeopardy, shall be taken into consideration in assessing administrative penalties as provided in this article and under Health and Safety Code section 1280.3(a) and (b) , which authorizes increasingly higher penalties for second, third and subsequent immediate jeopardy deficiencies. Therefore, the Department may take into consideration a hospitals compliance history when deciding upon the final penalty amount. Furthermore, as stated within section 70951(c) "Incidents occurring prior to (the effective date of this regulation as determined by OAL) shall be subject to administrative penalties as described in Health and Safety Code section 1280.1(d)," which means the penalty will be assessed at the lower section 1280.1(d) level amount and not at the higher rates, which will only become effective upon promulgation of the regulation.

8-14. Comment: San Diego County does not operate a hospital. As a result, Sharp hospitals are an important part of the region's safety net and in fiscal year 2011 provided almost $300 million in community benefits, $287 million of which represented direct medical care for un- and under-insured patients.
Commenter(s): 88
Department Response: No change is made to accommodate the recommendation for the reason that the comment does not fall within the scope of the regulation requirements.

8-15. Comment: Nurse-to-patient ratios as written in Title 22 is a black and white issue, that if this isn't done then real enforcement will continue to be unachievable.

Commenter(s): 101
Department Response: Changes have been made to the regulation following the Department's review of comments submitted during the 45-day comment period. The Department has amended the scope and severity matrix to include a scope assessment step, to focus on issues such as staffing ratios within the acute care environment and to identify whether they are isolated, pattern or widespread, and adjust the penalty accordingly. Furthermore, the Department has increased the penalty percentage for Level 2 deficiencies that are found to be pattern and or widespread.

8-16. Comment: Documentation: When a nurse supplies information needed regarding the mental or physical status of a patient, quite extensive documentation if the goal is to reach hospital compliance, an increase of workload that takes away from patient care, does it also violate HIPPA?
Commenter(s): 101
Department Response: No change is made to accommodate the recommendation for the reason that the comment does not fall within the scope of the regulation requirements. The Department does not enforce HIPAA. This regulation does not stipulate any changes in a hospitals daily operations therefore, there is no added work load, paperwork to be submitted, provided a hospital functions in accordance with the licensing requirements.

8-17. Comment: CHA agrees with experts that to improve patient care, hospitals must maintain a blame-free culture that encourages them to improve systemic problems to prevent future errors. These proposed regulations focus solely on penalizing hospitals without fully considering the adverse impacts that the focus on punishment may have on their ongoing quality improvements.
Commenter(s): 102
Department Response: No change is made to accommodate the recommendation for the reason that the scope and objectives of this regulation is to adopt criteria for assessment of administrative penalties in the event a hospital is found to be in noncompliance with hospital licensure requirements. The Department agrees with the commenter that it is important for hospitals to have systems in place for assessing, reporting, and responding to patient safety issues in hospitals for the purpose of quality improvement and improved patient outcomes; however, the Legislature has mandated that the Department develop administrative penalties for instances when patients are harmed or may be potentially harmed.

8-18. Comment: CDPH should consider the resources available to hospitals and CDPH prior to finalizing these regulations. These regulations may divert precious hospital resources away from patient care and strain CDPH's resources. CDPH should prioritize its enforcement efforts to maximize impact on hospital quality and timely response to self-reports or patient complaints.
Commenter(s): 102
Department Response: No change is made to accommodate the recommendation for the reason that the proposed regulations scope and objectives are to adopt criteria for assessment of administrative penalties in the event a hospital is found to be in

noncompliance with licensure requirements. In addition, this regulation has no effect on the Department's existing survey processes in response to patient complaints or facility-reported incidents.

8-19. Comment: Rather than adopting proposed regulations that seek to penalize even the smallest errors, CDPH should focus its efforts on the most egregious violations to direct its resources where they are most needed.
Commenter(s): 102
Department Response: No change is made to accommodate the recommendation for the reason that the Department is required to adopt criteria for assessment of violation of hospital licensure requirements as it has done and adopt criteria to assess such violations. Furthermore, in accordance with 1280.3, minor violations as defined in section 70952(a)(4) and Severity Level 1 deficiencies do not carry an administrative penalty.

8-20. Comment: California law already provides for a role for CDPH beyond punishing hospitals by helping facilities to provide the highest quality of care. Specifically, pursuant to Health and Safety Code section 1280, CDPH "may provide consulting services upon request to any health facility to assist in the identification or correction of deficiencies or the upgrading of the quality of care provided by the health facility."
Commenter(s): 102
Department Response: The Department is required to write regulations in accordance with Health and Safety Code section 1280.3 to create a process for assessing administrative penalties in the event of a deficiency. The Department agrees that, in accordance with section 1280(a), the hospital may request consultative services in the event a deficiency has been identified or for improving the quality of patient care and receive suggestions from the Department. This, however, is outside of the scope of the proposed regulation.

8-21. Comment: Proposed Section 70951(a)(3) states "(3) Penalties assessed by the department under laws other than Health and Safety Code Section 1280.3, including but not limited to Health and Safety Code Sections 1278.5, 1280.15, 1280.4, 1317.3, 1317.4 and 1317.6(a)." Under Section 70951(a)(3), the proposed regulations do not apply to penalties assessed by the department under HSC § 1317.4.

However, the Initial Statement of Reason (ISOR) specifies that penalties under HSC §1317.4(f), pertaining to civil penalties for violations of whistleblower retaliation set forth in HSC § 1317.4(d) and (e), would be exempt from the proposed regulations. HSC § 1317.4, in its entirety, contains provisions not pertaining to penalties for whistleblower retaliations. For example, HSC § 1317.4(a) requires hospitals to maintain records of each transfer for a period of three years, and HSC § 1317.4(b) requires hospitals to annually report to CDPH the aggregate number of transfers made and received, as specified. Further, HSC § 1317.4(c) pertains to knowledge and reporting of violations of HSC Article 7, and provides that a failure to report such violations is not subject to civil penalties pursuant to HSC § 1317.6 (which is not subject to the proposed regulations). By referencing HSC § 1317.4 in its entirety, the proposed regulations may not be

applicable to violations of subdivisions other than (d) or (e). As such, in order to achieve the apparent intent of proposed § 70951(a)(3) as described in the ISOR, we recommend the subsection be amended as follows:
(3) Penalties assessed by the department under laws other than Health and Safety Code Section 1280.3, including but not limited to Health and Safety Code Sections 1278.5, 1280.15, 1280.4, 1317.3, 1317.4(f) and 1317.6(a).
Commenter(s): 49
Department Response: No change is made to accommodate the recommendation for the reason that the change is unnecessary because the regulation is only referring to *penalty* provisions in the cited Health and Safety Code sections. Section 70951(a) states "This article only applies to the assessment of penalties under Health and Safety Code Section 1280.3. *This article does not apply to: (3) Penalties* assessed by the department under laws other than Health and Safety Code Section 1280.3, including but not limited to Health and Safety Code Section . . . 1317.4 [emphasis added]." The regulation is only referring to the penalty in Health and Safety Code Section 1317.4, not to Section 1317.4 in its entirety, and the only penalty provision in Health and Safety Code Section 1317.4 is found in subdivision (f). As noted in the ISOR, Section 70951(a)(3) "provides that Article 10 shall not apply to *penalties* that may be assessed by the Department under laws other than H&SC Section 1280.3." [Emphasis added.] The ISOR then provides examples, stating "These laws include…1317.3 [transfer protocols and policies], 1317.4 (f) [whistleblower retaliation], and 1317.6 [H&SC Div. 2, Ch. 2, Art. 7]." The reference to 1317.4(f) in the ISOR reinforces the point that the regulation is not applicable to *penalties* in any provision of law outside of Health and Safety Code Section 1280.3.
It should be noted that the hospital requirements in Health and Safety Code section 1317.4(a) and (b) are *not* subject to administrative penalties under Health and Safety Code section 1280.3, contrary to the commenter's assertions. The commenter agrees that civil penalties under Health and Safety Code section 1317.6 are not subject to the proposed regulations. However, Health and Safety Code 1317.6 (a) provides that hospitals "responsible for a violation of this article [Article 7]," including Health and Safety Code Section 1317.4, are subject to a civil penalty not to exceed $25,000. Because Health and Safety Code section 1317.4(a) and (b) and the rest of Article 7 are covered by the civil penalty provision in Health and Safety Code Section 1317.6 (a), they are not subject to administrative penalties under Health and Safety Code Section 1280.3.

8-22. Comment: We concur with the department's interpretation of Health and Safety Code section 1280.3 with regard to the assessment of administrative penalties to violations that occurred prior to the effective date of the proposed regulations. The ISOR and proposed section 70951(b) and (c) make it clear that any violations that occurred prior to the effective date of the regulations would be subject to administrative penalties at the lower amounts prescribed by Health and Safety Code section 1280.1, and that their compliance history would be taken into consideration when determining the amount of an administrative penalty assessed under the proposed regulations. For the protection of patients, hospitals should be held accountable for violations to the

extent allowed under the law, and the proposed section 70951(b) and (c) are consistent with that philosophy.
Commenter(s): 49
Department Response: The Department appreciates the commenters input, no change was necessary to accommodate the recommendation.

8-23. Comment: Maintaining a record of no state or federal deficiencies resulting in patient harm or immediate jeopardy should be the minimum standard that hospitals strive for. To reward hospitals for following the law at a time when a violation has occurred, particularly if it is a serious violation in which a patient has suffered harm, is not appropriate. We recommend deleting section 70957(a)(2)(A) in its entirety. With regard to proposed Section 70957(a)(2)(B), we are concerned that the 5 percent upward adjustment for hospitals that have three or more repeat deficiencies that pose a risk of harm within the preceding three year period is too low. Again, for the safety of patients, these penalties should serve as strong deterrents to law violations and must be set at levels high enough to compel hospital compliance with the law. Hospitals that have multiple deficiencies resulting in patient harm should be appropriately penalized. As such, we recommend that the upward adjustment in proposed Section 70957(a)(2)(B) be increased.
Commenter(s): 49
Department Response: No change has been made to accommodate the recommendation. In the development of the proposed regulation, the Department considered repeated violations of the same or similar regulatory standards to be important in evaluating a hospital's compliance history, and, therefore, the regulation is specific that three or more repeat deficiencies poses a higher risk to patient health and/or safety. In this regard, the upward assessment of penalty is warranted because this indicates that the hospital has been unable or unwilling to correct a violation, and that previous penalties were not high enough to deter the hospital from violating again. The five percent upward adjustment for repeat deficiencies is not otherwise negotiable in the consideration of hospital compliance, and was considered sufficient by the Department to meet the requirements of the statute. Subdivision (b)(2) states that an upwards adjustment of five percent is made if the hospital has demonstrated a history of noncompliance - three or more repeat deficiencies that pose a risk of more than minimal harm to patient health or safety (Severity Levels 2 through 6, inclusive).

8-24. Comment: The principles of our arguments apply to the proposed regulations governing the hospitals covered under the proposed section 71701. As such, all applicable arguments and recommendations are extended to this section.
Commenter(s): 49
Department Response: The commenter has extended all of their comments to include section 71701, Acute Psychiatric Hospitals, and the Department responses also address all acute care hospitals across the board unless otherwise stated.

8-25. Comment: The proposed regulations lack clarity and are not consistent with the enabling legislation. The proposed regulations will hamper the ability of the department to enforce existing law and regulations in ways not contemplated in the enabling

legislation. The Department Failed to Consider Legislative Intent. A comparison of section 1280.3 and Title 28, section 1300.86 reveals the close parallels. The department failed to undertake rudimentary review of the intent of the Legislature in enacting the enabling statute.
Commenter(s): 99
Department Response: The Department reviewed DMHC Administrative Penalty process which is outlined in Title 28, section 1300.86 and the Department further explained within the ISOR, why the Department chose not to follow their example. Although the DMHC regulation lists eleven criteria to choose from, there are no procedures for penalty calculation and no guidance on how to weigh the criteria. The Department was required to create a more in-depth assessment process to satisfy the requirements set forth within Health and Safety Code section 1280.3 to enable them to weigh the criteria during the assessment process as it has done within the proposed regulation, but the DMHC has not provided any such assessment process.

8-26. Comment: We are disappointed that the department failed to consult us in the development of these regulations despite our well-established interest in the topic. We would look forward to working with the department on revising these important regulations and we appreciate the willingness of Debby Rogers, the Deputy Director, to meet with us for a brief, initial discussion of our concerns prior to our submission of these comments.
Commenter(s): 99, 100
Department Response: The Department provided several opportunities for anyone wishing to participate in the regulation writing process for the administrative penalty regulations along with several other regulation packages. The Department held two Open Public Pre-Notice Administrative Penalty meetings, the first on November 24, 2010 and the second January 10, 2011. Both events were noticed to the public and therefore, open for all to attend or submit suggestions. All suggestions and comments were taken into consideration during the development and regulation writing process.

8-27. Comment: We do not oppose the proposed section 70960. We do however urge that the department use it judiciously since in our experience, hospitals often cry poor when their balance sheets tell a different story. We also note that scaling penalties to the number of patients affected is beneficial to small and rural hospitals, which by definition have fewer patients than a large, urban institution.
Commenter(s): 99, 100
Department Response: No change is necessary to accommodate the suggested consideration at this time.

8-28. Comment: Proposed Section 70960 does not appropriately consider the situation of small and rural hospitals and should be clarified regarding the standards by which small and rural hospitals can request relief from administrative penalties. CDPH should clarify these standards before finalizing these regulations. Health and Safety Code section 1280.3(h) requires CDPH to “take into consideration the special circumstances of small and rural hospitals . . . in order to protect access to quality care in those hospitals.” Proposed Section 70960 purports to implement this subdivision. However,

in doing so, it introduces several new concepts that are not sufficiently defined, such as "extreme financial hardship" and the "potential severe adverse effects on access to quality of care in the hospital." Health and Safety Code section 1280.3(h) does not mention "extreme financial hardship." This term is not defined in the proposed regulations. The assessment of an administrative penalty may result in reduced access to quality of care in a small and rural hospital without the hospital experiencing "extreme financial hardship." Imposing a requirement that a hospital demonstrate "extreme financial hardship" unfairly, arbitrarily and capriciously narrows the consideration mandated by the Legislature. CDPH should delete all references to "extreme financial hardship" and amend proposed Section 70960 to permit relief for small and rural hospitals simply "in order to protect access to quality care in those hospitals." CHA recommends that CDPH revise proposed Section 70960 as follows:
§ 70960. Small and Rural Hospitals.
(a) A small and rural hospital that has been assessed an administrative penalty under Health and Safety Code section 1280.3 may request:
(1) Payment of the penalty extended over a period of time ~~if immediate, full payment would cause extreme financial hardship, o~~r
(2) Reduction of the penalty, ~~if extending the penalty payment over a period of time would cause extreme financial hardship~~, or
(3) Both a penalty payment plan and reduction of the penalty.
(b) The small and rural hospital shall submit its written request for penalty modification as described in subdivision (a) to the department within ten days after the issuance of the administrative penalty. The request shall describe the special circumstances showing that payment of the administrative penalty will affect access to quality care in the hospital. ~~extreme financial hardship to the hospital and the potential severe adverse effects on access to quality care in the hospital~~.
(c) Upon timely request from a small and rural hospital under subsection (b), the department may approve a penalty payment plan, reduce the final penalty, or both, if in the judgment of the department, if immediate, full payment of the penalty would affect ~~cause extreme financial hardship to the hospital and thereby severely reduce~~ access to quality care in the hospital. The department's decision shall be based on information provided by the small and rural hospital in support of its request and on hospital financial information from the Office of Statewide Health Planning and Development or other governmental agency.
Commenter(s): 102
Department Response: Following suggestions received during the 45-day comment period the Department made changes to the language in Section 70960 "Small and Rural Hospitals." The Department deleted the word "extreme" prior to "financial hardship," since using the word "extreme," when referring to financial hardship, suggests that the hospital would be required to go to a greater extent to prove a financial hardship, and thus setting a higher standard to meet than may be necessary. Additionally, Subsections (a)(1) and (a)(2) include an additional phrase "or a significant danger of reducing the provision of needed health care services," based on similar language in Welfare and Institutions Code Section 14168.32(n), relating to fee waivers. This phrase was also added to the penalty modification request provisions for clarity reasons, and to allow small and rural hospitals to present evidence of any actual or

potential impact to the community in the event the hospital is forced to shut down or reduce essential health care services due to high, unaffordable administrative penalties.

8-29. Comment: The Initial Statement of Reasons provides no explanation regarding why CDPH chose to adopt certain aspects of the federal nursing home enforcement system, i.e., the grid, and failed to include other important aspects of that system.
Commenter(s): 102
Department Response: No change is made to accommodate the recommendation for the reason that the Department's goal was to create a unique penalty assessment matrix that was consistent with state law and in the best interest of the citizens of the state. In reviewing various state and federal systems, the Department chose to model the scope and severity matrix largely on the CMS matrix, for many reasons that have been discussed. In doing so, the Department was able to incorporate elements that it believed to be beneficial, but also be selective in the inclusion of various elements that the Department determined were inconsistent with the law or the interests of patients.

Addendum III – List of 45-day Commenters

Comment letter representing:	Signature or submitted by:	CDPH Identifying #
Disability Rights California	Pamila Lew	1
St Bernardine Medical Center	Stefanie Morrell	2
Tri-City Medical Center	Jami Piearson	3
Santa Rosa (Medical Center)	Robin Hagenstad	4
CPMC	Warren Browner	5
Tracy	David Thompson	6
Mercy San Juan Medical Center	Brian Ivie	7
St. Mary Medical Center	Thomas Salerno	8
St. Joseph's Behavioral Health Center	Paul Raines	9
San Francisco General Hospital	Sue Currin	10
Mills Peninsula Health	Robert Merwin	11
Methodist Hospital of Sacramento	Eugene Bassett	12
Integrated Healthcare Holdings, Inc.	Kenneth Westbrook	13
Novato	Anne Hosfeld	14
Novato	Timothy Gee	15
Mercy Medical Center - Merced	David Dunham	16
Turner, Susan O.	Self	17
Solano (Medical Center)	Terry Gluoka	18
Kaiser Permanente - East Bay	Nathaniel Oubre	19
Association of California Nurse Leaders	Ginger Manss	20
Tenet - Corporate Office	Jeffrey Koury	21
St. Mary's Medical Center	Bro. George Cherrie	22
Kaiser Permanente - Vallejo	Max Villalobos	23
Kaiser Permanente - Vacaville	Max Villalobos	24
Santa Rosa (Medical Center)	Michael Purvis	25
Roseville (Medical Center)	Patrick Brady	26
Amador	Anne Platt	27
Maternity & Surgery	Stephen Gray	28
Kaiser Permanente - Fresno	Jeffrey Collins	29
Kaiser Permanente - South San Francisco	Frank Beirne	30
Sacramento (Medical Center)	Carrie Plietz	31
Providence Health & Services	Susan Hollander	32
Kaiser Permanente - Walnut Creek	Colleen McKeown	33
Sequoia Hospital	Glenna Vastelis	34
Past Chair of Dignity Health's – Sacramento..	Patricia Koda Coyle	35
Kaiser Permanente - South Sacramento	Patricia Rodriguez	36
Kaiser Permanente - Antioch	Colleen McKeown	37

Kaiser Permanente - San Jose	Irene Chavez	38
Prime Healthcare Services	Fred Ortega	39
LAC + USC	Christina Ghaly	40
Adventist Health - Feather River Hospital	Gloria Santos	41
Adventist Health - Napa Valley	Antonia Lendaris	42
Adventist Health - Clear Lake	Antonia Lendaris	43
Adventist Health - Center for Behavioral Health	Antonia Lendaris	44
Health Consumer Alliance	Shirley Sanematsu	45
Western Center on Law & Poverty, etc.	Shirley Sanematsu	46
AFSCME, CARA, CBHN, CIPC, CPEHN, etc	multiple signers	47
Health Access California	Anthony Wright	48
CNA/National Nurses Organizing Committee	Kelly Green	49
Kaiser Permanente - Santa Clara	Christopher Boyd	50
Kaiser Permanente - San Francisco	Christine Robisch	51
Kaiser Permanente - Sacramento	Ron Groepper	52
Kaiser Permanente - Redwood City	Frank Beirne	53
Kaiser Permanente - Hayward/Fremont	Debbie Hemker	54
Kaiser Permanente - San Rafael	Judy Coffey	55
Kaiser Permanente - Manteca/Modesto	Corwin Harper	56
Kaiser Permanente - Santa Rosa	Judy Coffey	57
Kaiser Permanente - Roseville	Edward Glavis	58
Woodland Healthcare	Kevin Vaziri	59
Saint Francis Memorial Hospital	Tom Hennessy	60
Mercy Hospital of Folsom	Michael Ricks	61
St. Joseph's Medical Center	Sr. Abby Newton	62
Dignity Health	Shelly Schlenker	63
St. John's Hospitals	Laurie Eberst	64
Mercy Hospitals of Bakersfield	Russell Judd	65
Community Hospital of San Bernardino	June Collison	66
St. Bernardine Medical Center	Steven Barron	67
Mercy General Hospital	Sr. Clare Dalton	68
French Hospital Medical Center	Alan Iftiniuk	69
Glendale Memorial Hospital and Health Center	Jack Ivie	70
Mercy General Hospital	Edmundo Castaneda	71
Mercy General Hospital	Patti Monczewski	72
Mercy Medical Center Redding	Mark Korth	73
Northridge Hospital Medical Center	Noachim Marco	74
Bakersfield Memorial Hospital	Jon Van Boening	75
Dominican Hospital	Nanette Mickiewicz	76
Sierra Nevada Memorial Hospital	Katherine A. Medeiros	77
St Joseph Medical Center	Donald J Wiley	78
Memorial Hospital Los Banos	Richard Liszewski	79

Auburn Faith	Mitchell Hanna	80
Davis	Janet Wagner	81
Sharp - Chula Vista	Pablo Velez	82
Sharp - Coronado	Marcia Hall	83
Sharp - Mesa Vista	Kathi Lencioni	84
Sharp - Mary Birch	Trisha Khalegi	85
Sharp - Grossmont	Michele Tarbet	86
Sharp - Memorial	Janie Kramer	87
Sharp	Daniel Gross	88
Methodist Hospital	Dan Ausman	89
Providence Little Company of Mary	Jan Brewer	90
Salinas Valley Memorial Healthcare System	Louella Freeman	91
Olympia Medical Center	Peter Friedman	92
Glendale Adventist Medical Center	Val Emery	93
Saint Agnes Medical Center	Nancy Hollingsworth	94
University of California	John Stobo	95
Arrowhead Regional Medical Center	Patrick Petre	96
Consumers Union	Betsy Imholz, etc	97
Harbor-UCLA Medical Center	Delvecchio Finley	98
UNAC/UHCP	Ken Dietz	99
AFSCME	Willie Pelote	100
SEIU Nurse Alliance	Ingela Dahlgren	101
California Hospital Association	David Perrott	102
Corcoran District Hospital	Jonathan Brenn	103
Lakeside	Siri Nelson	104
Sacramento (Medical Center)	Janet Frain	105
Kindred Hospital	Joyce Winters	106
Menlo Park Surgical	Kathi Palange	107

ADDENDUM IV
15-Day Public Notice
Summary of Comments and Responses to Comments Received

Section 1: Relevant 15-Day Comments

1-1. Comment: We appreciate that CDPH modified the threshold of financial distress to eliminate the requirement of "extreme financial distress" to allow small and rural hospitals to mitigate a penalty assessed.
Commenter(s): 3, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 23, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 40, 41, 46
Department Response: The California Department of Public Health (Department) appreciates the comment.

1-2. Comment: The regulations lack clarity because the changes create an internally contradictory regulation. The regulations as changed continue to severely limit the Department's enforcement authority, in contradiction to the enabling statute. Also, the changes constitute major changes which should have been noticed for a 45-day comment period rather than a 15-day comment period which is used for substantial changes. Because the Department has provided only a 15 day comment period despite the major changes proposed, we did not have the opportunity to offer an alternative.
Commenter(s): 43
Department Response: No changes were made in response to the recommendations for the reason that a 15-day public comment period was appropriate in accordance with the Administrative Procedures Act, as the changes made were "sufficiently related" to the original text. Under section 42 of Title 1 of the California Code of Regulations, "changes to the original text of a regulation shall be deemed to be "sufficiently related"…if a reasonable member of the directly affected public could have determined from the notice that these changes to the regulation could have resulted." Thus, a 15-day comment period was appropriate.

1-3. Comment: The regulations appear to be an interpretation of federal guidance rather than California law. We infer this from the supporting documents provided in both regulatory filings as well as our familiarity with federal law. The Administrative Procedures Act requires that regulations developed by state agencies be consistent with state law. Nothing in Section 1280.3 refers to or contemplates that the regulations would be limited to, constrained by, or based on the requirements of federal law or guidance. Instead, Health and Safety Code section 1280.3 is plainly intended to create penalties for violations of California law and regulations. The only place in Section 1280.3 that federal law is mentioned is subdivision (b) (5) in which the department is directed to take into account "the facility's history of compliance with state and federal statutes and regulations."
Commenter(s): 43

Department Response: No changes were made in response to the recommendations for the reason that the proposed regulations are not an interpretation of federal law and are wholly consistent with the statute and the express intent of the Legislature. The Department reviewed similar state and federal laws to determine best practices. In the Department's judgment, creating a scope and severity matrix that incorporates many elements of the federal matrix is optimal for the reasons provided in both the ISOR & FSOR. In doing so, however, the Department and the proposed regulations are in no way limited to or constrained by the federal guidelines as the commenter suggests.

1-4. Comment: One modest grammatical change was made by CDPH to Title 22, Section 70952(a)(5) with removal of the term "violations" for sentence clarity. Lack of specificity without vital and precise definitions will lead to uninformed and arbitrary application of regulations.
Commenter(s): 5, 21
Department Response: No changes were made in response to the recommendations for the reasons that the term "violations" at section 70952 (a)(5) was removed in response to a comment received during the 45-day comment period as it was determined to be superfluous and was deleted for clarity.

1-5. Comment: The fines are proposed to be changed from $1,000 to $12,500 for a "moderate" violation, and from $2,000 to $25,000 for a "major" violation. While this is a slight increase over the previous proposed fines, it is not nearly adequate. A fine of $12,500 or $25,000 in no way reflects the actual financial harm faced by Californians with hospital bills of thousands of dollars and with hospital collection practices that endanger credit rating, primary residence, and wages. These low fines also violate the express language of Section 1280.3 (b) (3) which requires that administrative penalties be based on actual financial harm. We ask specifically that the regulations be amended to impose a fine equal to the greater of the actual financial harm or the specified amounts.
Commenter(s): 42
Department Response: No changes were made in response to the recommendations as the Department believes that the proposed initial penalties for both moderate and major in the Penalties for Violations of Hospital Fair Pricing Requirements section 70959 are reasonable. The statute does not require the penalty assessment amount to be equal to or exceed the totality of financial harm to the patient. Health and Safety Code section 1280.3 stipulates that non immediate jeopardy violations are to be assessed at a maximum penalty amount of $25,000.

1-6. Comment: By striking the initial §70954(c) and replacing it with new language establishing the "scope of noncompliance" to be used in the matrix, and definitions of the categories of noncompliance (isolated, pattern, widespread), CDPH is establishing new criteria to determine the scope of noncompliance. However the new language in § 70954(c) still does not provide the level of clarity needed to fully understand how CDPH will determine the scope of noncompliance, and how it will objectively assess initial penalty amounts.
Commenter(s): 43, 44

Department Response: No changes were made in response to the recommendation for the reason that following the 45-day comment period, suggestions were submitted to the Department to revise the original matrix within this section and replace the “extent” of a deviation from policy and procedure requirements, to the “scope” or degree of a noncompliance of licensure requirements. This change resulted in a matrix consistent with the assessment process used by CMS and State survey agencies for long-term health care facilities. The revised survey process will now measure the scope of the noncompliance on a case-by-case basis, the numbers of patients affected, locations, and/or staff involved.

Based on its many years of hands-on experience as the State Survey Agency for CMS, the Department has determined within the three levels of scope as defined that there will be enough specificity to apply the penalty assessments consistently and fairly across the board. Each noncompliance scenario will be based upon its individual supporting facts, which will be taken into consideration in order to determine the final level of scope.

1-7. Comment: We do not find that these definitions provide CDPH objective means by which they will be able to determine the scope of noncompliance. Each definition would require the department to make a subjective determination as to what would constitute isolated, pattern, or widespread noncompliance. However, the criteria establishing isolated, pattern, or widespread noncompliance is vague, and begs many questions. For example:

1. In order to determine whether the scope of noncompliance is isolated, how do you quantify a "very limited number" of patients affected, or staff involved?
2. How do you quantify a determination that a situation that occurs only occasionally"?
3. To determine whether the scope of noncompliance is patterned, how do you quantify "more than a very limited number" of patients affected or staff involved?
4. How do you quantify when a situation has occurred in "several locations"? Does "several" mean more than two or three? If so, how many more?
5. To determine whether the scope of noncompliance is widespread, how will CDPH determine a situation was "pervasive" throughout the hospital? Does that mean a situation occurred on more than one unit? How many units would it take to qualify as "pervasive"?
6. In determining whether noncompliance is pattern or widespread, how will CDPH determine, for example, when a situation occurs in several locations in the hospital versus pervasive throughout the hospital? What will be the threshold?
7. We would also like to point out that any given type of noncompliance could transcend one or more scope categories. Under the modified language in this section, depending on how you interpret the definitions of the categories of noncompliance scope, a hospital could have committed a violation that simultaneously meets the criteria for two or all three categories. For example, the noncompliance could involve a situation that "occurred only occasionally" (isolated), that involved "more than a very limited number of staff" (pattern), and

that "represented a systemic failure that had the potential to affect a large portion of the hospital's patients" (widespread).

8. As another example, violations of nurse-to-patient ratios often affect more than a very limited number of patients (pattern) and are generally pervasive throughout a hospital (widespread). Under the modified language, which category would these situations fall under and which penalty amount would be triggered?
9. How do you quantify "a large portion" of the hospital's patients?

Commenter(s): 44

Department Response: The Department received comments during the 45-day open comment period stating that the “extent” of a noncompliance within the original matrix is too vague for consistent application in the acute care environment, along with suggestions to replace the “extent” of a noncompliance with the “scope” of a noncompliance as used in the federal scope and severity grid, based on the factors in 42 CFR § 488.404(b)(2). The Department had initially created the original matrix to assess the “extent” that a hospital deviated from hospital licensing standards. In response to comments, the Department has revised the original matrix and has replaced the “extent” of deviation from licensure requirements, with the “scope” or degree of a noncompliance of licensure requirements. This change results in a matrix consistent with the well-known assessment process used within the long-term care community, and is commonly referred to as the Federal CMS scope and severity matrix or grid. The revised survey process will now measure on a case-by-case basis, the scope of the noncompliance based on the numbers of patients affected, locations, and/or staff involved.

The scope is further comprised of three levels within the scope and severity matrix that will be taken into consideration to determine whether the violation has an isolated, a pattern or a widespread impact upon the deviation from licensure requirements. Subparagraphs (A), (B) and (C) provide further specific factors that will be used when assessing the scope of a violation. It is important to assess the scope on a case-by-case basis and take into account the case-by-case variables to determine whether the scope of a violation is considered to be isolated, pattern or widespread. For example, when assessing an infection control issue the surveyor will take into consideration the size of the unit under review and the degree that the infection control issue is prevalent throughout that area of concern. The surveyor would then check with colleagues to see if there were similar problems on other units within the hospital in an effort to determine the degree that the problem has been noted throughout the hospital. If infection control issues were noted in one unit in a large hospital, this could be classified as an isolated occurrence, however further assessment will be considered before reaching the final scope level. For example, the infection control occurrences may be considered to be isolated to one unit, but if this situation is an ongoing infection control issue, or has consistently happened over a period of time within the one unit, this may be assessed as a pattern instead of an isolated scope level. Surveyors are well versed in the use of this assessment process, and in fact, provide similar assessments under the CMS federal assessment process.

In addition, Subparagraphs (A) and (B) include the phrase “a very limited number” as part of the assessment process and “a very limited number” will also vary depending

upon the size of the hospital or area in question; for example a very limited number would not be the same for a large hospital, versus a small or rural hospital with limited space. Furthermore, 10 occurrences of an incident may not appear to be widespread in the 200 bed hospital, but could be considered to be widespread within the 20 bed hospital. Therefore the Department has determined to leave the isolated, pattern or widespread and the term “a very limited number” as unspecified with no set assigned number. Based on its many years of hands-on experience as the State Survey Agency for CMS, the Department has determined within the three levels of scope as defined that there will be enough specificity to apply the penalty assessments consistently and fairly across the board, on a case-by-case basis. Each noncompliance scenario will be based upon its individual supporting facts, which will be taken into consideration in order to determine the final level of scope. Because the severity levels are applied to a wide range of violations – patient care, medication management, infection control, etc. – further definitions of this standard could reduce the overall utility of the Scope and Severity Matrix, and generate confusion without improving clarity.

Lastly, the commenter has questioned the determination of what constitutes “several” in a pattern of noncompliance. Here, like the concept of “very limited number”, the surveyor would make a determination while weighing the totality of the facts. Further, as provided in 22 CCR § 70001, “words shall have their usual meaning unless the context or a definition clearly indicates a different meaning.”

Here, “several” means “being more than two but fewer than many in number or kind” (Dictionary.com <http://dictionary.reference.com/browse/several> [as of Sept. 12, 2013]) as it is understood in its common meaning. Likewise, such an understanding applies to the definitions of “pervasive” and “several” as provided in the regulation text.

1-8. Comment: The administrative fines and penalties for acute care hospitals, which will result from these regulations, will be an important enforcement mechanism, which will strengthen the department's mission to ensure the well-being of all Californians and its responsibilities to ensure compliance with the state's licensing and certification requirements for acute care hospitals.
Commenter(s): 45
Department Response: Thank you for your comment in support of the proposed regulation.

1-9. Comment: We acknowledge and thank the Department for addressing our concerns related to integrated systems and the balancing of findings and administrative penalties against Department of Managed Care investigations and penalties. This is now addressed through the proposed Health and Safety Code regulation 70958.1.
Commenter(s): 37
Department Response: Thank you, the Department appreciates the comment in support of the proposed revised regulation.

1-10. Comment: We appreciate the department's revision of the upper payment limit for pattern and widespread violations under Severity Level 2, However, SEIU believes

that, consistent with the intent of the law, the purpose of these administrative penalties should seek as much to prevent patient injury or death as to penalize health facilities after the harm has been done. Therefore, the upper penalty limit for the Severity Level 4 category should also be revised upward to account for situations where patients are in immediate jeopardy of likely serious injury or death. The department's attempt to address these dynamics through the initial penalty adjustment factors might also be a mechanism to account for these instances if the department had the ability to, in effect, assess a penalty at the maximum allowable by law in cases where it is merited.
Commenter(s): 45
Department Response: Thank you for your support of the Severity Level 2 changes made following the 45-day comment period. However, the remainder of this comment is outside the scope of the changes noticed during the 15-Day comment period and not relevant as provided under Government Code section 11346.9(a)(3).

1-11. Comment: We appreciate that the revised proposed rulemaking responded to several points made by the Nurse Alliance and other interested stakeholders. Specifically, the deletion of the "Extent of Noncompliance with Requirements of Licensure" with Major, Moderate and Minimal categories to a "Scope of noncompliance" framework which allows the department to assess the frequency and extent of violations. Although the added specificity of the new construct allows for a more thorough assessment of the scope of noncompliance, the proposed definitions should be strengthened, especially when one considers that these factors will directly correlate to the amount of administrative penalties assessed for a given health facility found in violation of licensure requirements. Again, patient safety should be the department's guiding principle.
Commenter(s): 45
Department Response: While the Department appreciates the commenter’s input no change is to be made. As noted previously, the Department believes the definitions to be sufficient, given the context of the variety of assessment areas. Furthermore, the definitions are consistent with the federal system used in long-term care facilities. The Department believes that use of this system, and its definitions, provides a strong framework when used to relate the scope and severity, which includes consideration of patient health and safety, and adapts well in the assessment of an administrative penalty.

1-12. Comment: We are very concerned that the language in modified §70954(c)(2) does not provide the clarity necessary to ensure objective, consistent enforcement across all hospitals. Nor, given the numerous questions outlined above, do we believe that the language would meet the requirements for clarity set forth in the Administrative Procedures Act (APA) (Government Code § 11349(c)) which require regulations to be written or displayed so that the meaning of the regulations will be easily understood by those persons directly affected by them. We are concerned that the lack of clarity does not provide patients and the public with a clear understanding of how administrative penalties will be initially assessed, will lead to varying enforcement across CDPH district offices, will undermine the ability of the department to appropriately and consistently classify violations in accordance with the proposed Scope and Severity Matrix, and will

undermine the department's ability to properly enforce the law and regulations given the wide latitude by which hospitals could appeal a penalty based on such vague language.
Commenter(s): 44
Department Response: No change was made in response to the recommendations for the reason that following comments received by the Department determined that the use of the revised matrix, which is based on the federal model, along with its definitions offers the best approach to assessing penalties on a case-by-case basis. The Department believes that the definitions offer enough clarity for both patients and the industry, especially in light of the fact that these concepts will also result in a standardized penalty process within the health care industry.

1-13. Comment: With regard to §70954(d), we question the penalty percentage assignments provided for "isolated," "pattern," and "widespread" scopes of noncompliance. Specifically, we do not necessarily agree that "isolated" noncompliance should automatically trigger a lower penalty for Severity Levels 2 through 5, than "pattern" noncompliance? Similarly, "pattern" noncompliance should not necessarily carry a lower penalty than "widespread" noncompliance. This assertion arises out of our experiences that hospital noncompliance at any level can result in serious negative outcomes for patients, and the categories for noncompliance, and associated penalty percentage, may not necessarily correlate with the level or harm, or potential for harm, that is suffered by the patient.
Commenter(s): 44
Department Response: No change was made in response to the recommendations for the reason that the increasing penalty percentages represent the Department's belief that the greater the scope of the noncompliance, the greater the penalty. Though the revised matrix does away with the extent of the noncompliance ("minimal," "moderate," and "major") and replaced these concepts with the scope component, in either case increasing penalties correspond to greater potential patient harm. For example, if a noncompliance is noted at Severity Level 5 ("immediate jeopardy to patient health or safety -- serious injury"), if the immediate jeopardy was found to be widespread throughout the hospital ("widespread") versus being confined to one or very limited number of patients ("isolated"), reason suggests that the widespread harm to patients should be met with a more severe penalty than one that is merely isolated.

1-14. Comment: The new language added in §70958.1 would implement Health and Safety Code § 1280.6 which requires CDPH to, in assessing an administrative penalty pursuant to Health and Safety Code §1280.3 against a licensee of a health facility owned by a nonprofit corporation that shares an identical board of directors with a nonprofit health care service plan licensed by the Department of Managed Health Care (DMHC), consider whether the deficiency arises from an incident that is also being investigated by, or resulted in a fine from DMHC. According to Health and Safety Code §1280.6, CDPH is required to limit the administrative penalty to take into consideration the penalty imposed by DMHC.

In our point of view, this law inhibits the ability of CDPH to properly enforce law and regulations governing hospitals that fall under its jurisdiction, and makes the amount

and assessment of administrative penalties contingent upon investigations and fines by DMHC, which has an entirely separate mission and charge than CDPH. By requiring CDPH to consider whether the deficiency arises from an incident that is "subject of investigation or, or has resulted in a fine to, the health care service plan by" DMHC, the assessment of administrative penalties by CDPH could be delayed and the amounts of administrative penalties could be reduced.

We disagree with the premise of the law, which impacts penalties relating to hospital operation and patient safety based on deficiencies relating to health care service plan laws and regulations.

Should CDPH continue to move forward with regulations, we believe that the text provided in §70958.1 should be clarified and explain in greater detail how CDPH will assess penalties in light of the requirements of Health and Safety Code § 1280.6. For example, will adjustments made pursuant to Health and Safety Code § 1280.6 be made to the final penalty amount? Will CDPH delay assessment of a penalty pending DMHC's investigation of a deficiency? We do not believe the current text in § 70958.1 provides sufficient clarity.
Commenter(s): 44
Department Response: No change was made in response to the recommendations for the reason that the Department's addition of section 70958.1 is needed to account for the provisions of Health and Safety Code section 1280.6. In that section, generally, the Department must consider penalties assessed by the Department of Managed Health Care (DMHC) in the event the DMHC's penalties result from the same incident. While the Department appreciates the commenter's concerns about the premise of the law, the Department is required to abide by section 1280.6. In regard to the commenter's questions regarding an on-going investigation and delays in assessing a penalty, the revised regulation text provides that any limitation on a penalty will go into effect after the DMHC penalty has been issued.

1-15. Comment: We oppose the non-justified increase in penalties for violation of Hospital Fair Pricing Policies requirements. This is not an area in which hospitals have demonstrated noncompliance. In fact, California is a leader in the nation with regard to its Hospital Fair Pricing Policies requirements. The new Internal Revenue Code ("Code") Section 501(r) added to the Code by Section 9007(a) of the Patient Protection and Affordable Care Act of 2010 ("Affordable Care Act"), enacted on March 23, 2010, Pub. L.No.111-148. Section 501(r)(4), requires a hospital organization to establish a financial assistance policy and a policy relating to emergency medical care. This law was modeled after California's Hospital Fair Pricing Policies law, which became effective January 1, 2008, and is designed to reduce the financial hardship of high medical costs on the uninsured by regulating hospital charges and collection procedures. This law is extensive in its reach, and hospitals have demonstrated compliance with the law.
Commenter(s): 3, 5, 8, 11, 17, 21, 22, 36, 39, 40, 43, 46
Department Response: No change has been made in response to the recommendation for the reason that the change made to increase the initial penalty

from $2,000 for a “major” noncompliance to $25,000, and to increase the initial penalty from $1,000 for a “moderate” noncompliance to $12,500 was made in response to strong opposition to the initial penalty amounts set for the original requirements during the 45-day comment period. Lastly, if hospitals are compliant with the law as the commenter suggests, the assessment of penalties will not be an issue.

1-16. Comment: Health and Safety Code §1280.3(b) provides that a penalty for a violation not constituting immediate jeopardy may be set at an amount up to $25,000. By providing that subdivision (b) also applies to a violation of the hospital fair pricing policies, penalty amounts for such violations may also be set at an amount up to $25,000. As such, we disagreed with CDPH's assertion in its Initial Statement of Reason that, because violations of fair pricing laws do not involve physical injury or risk of physical harm, penalty amounts should be substantially lower than those proposed in the penalty matrix. Instead, we argued that patients can and do suffer physical injury or risk of physical harm when the cost of their medical care is out of reach as many patients will delay or avoid needed care, or take other measures to prevent medical debt; and, that a real and meaningful deterrent to noncompliance with hospital fair pricing laws should come in the form of higher administrative penalties. We urged CDPH to modify the proposed regulations in order to increase the proposed initial penalty amounts and bring them close to the maximum allowed under the law. This said, we appreciate the modifications made to §70959 and want to thank CDPH for taking these concerns into consideration, and for ultimately increasing the initial penalty amounts from $2,000 and $1,000 to $25,000 and $12,500, respectively. The increase in penalty amounts better reflects the severity and impact of fair pricing violations, and will likely improve hospital compliance with the law.
Commenter(s): 44
Department Response: Department appreciates the support and thanks the commenter for their comment.

1-17. Comment: In response to your request for comments to the above proposal – here are my comments: S 70954 (c) Instead of “Scope of the noncompliance” would recommend “Incidence of noncompliance”; (1) and (2) would change “scope” to incidence; (A) Would change “Isolated” to “Effect on patients and personnel” – and would include (A) (i), (ii) and (B) (i), and (ii) in this category; (B) Would change “Pattern” to “Occurrence Level” and include (A) (iii) and (iv) and (B) (iii) and (iv); (C) Would change “Widespread” to “Prevalence”; On the Scope and Severity Matrix – would re-word that to be “Incidence and Severity Matrix”; On the Matrix - Do not understand why the Severity Level 3 penalty is greater than Severity level 4.
Commenter(s): 1
Department Response: The Department appreciates the input and has made no change in response to the comment. The suggestion that the Scope and Severity Matrix be re-worded to “Incidence and Severity Matrix” by changing the term “scope” to “incidence” and, “isolated” to “effect on patients and personnel”, “pattern” to “occurrence level” and “widespread” to “prevalence” is feasible, but after consideration, the Department felt such changes would for the most part be semantic. The Department has decided to keep the terminology of the proposed Scope and Severity Matrix as it is

similar to the federal matrix, which has been used in the long-term care setting for decades. The Severity Level 3 percentage amounts are greater than the Severity Level 4 percentage amount in the isolated and pattern categories as identified by the commenter, however, those percentile factors are based on differing base amounts for immediate jeopardy situations, and would not result in greater penalty amounts assessed at Severity Level 3.

1-18. Comment: How does the Scope and Severity Matrix on page 6 align with page 7 (70959) penalties for violations? Penalties are still categorized as Major, Moderate, and Minimal on page 7; so do these titles need to change to Isolated, Pattern and Widespread? 2. When will scope and severity be determined? Will it be part of the letter received as part of the 2567? Or, how will facilities know this penalty is coming. 3. Once changes adopted, when will fines/penalties begin? How will hospitals know if we have penalties coming?
Commenter(s): 2
Department Response: No change has been made in response to comments received for the following reasons: First, the Department did not change the Hospital Fair Pricing assessment process, only increased the penalty amounts as it has done and posted for 15-day comment period. Secondly, the 15-day changes do not address timelines of when hospitals will receive penalties and therefore this comment does not fall within the scope of the 15-day comment period. Lastly, should these regulations be approved by the Office of Administrative Law, adopted changes would become effective January 1, 2014.

Section 2: 15-Day Notice - Other Comments

2-1. Comment: In terms of the required criteria, the department should also increase the amount that a penalty can be adjusted upward for willful violations. Given that this is one of the required criteria called out in statute, the 10% adjustment factor for willful violations is too low, especially when one considers the potential for serious injury or death to patients. Again, this modest adjustment factor is inconsistent with the weight this factor is given in statute and the enforcement arm of CDPH should have greater flexibility to account for willful violations.
Commenter(s): 45
Department Response: This comment is outside the scope of the changes noticed during the 15-Day comment period and not relevant as provided under Government Code section 11346.9(a)(3).

2-2. Comment: We note a lack of clarity in the definitions of "major" and "moderate" violations. A "major" violation is defined as one in which the action deviates from the requirement to such an extent that the requirement is completely ignored and none of its provisions are complied with, or the function of the requirement is rendered ineffective. A "moderate" violation is defined as one in which the action or inaction deviates from the requirement to some extent, although not all of its important provisions are complied. If a lien is placed on someone's home in violation of the law, is that a "major"

or a "moderate" violation? What if someone is not offered the opportunity to agree to a payment plan? What if the hospital fails to provide notice as required? This was a common violation in our surveys of hospitals in prior years.
Commenter(s): 42
Department Response: This comment is outside the scope of the changes noticed during the 15-Day comment period and not relevant as provided under Government Code section 11346.9(a)(3).

2-3. Comment: The proposed regulations are ambiguous on a critical point: under what circumstances would a violation of the nurse to patient ratios constitute actual or potential patient harm? Furthermore, to summarize, the proposed regulation lacks clarity in how violations of staffing ratios would be penalized. The proposed regulation is not consistent with the statute since subdivisions (b) and (d) still rest on potential or actual patient harm. If a hospital litigated an administrative penalty related to staffing ratios, the department might or might not be successful in asserting patient harm, even though it could easily assert “the nature, scope and severity of the violation”.
Commenter(s): 43
Department Response: This comment is outside the scope of the changes noticed during the 15-Day comment period and not relevant as provided under Government Code section 11346.9(a)(3).

2-4. Comment: To summarize, the proposed regulation and the statement of reasons lack clarity in how some of the most common violations of the regulations regarding patient classifications systems would be penalized. The proposed regulation is not consistent with the statute since it rests on actual or potential patient harm. And if a hospital litigated a penalty arising from a violation of the regulations related to patient classification systems, the department would likely have difficulty demonstrating that the violation of the patient classification regulations constituted potential patient harm, but no difficulty in demonstrating that the patient classification regulations were violated and that the penalty reflected the nature, scope or severity of that violation. Most California hospitals have patient classification systems but few comply with these systems. Hospitals routinely ignore the requirement that acuity systems be validated annually. Similarly, hospitals often ignore the requirement that direct care nurses be included in the review committee and appoint only management nurses, in direct violation of the requirements of Title 22. These requirements have been in place for almost 20 years but hospitals routinely ignore them because the department has no intermediate sanctions with which to enforce them. Because the proposed regulations retain the provisions of subdivisions (b) and (d) limiting penalties to circumstances in which the department can demonstrate potential or actual harm to specific patients, we question whether the department could use administrative penalties to enforce the requirements related to the patient classification system. This is inconsistent with the statute and limits the enforcement authority of the department in a manner not contemplated by the law. How would the department demonstrate that a hospital which had never relied on its patient classification system (despite having one in a file drawer or on a computer) had led to actual patient harm, even though the hospital had plainly violated the patient classification system regulations?

Commenter(s): 43
Department Response: This comment is outside the scope of the changes noticed during the 15-Day comment period and not relevant as provided under Government Code section 11346.9(a)(3).

2-5. Comment: We maintain our position that the matrix proposed in §70954(d) inappropriately establishes three levels of severity involving immediate jeopardy. Only Severity Level 6 (immediate jeopardy to patient health or safety - death) would automatically trigger the maximum initial penalty, regardless of the scope of noncompliance by the hospital. Severity Level 5 (immediate jeopardy to patient health or safety - serious injury) would not trigger the maximum penalty. According to the matrix, an immediate jeopardy violation at Severity Level 5 would result in an initial administrative penalty that is only 60, 70, or 80 percent of the maximum penalty amount based on the extent of noncompliance. We also believe that the percentages in the proposed matrix established for Severity Level 4 are far too low. To limit the initial penalty for an immediate jeopardy violation to 40 to 60 percent of the maximum allowed under the law is not commensurate with the severe effects on a patient who suffers immediate jeopardy due to a hospital's noncompliance. We continue to recommend that Severity Levels 4, 5, and 6 be combined into one category and that the maximum penalty applied, regardless of the extent of noncompliance. Until then, we must continue to oppose. While an increase in the penalty percentage for "pattern" and "widespread" noncompliance at Severity Level 2 is a step in the right direction, because of the concerns mentioned above, the changes do not impact our opposition.
Commenter(s): 44
Department Response: This comment is outside the scope of the changes noticed during the 15-Day comment period and not relevant as provided under Government Code section 11346.9(a)(3).

2-6. Comment: Actual Financial Harm Patient cost sharing due to preventable readmissions, hospital-acquired infections, and longer stays due to preventable complications are some examples of actual financial harm to patients due to the failure of hospitals to comply with California laws and regulations. If Medicare has reduced payment to three quarters of hospitals for such preventable errors, then surely consumers should not face actual financial harm from such errors. Yet nowhere in the regulations is actual financial harm contemplated. This is not consistent with the statute, which requires the department to take into account actual financial harm.
Commenter(s): 43
Department Response: This comment is outside the scope of the changes noticed during the 15-Day comment period and not relevant as provided under Government Code section 11346.9(a)(3).

2-7. Comment: California law requires hospitals to have in place protocols and procedures to minimize hospital-acquired infections and adverse events. When we look at the proposed structure of the regulations, we question whether the proposed regulations give the department the enforcement tools necessary to enforce the existing law regarding hospital-acquired infections and adverse events. While both hospital-

acquired infections and adverse events are examples of potential or actual patient harm, the department might find its enforcement capacity enhanced if it looked to the nature, scope and severity of the violation rather than being forced to determine actual or potential patient harm.
Commenter(s): 43
Department Response: This comment is outside the scope of the changes noticed during the 15-Day comment period and not relevant as provided under Government Code section 11346.9(a)(3).

2-8. Comment: Immediate Jeopardy Violations: Serious Injury, Likely to cause serious injury or death. Under what statutory authority does the department propose to reduce the maximum penalty for violations that cause serious injury or are likely to cause serious injury or death? The plain language of the statute treats serious injury and jeopardy that is likely to cause serious injury or death in the same manner as violations that cause death of a patient. Yet the department proposes that a violation that is likely to cause serious injury or death have a maximum penalty of 40%-60% of the penalty for a violation that causes death. This is not consistent with Section 1280.3 subdivisions (a) or (g).

For purposes of penalties imposed under California law, the structure of penalties under federal law is not germane, particularly since in enacting Chapter 895 the Legislature did not look to federal law. If the department wishes to rely on the federal administrative penalty structure, it should seek legislation permitting it to do so. We note that on policy grounds, we would oppose legislation allowing lower penalties for immediate jeopardy for serious injury or lower penalties for immediate jeopardy likely to cause death or serious injury.

For both policy reasons and lack of statutory authority, we oppose the proposed diminution of immediate jeopardy violations in the manner proposed by the department.
Commenter(s): 43
Department Response: This comment is outside the scope of the changes noticed during the 15-Day comment period and not relevant as provided under Government Code section 11346.9(a)(3).

2-9. Comment: The changes to the proposed regulations are not consistent with Health and Safety Code Section 1280.3 and lack clarity. The proposed changes do not amend subdivision (b) of Section 70954 in which the severity of the deficiency is based on the severity of actual and potential harm to patients.
Commenter(s): 43
Department Response: This comment is outside the scope of the changes noticed during the 15-Day comment period and not relevant as provided under Government Code section 11346.9(a)(3).

2-10. Comment: We have noted in the proposed regulations:
1. The application of a hospital penalty determination based on a long term care methodology without a proven track record for improving care and safety to residents.

2. The scoring index allows for administrative penalties to be assessed even when there is "no actual patient harm but with the potential for more than minimal harm ~ even if there is no finding of immediate jeopardy. Because "more than minimal harm" is not defined, it appears that any clinical finding could be subjectively viewed as having the potential for meeting this undefined criterion.
The proposed regulation is internally contradictory: are penalties assessed for noncompliance with hospital licensure requirements, as intended under Section 1280.3, or are penalties assessed only in those instances in which actual or potential harm to a specific patient or patients is determined?
Commenter(s): 37, 43
Department Response: This comment is outside the scope of the changes noticed during the 15-Day comment period and not relevant as provided under Government Code section 11346.9(a)(3).

2-11. Comment: Proposed Regulations Not Consistent with California Law. Health and Safety Code Section 1280.3, subdivision (b) includes several provisions that could be construed as actual or potential patient harm though it never uses that phrase. Instead, California law is focused on penalties for violations of hospital licensing requirements. The regulations are not.
Commenter(s): 43
Department Response: This comment is outside the scope of the changes noticed during the 15-Day comment period and not relevant as provided under Government Code section 11346.9(a)(3).

2-12. Comment: Factors Beyond the Hospital's Control As noted in the Nurse Alliance's December 2012 comments, the description of "factors beyond the facility's control that restrict the facility's ability to comply with this chapter or rules and regulations," is vague and requires additional clarity.
Currently, the proposed regulation reads:
(3) For factors beyond the hospital's control that restrict the hospital's ability to comply with licensure requirements, the initial penalty shall be adjusted downward by 5 percent, if the hospital developed and maintained disaster and emergency programs as required by state and federal law that were appropriately implemented during a disaster. This paragraph should be changed to be clear that this option to adjust a penalty downward by 5% is available for occurrences during a disaster where the hospital developed and maintained disaster and emergency programs required by state and federal law. As it read now, it is unclear whether this adjustment would be available in other circumstances, which does not seem to be the department’s intent.
Commenter(s): 45
Department Response: This comment is outside the scope of the changes noticed during the 15-Day comment period and not relevant as provided under Government Code section 11346.9(a)(3).

2-13. Comment: The proposed regulations provide the department with the ability to assess a 1% upward adjustment factor for a violation that caused actual financial harm to a patient based on information acquired by the department during the normal course

of the investigation. This would allow for an adjustment for financial harm to patients, such as prolonged hospital stays due to harm or complications caused by the hospital and not covered by health insurance. However, as developed in the proposed regulation, it would allow the department to **not** consider actual financial harm to a patient if it did not come by way of information gathered by the department in the normal course of the investigation which would be inconsistent with the authorizing statute.
Commenter(s): 45
Department Response: This comment is outside the scope of the changes noticed during the 15-Day comment period and not relevant as provided under Government Code section 11346.9(a)(3).

2-14. Comment: We are concerned that the revised proposed regulations did not comprehensively address or even acknowledge most of the comments submitted by the California Hospital Association (CHA). We, in concert with the hospital community, urge CDPH to address the concerns raised by CHA. To the contrary, CDPH remains steeped in a culture of blame, rather than one that is proven effective by encouraging reporting, sharing information, and designing together new processes or systems to enhance quality. This culture of blame is also evidenced by CDPH's failure to address and include each of the eight statutory requirements, including those that mitigate penalties that are necessary to clarify and make specific the requirements of Health and Safety Code Section 1280.3. Authority to levy **huge administrative** penalties for any deficiency in statute or regulation mandates that hospitals receive clarification and specificity to fairly and appropriately assess penalties using a process that puts all on notice of the expectations, and the consequences for failing to meet them.
Commenter(s): 3, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 43
Department Response: This comment is outside the scope of the changes noticed during the 15-Day comment period and not relevant as provided under Government Code section 11346.9(a)(3).

2-15. Comment: Prioritizing its focus on identifying errors, rather than offsetting some of this imbalance by the vast amount of literature and research, has proven time and again that change is driven by a culture that promotes and does not chill self-critical analysis and action. A penalty-based system for deficient compliance stifles a collaborative system of reporting problems and seeking assistance. Solutions to advance patient safety and care will stall if the fear of huge financial penalties outweighs or chills the willingness to report problems and seek assistance. An enforcement penalty system that overvalues punitive factors and undervalues mitigating factors does not promote a safe and just culture.
Commenter(s): 3, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 38, 39, 40, 41, 42, 46
Department Response: This comment is outside the scope of the changes noticed during the 15-Day comment period and not relevant as provided under Government Code section 11346.9(a)(3).

2-16. Comment: The scope and severity calculations are devoid of clear and objective criteria or rationale for how they were chosen and compartmentalized. They are vague and open to interpretation. The vetting process for the development and validation of the criteria used to determine the penalties is biased if validation criteria were performed by CDPH department personnel. Neither is there any clarity or specificity on how the percentages were assigned and the resulting penalties will be calculated in a way that implements the full range contemplated by statute.
Commenter(s): 11
Department Response: This comment is outside the scope of the changes noticed during the 15-Day comment period and not relevant as provided under Government Code section 11346.9(a)(3).

2-17. Comment: We believe the department needs to recognize the importance of establishing a different approach to assessing administrative penalties that are specifically tailored for the acute care setting. Modernizes the current regulatory system on which the penalty structure is based, providing a clear rationale for weightings of the initial penalty and adjustment factors and establishing amounts that are in line with other similar monetary penalty systems and demonstrates consistency between California and federal and other state penalty systems.
Commenter(s): 24
Department Response: This comment is outside the scope of the changes noticed during the 15-Day comment period and not relevant as provided under Government Code section 11346.9(a)(3).

2-18. Comment: While we advocate for a more dramatic move from culpability to a new paradigm of error reduction and quality improvement, at the least we would request that monetary penalties be utilized for investments in systems improvements to reduce risk of harm to patients
Commenter(s): 8
Department Response: This comment is outside the scope of the changes noticed during the 15-Day comment period and not relevant as provided under Government Code section 11346.9(a)(3).

2-19. Comment: The proposed rule magnifies the arbitrary and capricious nature of the methodology developed to assess penalties and the failure to provide important procedural safeguards for hospitals. We encourage CDPH to amend the rule so that it is rational, clear, and fair to hospitals in their ongoing efforts to deliver high-quality care. The revised proposed regulations are devoid of procedural safeguards, and clear and objective criteria, to inform and insulate hospitals using all best efforts to assure full compliance.
Commenter(s): 3, 8, 5, 11, 21, 24, 36, 38, 39, 40, 46
Department Response: This comment is outside the scope of the changes noticed during the 15-Day comment period and not relevant as provided under Government Code section 11346.9(a)(3).
2-20. Comment: CHA highlighted significant concerns with definitions and interpretation of several of the stated terms are either unclear, ill-defined, or undefined – for example,

"actual patient harm" which is inferred in the scoring grid but not defined. As another example, we would not know if, under the definition of "deficiency," would that apply to a single occurrence or event (i.e., charting) or might it be multiple deficiencies if the same error is repeated several times in a day by the same staff? Given the disastrous financial consequences for hospitals, this is the level of interpretation, clarification and specificity that is necessary to adequately provide notice of what is required by law, and the resulting consequences of noncompliance.
Commenter(s): 3, 5, 8, 11, 17, 21, 22, 36, 38, 39, 40
Department Response: This comment is outside the scope of the changes noticed during the 15-Day comment period and not relevant as provided under Government Code section 11346.9(a)(3).

2-21. Comment: The regulations were not revised to delete the retroactive impact to hospitals with prior occurrences resulting in deficiencies, such that a heightened penalty would apply for a second or third deficiency. Whereas with any law, not the least of which is this regulatory package, and in accordance with Section 1280.3(e), "the regulations shall apply only to incidents occurring on or after the effective date of the regulations," demonstrating the statute's prospective only application.
Commenter(s): 5, 11, 17, 21, 22, 36, 38, 39, 40, 46
Department Response: This comment is outside the scope of the changes noticed during the 15-Day comment period and not relevant as provided under Government Code section 11346.9(a)(3).

2-22. Comment: Inappropriate use of the scope and severity grid and guidelines in the State Operations Manual used for long-term care facilities – a model that has proven hugely defective and ineffective in promoting quality and change – are used to design its model to implement administrative penalties for acute care hospitals. Instituting a severity grid and describing the levels of harm has a stated goal of equalizing and eliminating the subjectivity to a deficiency investigation. However, there continues to be a large disparity between district offices and individual surveyors as to what constitutes a specified deficiency. A level 2 or level 3 deficiency, for example, while not an immediate jeopardy classification, could be defined multiple ways depending on the surveyor's point of view.
Commenter(s): 3, 5, 8, 11, 17, 21, 22, 36, 38, 39, 40, 46, 47
Department Response: This comment is outside the scope of the changes noticed during the 15-Day comment period and not relevant as provided under Government Code section 11346.9(a)(3).

2-23. Comment: Any benefit from ambiguity or lack of specificity certainly does not facilitate quality improvements. What does result, however, are significant financial penalties that are levied against the hospital, and paid to CDPH. Any benefit from ambiguity or lack of specificity certainly does not facilitate quality improvements. What does result, however, are significant financial penalties that are levied against the hospital, and paid to CDPH. All fines are allocated to a special account to be used by the department to promote improvements in the quality of care. To date, reports indicate that over $7 million has been collected by CDPH. We are not aware of any

efforts or programs funded and provided by CDPH through use of these funds collected, to assist hospitals improve care delivery and quality.
Commenter(s): 3, 6, 7, 8, 9, 11, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 38, 39, 40, 41, 46
Department Response: This comment is outside the scope of the changes noticed during the 15-Day comment period and not relevant as provided under Government Code section 11346.9(a)(3).

2-24. Comment: The revised proposed regulations completely failed to address requests to interpret, clarify and make specific the calculations based on statutory criteria to assess penalties. Yet when faced with major penalties that would have a substantial impact on the continued viability of California hospitals across the state, the administrative procedure mandates that agencies like CDPH include sufficient specificity and guidance necessary to inform and advise all those subject to the regulations of what is expected, and how the consequences of noncompliance will apply. In this case, however, no such clarity and specificity were provided. CHA and its member hospitals lack the information necessary to be on notice of the process and outcome that is necessary to fairly and appropriately guide rules of general application that implement the statutory mandate.
Commenter(s): 3, 4, 5, 8, 9, 11, 17, 21, 22, 24, 36, 37, 38, 39, 40, 46,
Department Response: This comment is outside the scope of the changes noticed during the 15-Day comment period and not relevant as provided under Government Code section 11346.9(a)(3).

2-25. Comment: It has been our experienced that most reported events and/or occurrences are not reviewed in a timely manner by CDPH, and in some cases take years to be finalized. This inordinate amount of time brings to question the likelihood of unique complications in ascertaining facts and details to an event which may be forgotten over time and not easily brought forward during the review process. Reason would stand that details of events are better recalled immediately or soon after an event and not months to years when one is asked, "can you tell me what happened on …? Consequently, this delay by CDPH in allowing the hospital an opportunity to explain all the underlying variables would certainly compromised the review process and place the hospital in a disadvantage which may unjustly lead to an unwarranted fine.
Commenter(s): 38, 41
Department Response: This comment is outside the scope of the changes noticed during the 15-Day comment period and not relevant as provided under Government Code section 11346.9(a)(3).

2-26. Comment: Base penalty upward adjustments for hospitals with a short-term history of multiple deficiencies that pose a risk of harm to patients should be increased. The proposed 5 percent upward adjustment is too low for hospitals with such a compliance history and does not provide an adequate deterrent to future violations. Upward adjustments for violations resulting in financial harm to patients are de minimis and should be increased.
Commenter(s): 44

Department Response: This comment is outside the scope of the changes noticed during the 15-Day comment period and not relevant as provided under Government Code section 11346.9(a)(3).

2-27. Comment: Base penalty reductions for compliance history should be eliminated entirely. At a time when a hospital is being penalized for violating the law, they should not simultaneously be rewarded with a penalty discount for maintaining a record of no state or federal deficiencies. Maintaining a clean record is a minimum standard that hospitals should meet. It should not be considered exemplary behavior that is rewarded at the same time a penalty is being issued for a violation.
Base penalty reductions for immediate correction should be eliminated entirely. It is the responsibility of the hospital to immediately correct noncompliance without the need for a positive incentive. Instead, we recommend that the penalty reduction be replaced with a penalty increase for any hospital that does not immediately correct the noncompliance that led to the violation.
All initial penalty upward adjustments should be increased to properly influence facility behavior and reflect the potentially severe impact violations may have on patients.
Commenter(s): 44
Department Response: This comment is outside the scope of the changes noticed during the 15-Day comment period and not relevant as provided under Government Code section 11346.9(a)(3).

2-28. Comment: We note that most of our comments and concerns were not addressed in this most recent release of the proposed regulations. As previously stated, there is no evidence that imposing penalties for any deficiency improves patient safety and quality. In fact, the proposal to impose penalties for all but the most minor level I regulatory violations threatens patient safety and quality by diverting scarce hospital resources away from patient care. This is particularly troubling at a time when KFH, along with all other hospitals in California, prepares for implementation of the Affordable Health Care Act and the fiscal challenges that are being created. Some of the specific issues our hospitals faces under the current regulatory environment that make the proposed regulations ineffective and counterproductive include: 1) The use of outdated hospital regulations in Title 22 as the basis for determining a deficiency; 2) The lack of a system for surveyor inter-rater reliability and the current demonstrated inconsistency in interpreting the outdated regulations that currently exist, and 3) The lack of a consistent timely process across CDPH for investigation of self-reported events or complaints and the subsequent submission of findings to hospitals.
Commenter(s): 37
Department Response: This comment is outside the scope of the changes noticed during the 15-Day comment period and not relevant as provided under Government Code section 11346.9(a)(3).

2-29. Comment: While Health and Safety Code 1280.1 allows hospitals to dispute alleged deficiencies within 10 days, there is no substantial appeal methodology outlined in these regulations. The inherent fallibility in humans on both sides of the table is inevitable and thus we should treat adverse occurrences as opportunities for learning

and improvement. An appeal process could be strengthened in a manner by which both the licensee and the CDPH benefit from the opportunities for synergy, collaboration, and innovation. The appeals process that is offered in the current “Assessment of Administrative Penalties" letters from CDPH and noted in the regulations (Health and Safety Code 128O.1(b) is not included in the proposed regulations.
Commenter(s): 3, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 46
Department Response: This comment is outside the scope of the changes noticed during the 15-Day comment period and not relevant as provided under Government Code section 11346.9(a)(3).

2-30. Comment: We are especially concerned that CDPH fails to address and include each of the eight statutory requirements, including those that mitigate penalties that are necessary to clarify and make specific the Requirements of Health and Safety Code Section 1280.3. Authority to levy huge administrative penalties for any deficiency in statute or regulation mandates that hospitals receive clarification and specificity to fairly and appropriately assess penalties using a process that puts all on notice of the expectations, and the consequences for failing to meet them.
Commenter(s): 3, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 43, 46
Department Response: This comment is outside the scope of the changes noticed during the 15-Day comment period and not relevant as provided under Government Code section 11346.9(a)(3).

2-31. Comment: We respectfully request that CDPH extend the comment period to allow for CHA to provide further input on developing useful and meaningful regulations that are not punitive, but rather encourage hospitals to report and learn from the incidents, particularly those where no harm occurred. As drafted, however, the revised proposed regulations simply lack the necessary detail to guide, clarify, and specify hospital expectations and surveyor penalty assessments, to ensure that the rules meet the requirements to implement the statute consistently as applied generally to all hospitals within California.
Commenter(s): 5
Department Response: This comment is outside the scope of the changes noticed during the 15-Day comment period and not relevant as provided under Government Code section 11346.9(a)(3).

2-32. Comment: The scope and severity calculations are devoid of clear and objective criteria or rationale for how they were chosen and compartmentalized. They are vague and open to interpretation. The vetting process for the development and validation of the criteria used to determine the penalties is biased if validation criteria were performed by CDPH personnel only. Neither is there any clarity or specificity on how the percentages were assigned and the resulting penalties will be calculated in a way that implements the full range contemplated by statute.
Commenter(s): 43

Department Response: This comment is outside the scope of the changes noticed during the 15-Day comment period and not relevant as provided under Government Code section 11346.9(a)(3).

2-33. Comment: Section 1280.3 is modeled on the regulations of the California Department of Managed Health Care, regulations which the Department of Public Health gives no evidence of having reviewed and a regulator which the Department of Public Health shows no signs of having consulted, despite the fact that both entities are in the Health and Human Services Agency, as requested by this Administration.
Commenter(s): 43
Department Response: This comment is outside the scope of the changes noticed during the 15-Day comment period and not relevant as provided under Government Code section 11346.9(a)(3).

Addendum V – List of 15-day Commenters

Comment letter representing:	Signature or submitted by:	CDPH Identifying #
Dominican Hospital	Monica Hamilton	1
Salinas Valley Memorial Healthcare	Sylvia Lozano	2
Sutter Medical Center Santa Rosa	Robin Hagenstad RN	3
Los Robles Hospital & Medical Center	Greg Angle, President	4
California Hospital Association	BH Bartleson	5
Dignity Health Group of Hospitals	Jo Ann Costa	6
St. Mary's Medical Center #1	Bro. George Cherrie	7
St. Bernardine Medical Center.	Stefanie Morrell	8
Woodland Healthcare	H. Kevin Vaziri	9
Northridge Hospital Medical Center	Saliba H. Salo	10
San Dimas Community Hospital	Dora Noriega	11
Mercy Medical Center	Chuck Kassis	12
Mercy Hospital of Folsom	Michael R. Ricks	13
Sequoia Hospital	Glenna L. Vaskelis	14
St. Elizabeth Community Hospital	Todd Smith	15
Dominican Hospital	Nanette Mickiewicz	16
Hi Desert Memorial Health Care District	Lionel Chadwick, PhD	17
St Joseph's Behavioral Center	Paul Rains	18
Methodist Hospital of Sacramento	Gene Bassett	19
St Joseph's Medical Center	Donald J Wiley	20
Association of California Nurse Leaders	Patricia Lenihan MacFarland	21
Sharp HealthCare	Daniel L. Gross	22
Community Hospital of San Bernardino	June Collison	23
Dignity Health	Shelly L. Schlenker	24
Dignity Health California Hospital	Bob Quarfoot	25
Glendale Memorial Hospital	Jack Ivie	26
Mercy General Hospital -	Edmundo Castaneda	27
Mercy General Hospital - Mt Shasta	Morris Eagleman	28
Mercy San Juan Medical Center	Brian K. Ivie	29

Sierra Nevada Memorial Hospital	Debbie Plass	30
St. Bernardine Medical Center	Steven R. Barron	31
St. Francis Memorial Hospital	Tom Hennessy	32
St. Joseph's Medical Center - Stockton	Sister Abby Newton #1.	33
St. Joseph's Medical Center - Stockton	Patricia A Collier-Director #2.	34
St. Mary Medical Center	Thomas Salerno	35
Henry Mayo Newhall Memorial	Roger Seaver	36
Kaiser Permantente Hospitals	Barbara Crawford	37
LAC+USC Medical Center	Dr. Stephanie Hall, MD	38
Palomar Health	Michael H. Covert	39
Prime Healthcare Services, Inc.	Fred Ortega	40
Providence Health & Services	Michael Hunn	41
Multiple Advocate &AFL-CIO Groups	Multiple Advocates	42
AFSCME	Willie L. Pelote, Sr & Ken Deitz	43
C.N.A.	Kelly Green	44
SEIU	Jon Youngdahl	45
Kern Valley Healthcare District	Mark Gordon	46
Cedars-Sinai Health System	Thomas M. Priselac	47

UPDATED INFORMATIVE DIGEST

There have been no changes in applicable laws or to the effect of the proposed regulations from the laws and effects described in the Informative Digest/Policy Statement Overview as published in the Notice of Proposed Regulatory Action.