December 3, 2012

California Department of Public Health  
Office of Regulations  
Attn: Coleen Keelan  
MS 0507  
P.O. Box 997377  
Sacramento, CA  95899-7377

BY ELECTRONIC CORRESPONDENCE AND HAND DELIVERY

RE: CDPH-09-012, Administrative Penalties – General Acute Care Hospitals, Acute Psychiatric Hospitals, and Special Hospitals

Dear Ms. Keelan:

On behalf of our nearly 400 member hospitals and health systems, the California Hospital Association (CHA) appreciates the opportunity to comment on the proposed regulations by the California Department of Public Health (CDPH) on administrative penalties for general acute care hospitals, acute psychiatric hospitals and special hospitals. This proposed rule seeks to implement Health and Safety Code Section 1280.3, which was enacted by SB 1312 (Chapter 895, Statutes of  2006).

Health and Safety Code Section 1280.3 authorizes the CDPH to adopt regulations establishing the criteria to assess an administrative penalty against a general acute care hospital, an acute psychiatric hospital or a special hospital. In enacting this statute, the Legislature mandated that CDPH include in those criteria the following: (1) the patient’s physical and mental condition; (2) the probability and severity of the risk that the violation presents to the patient; (3) the actual financial harm to patients, if any; (4) the nature, scope, and severity of the violation; (5) the facility’s history of compliance with related state and federal statutes and regulations; (6) factors beyond the facility’s control that restrict the facility’s ability to comply with licensure requirements; (7) the demonstrated willfulness of the violation; and (8) the extent to which the facility detected the violation and took steps to immediately correct the violation and prevent the violation from recurring. (Health and Safety Code Section 1280.3(b).)

The statute establishes maximum penalties for deficiencies of $25,000 for a deficiency that does not constitute immediate jeopardy, $75,000 for a first immediate jeopardy deficiency, $100,000 for the second subsequent immediate jeopardy deficiency and $125,000 for the third and every subsequent immediate jeopardy deficiency.

Overview of Comments

CHA shares CDPH’s goal to maintain the highest level of quality care at California’s hospitals. However, CDPH should fully consider the context of these proposed regulations.
The delivery of healthcare services is unique from many other industries in three key respects: (1) unpredictability; (2) the professional nature of service delivery and (3) the focus on patients.¹ The delivery of quality care is an art as well as a science, often requiring professionals to decide between actions or inaction that may all present risks to a patient. Sometimes, adverse outcomes result despite a hospital’s best efforts. In other instances, because this industry relies on people for decisions and implementation of those decisions, human errors may contribute to adverse outcomes.

CHA has serious concerns about the general direction of these proposed regulations. These proposed regulations should adopt criteria for the assessment of administrative penalties in a manner that will focus on promoting quality of care and regulatory compliance, not penalizing hospitals. As discussed below, penalizing hospitals for minor or isolated lapses is not an effective means of improving quality of care. To do so, CDPH should amend these regulations to develop criteria that prioritizes the most egregious violations and “repeat offenders.”

CDPH has sought to fulfill its mandate under SB 1312 by borrowing from the federal nursing home enforcement system. This proposed system does not give proper weight to the eight factors established by the Legislature and is not suitable for an acute care environment. This federal nursing home enforcement system has repeatedly led to inconsistent and unfair results. If adopted without revision, CDPH’s proposed rules will result in establishing a system that is overly complex; this complexity will lead to inconsistency in its application to hospitals.

These problems will be magnified by the arbitrary and capricious nature of the methodology developed to assess penalties and the vague nature of the proposed regulations. These proposed rules also fail to provide important procedural safeguards for hospitals. CDPH should amend these proposed rules so that they are rational, are fair to hospitals and lead to consistent results through the promulgation of clear and objective criteria. CHA is also concerned that CDPH proposes to give these regulations retroactive effect, which was not authorized by the Legislature.

CHA does not believe that this proposal provides fair criteria for the consistent assessment of administrative penalties. CHA therefore requests that CDPH withdraw these regulations and convene stakeholder meetings to develop a better system for assessing administrative penalties. CHA stands ready and willing to collaborate with CDPH to develop criteria for assessing administrative penalties that properly respond to lapses in care, while promoting long-term regulatory compliance.

¹ See Morton, A and Cromwell, J, What’s the Difference Between a Hospital and a Bottling Factory?, 339 British Medical Journal 428-30 (Aug. 22, 2009). This article is attached as Exhibit 14.
Specific Comments

1. Broaden the perspective from a punitive penalty-based system to one focused on quality of care.

A. 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. CHA believes the regulations should be clear that administrative penalties will be assessed by CDPH only when appropriate, e.g., when there has been deliberate malfeasance.

A “just culture” is foundational to quality improvement and better patient outcomes, which is the goal of all hospitals. 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.

In 1999, the Institute of Medicine (IOM) issued a report on medical errors — To Err Is Human — attached hereto as exhibit 1. The IOM report acknowledges that 80 percent of medical errors result from human error. The report also distinguishes between active errors, which are errors by the front-end user, and latent errors, which are errors removed from the control of the operator, such as poor design, bad management decisions and poorly structured organizations. The report states that “Latent errors pose the greatest threat to safety in a complex system because they are often unrecognized and have the capacity to result in multiple types of active errors. (To Err Is Human, p. 55).

The IOM also explains in the report why penalties are not effective at improving quality of care with respect to many latent errors:

Current responses to errors tend to focus on the active errors by punishing individuals (e.g., firing or suing them), retraining or other responses aimed at preventing recurrence of the active error. Although a punitive response may be appropriate in some cases (e.g., deliberate malfeasance), it is not an effective way to prevent recurrence. Because large system failures represent latent failures coming together in unexpected ways, they appear to be unique in retrospect. Since the same mix of factors is unlikely to occur again, efforts to prevent specific active errors are not likely to make the system any safer.

For these reasons, the IOM report recommends the development of nonpunitive systems for reporting and analyzing errors.
Congress has similarly acknowledged that improving quality of care is more important than penalizing hospitals in passing the Patient Safety and Quality Improvement Act of 2003 (PSQIA). A report from the U.S. Senate Committee on Health, Education, Labor and Pensions found that PSQIA “will promote a learning environment that is needed to move beyond the existing culture of blame and punishment that suppresses information about health care errors to a "culture of safety" that focuses on information sharing, improved patient safety and quality and the prevention of future medical errors. The committee believes that it is important to shift the current focus from culpability to a new paradigm of error reduction and quality improvement.”

Recent research published in the New England Journal of Medicine supports these views. In “Effect of Nonpayment for Preventable Infections in U.S. Hospitals,” Harvard researchers concluded that the Centers for Medicare & Medicaid Services’ (CMS) implementation of a punitive nonpayment policy for hospital-acquired conditions has had no measurable impact on rates of central line-associated bloodstream infections or catheter-associated urinary tract infections, two types of health care-associated infections targeted by the program.

DPH can encouraging the voluntary reporting of systemic, or latent, errors to improve quality of care and regulatory compliance by minimizing the link between adverse event reporting and punishment (administrative penalties). For example, the IOM Report used the aviation reporting and regulatory system as a model for responding to healthcare-related errors. The aviation system separates the regulatory enforcement arm (the Federal Aviation Administration) from accident investigation agency (National Transportation Safety Board) and its reporting system (the National Aeronautics and Space Administration Aviation Safety Reporting System). The Aviation Safety Reporting System (“ASRS”) is a voluntary, confidential incident reporting system used to identify hazards and latent system deficiencies in order to eliminate or mitigate them. The ASRS is administered independently from the Federal Aviation Administration. This helps to encourage confidential reporting as pilots were reluctant to report incidents to a regulatory agency. With respect to DPH’s proposed rules, the assessment of extensive administrative penalties for self-reported incidents will likely make hospitals more reluctant to report adverse events or request technical assistance from DPH.

Regulatory theorists refer to the perspective of regulators working with regulated entities to effectuate compliance as the “compliance paradigm,” and that of regulators penalizing regulated entities as the “deterrence paradigm.” The deterrence paradigm focuses on punishing

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4 IOM Report, p. 72.

5 IOM Report, pp. 95-97.

6 See Walshe, Regulating U.S. Nursing Homes: Are We Learning from Experience? (2001) Health Affairs, No. 6, 128-44.
“wrongdoers” while the compliance paradigm focuses on supporting the regulated entities to comply. Deterrence regulation “is usually more costly and can provoke defensive behavior by regulated organizations.” CHA proposes that the regulation of California hospitals should be “responsive” or “smart” regulation:

The main principle of responsive regulation is that regulatory methods and approaches should be adapted in response to the behavior of individual regulated organizations. A broad, graduated hierarchy of regulatory interventions and enforcement actions is used, and while most regulation takes place at lower levels, the regulator has the capacity and the will to use higher-level interventions and actions if need be. In this way, most of the benefits of compliance regulation—such as cooperation, information sharing, negotiated agreement, and low regulatory costs—are retained, but the powerful incentives and sanctions of deterrence regulation are still available.

By implementing “responsive” or “smart” regulation, CHA suggests that CDPH can focus on working with hospitals to achieve a high level of quality care and regulatory compliance, while reserving its punitive authority, such as administrative penalties, for the most egregious lapses or for “repeat offenders.”

B. 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. CHA recommends that CDPH focus on cooperative models that are more effective than punitive models. These models provide for more consistency and more clarity as to the requirements of law. The monies collected from administrative penalties should be used to fund these collaborative efforts.

In 2008, the American Association of Homes and Services for the Aging (AAHSA) Task Force on Survey, Certification and Enforcement released a report, *Broken and Beyond Repair: Recommendations to Reform the Survey and Certification System* attached as Exhibit 2 (AAHSA Report). The AAHSA report reviews the efficacy of the federal nursing home system that is the model for these proposed regulations. The task force interviewed high-level survey staff who overwhelmingly supported a more consultative role for enforcement teams:

Staff in several states recommended that consultation be built into the survey system, either by scheduling regular consultation visits by surveyors or by mandating ongoing consulting for poor-performing facilities. One survey staff member summed up his colleague’s comments by suggesting, “providers could learn strategies from surveyors if a consultative process was permitted.”

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7 Id.
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.” CHA requests that CDPH use this authority to advise hospitals on CDPH’s expectations with respect to licensure requirements and to develop more of a consultative role for CDPH during surveys. This will provide hospitals with greater opportunities to learn about best practices, help hospitals to increase quality of care and regulatory compliance, increase communication between hospitals and evaluators and reduce fear among hospitals about punishment or retaliation.

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. CHA requests that CDPH consider providing joint education for its evaluators and hospitals so that they have the same understanding about what hospitals need to do to maintain regulatory compliance. Such joint education should (1) be held regionally for accessibility, (2) provide consistent information, (3) focus on regulatory requirements and (4) be a dialogue, not a lecture.

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.

As a complement to these proposed regulations, CDPH should request an appropriation from the Legislature to use the funds from the Internal Departmental Quality Improvement Account to analyze data from hospital self-reports in an attempt to identify problem areas for hospitals and to provide them with consultation services pursuant to Health and Safety Code Section 1280 on best practices to prevent lapses in these problem areas. This important feedback mechanism can form a more cooperative relationship between CDPH and hospitals to improve quality of care and regulatory compliance.

C. The current regulatory scheme for general acute care hospitals and acute psychiatric hospitals is outdated and muddled, making full regulatory compliance effectively impossible. CDPH should review its regulations to ensure that requirements are up-to-date and relevant before implementing this enforcement system.

Hospitals are governed by a myriad of complex regulations that are woefully out-of-date. The licensure regulations contained in Title 22 of the California Code of Regulations (CCR) for general acute care hospitals were adopted in 1975. A great many of these regulations have not been updated since their initial adoption or for nearly as many years. (See, e.g., CCR, Title 22, sections 70129 [program flexibility, never substantively amended]; 70203 [medical service
general requirements, never amended], 70223 [surgical service general requirements, last amended in 1978], 70523 [radiological service general requirements, never amended], 70411-17 [basic emergency medical service, never amended], 70487 [intensive care newborn nursery service equipment and supplies, never amended], 70533 [outpatient service space, never amended], 71213 [psychiatric nursing service general requirements, never amended].) However, technology and the practice of medicine has changed greatly in the last four decades.

Following are some examples of the outdated nature of these requirements:

- The CDPH Licensing and Certification Policy and Procedure Manual permits program flexibility without formal approval from the department for eleven regulatory requirements when alternative requirements are met, partly because those requirements are outdated. (See Exh. 3.) For example, CDPH’s policy is to grant program flexibility with respect to the requirement that syringes and needles be rendered unusable prior to being discarded into waste containers if used intact needles are disposed of in rigid, puncture proof containers with a special one-way opening.

- The CDPH Policy and Procedure Manual acknowledges that CCRs, Title 22, Section 70801(a), is “obsolete” with respect to its references in conformance with Chapter 1, Division T17, Part 6, Title 24, California Administrative Code. Title 24 no longer exists.

- The CDPH Policy and Procedure Manual also acknowledges that CCRs, Title 22, Section 70847, is obsolete due to its references to the old Hazardous Waste Control Law, which was superseded by the Medical Waste Management Act of 1990.

- Health and Safety Code Section 1255.5(f) requires that policies, procedures and space requirements for intensive, intermediate and continuing intensive care newborn nursery services “shall be based upon the standards and recommendations of the American Academy of Pediatrics Guidelines for Perinatal Care, 1983.” (Emphasis added.)

- CCRs, Title 22, Section 70357, provides that “no special permit shall be issued for new special services for which there is no valid, subsisting, and unexpired Certificate of Need or Certificate of Exemption.” California suspended the requirement for a Certificate of Need more than 25 years ago.

- CCRs, Title 22, Section 70547, requires that policies and procedures for perinatal units reflect the standards and recommendations of the American College of Obstetricians and Gynecologists “Standard for Obstetric-Gynecologic Hospital Services,” 1969, and the American Academy of Pediatrics “Hospital Care of Newborn Infants,” 1971.

- CCRs, Title 22, Section 70549, provides that “[a] ratio of one licensed nurse to eight or fewer infants shall be maintained for normal infants.” However, the more
recently adopted Section 70217(a)(3)-(5) provides different ratios for different areas of perinatal units.

- CCRs, Title 22, Section 70217(a)(13) is also inconsistent with the staffing requirements in California Code of Regulations, Title 9, Section 663 for acute psychiatric departments.

- CCRs, Title 22, sections 70017 and 71017 define “conservator,” in part, by reference to Probate Code Section 1701 et seq., which was repealed in 1979.

Compliance with these outdated requirements is neither possible nor desirable. As the standards of practice have changed, compliance with out-of-date regulations could potentially create liability for hospitals. Prior to finalizing regulations intended to increase the administrative penalties for hospitals, CDPH should review its regulations and update them. Failure to do so may result in hospitals finding themselves having to choose between regulatory compliance and providing the highest quality of care.

**D. 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.**

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.

As a result of CDPH’s limited resources, CHA members have reported significant delays in CDPH’s responses to self-reports and complaints. In some cases, CDPH surveyors do not survey a hospital until two years after an adverse incident, which CDPH then after-the-fact labels an “immediate jeopardy.” If, in CDPH’s determination, these situations involve the likelihood of serious injury or death, they should be prioritized over other types of investigations. CDPH should also focus on hospitals with poor compliance records. For example, CMS has established time frames of two working days of the receipt of a complaint to commence immediate jeopardy complaint investigations and 10 working days to commence actual harm, self-report and complaint investigations. 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.

Moreover, CDPH’s proposed regulations focus almost exclusively on assessing administrative penalties without considering the impact they may have on hospitals or on CDPH. Based on data that CHA has gathered from sources such as the Office of Statewide Health Planning and Development, roughly 40 percent of hospital facilities in the state already have negative operating margins, which means their operating expenses exceed all revenue derived from operations. Since 1996, roughly 90 California hospitals have closed their doors completely or been converted into non-hospital facilities. The financial state of California hospitals affects the
availability of health care services: California ranks 49th among the states in terms of hospital bed availability, with only 1.9 hospital beds per 1,000 population.

CDPH’s proposed rules will further strain hospitals’ budgets by imposing substantial administrative penalties at a time when many hospitals strive to provide a high level of quality care with the limited and diminishing resources they have. As acknowledged in the IOM report, the assessment of administrative penalties for “active” errors will do little to prevent future errors, and has the consequence of pulling resources away from patient care. This will affect acute psychiatric hospitals even more than general acute care hospitals since they tend to be smaller and have fewer resources. Due to the grave impact these regulations may have on hospitals and the safety net in California, CDPH should reconsider the scope of these proposed regulations and focus its efforts on the most serious deficiencies and the most frequent offenders, instead of proposing a system that penalizes nearly any deficiency with a potential for more than minimal harm.

II. The proposed regulations are modeled on a nursing home system, which is not tailored to an acute care setting. CHA recommends that CDPH develop a different approach to assessing administrative penalties, specifically tailored to the acute care environment and following the Legislature’s mandate.

A. 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 has proposed to use the federal nursing home scope and severity grid as a model for its proposed regulations regarding acute care hospital administrative penalties. CDPH chose this approach because CDPH surveyors have been trained and are well-versed in the use of the parameters on the grid to evaluate deficiencies and because the “U.S. healthcare industry is also familiar with how this grid is used by CMS.” (Initial Statement of Reasons, p. 5.)

CHA questions CDPH’s rationale for using the nursing home system as a model. While CDPH surveyors may have been trained to use the nursing home system, the federal government has cited concerns about CDPH surveyors’ ability to appropriately designate the severity of deficiencies using this grid, as discussed below. Moreover, surveyors do not use this grid when surveying general acute care hospitals. Therefore, aside from distinct-part skilled-nursing facilities (SNFs), general acute care and acute psychiatric hospitals are not generally “familiar with how this grid is used by CMS.”

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. CDPH should develop a system to evaluate deficiencies and assess penalties that is specific to the acute care environment to address deficient practices appropriately, and facilitate solutions for the acute care setting.
B. The Legislature did not intend for CDPH to model its proposed regulations after the federal nursing home model. Instead, the Legislature mandated that the general acute care model be based on eight statutory criteria. Those criteria are the model for CDPH to specify, clarify, and make specific — not the scope and severity grid used by the federal government in the SNF setting.

SB 1312 involved two different reforms: (1) enforcement of deficient practices in a SNF and (2) the assessment of administrative penalties in hospitals. The legislative history of SB 1312 demonstrates that the Legislature considered the federal enforcement grid, attached as Exhibit 4. However, the Legislature specifically chose not to adopt the federal nursing home enforcement system’s scope and severity grid. Instead, the Legislature mandated that CDPH establish criteria for assessing administrative penalties, discussed above.

CDPH’s decision to use the nursing home grid as a model does not meet the Legislature’s mandate. The nursing home model considers only one out of the eight criteria set forth by the Legislature. While the proposed rules permit a variance of approximately +/- 28 percent, the most substantial amount (>70 percent) of the administrative penalties are assessed on only one set of criteria: the scope and severity of the violation.

The proposed rules only give lip service to the remaining criteria. For example, proposed Section 70954(b)(2) states:

In determining the level of severity using the matrix in subdivision (d), the following factors shall be considered:

(A) The patient’s physical and mental condition.

(B) The probability and severity of the risk that the violation presents to patients.

However, the definitions of the different severity levels in the matrix do not permit consideration of a patient’s physical and mental condition. The same act or omission may have vastly different impacts depending on the acuity of a patient, thereby giving rise to differing levels of severity for the same violation.

Similarly, the severity level does not properly take into account the probability and severity of the risk that the violation presents to patients. The main focus of the matrix is the severity of the resulting harm, i.e., whether it is likely to cause serious injury or death or has the potential for more than minimal harm that does not rise to the level of an immediate jeopardy. The proposed regulations do not distinguish between a one in 1,000,000,000 chance of death and a one in 100 chance of death. Because the provision of health care services often involves choices between different risks, properly assessing the probability and severity of risk involved is of utmost importance.

The attempt to consider the Legislature’s other prescribed criteria through the utilization of “adjustment factors” similarly gives little weight to those factors. Added together, those factors
affect less than 30 percent of the amount of an administrative penalty. None can prevent a provider from receiving any administrative penalty at all.

CHA requests that CDPH properly give weight to the eight criteria in Health and Safety Code Section 1280.3. In order to do so, CDPH should not use an underlying model that was rejected by the Legislature.

C. There are significant and long-term problems associated with the nursing home model that include (1) inconsistency, (2) questionable efficacy, (3) overburdening of the system, (4) poor definitions of measure and methods of measurement, and (5) rules that are confusing. The model for general acute care hospitals should be premised on evidence-based criteria to improve quality and patient outcomes. This model is not well-suited as an implementation tool, or as a model for quality advances to patient care in general acute care hospitals.

Since the implementation of the nursing home survey system, a wide variety of sources have evaluated the system. While earlier evaluations found that the nursing home system needed some changes, the most recent evaluations suggest that it needs to be revamped in its entirety. These studies are attached as exhibits 2 and 5 to 10. In summary:

- In December 1996, CMS received a report, Evaluation of the Long Term Care Survey Process, that it had commissioned from Abt Associates Inc. The report, attached as Exhibit 5, acknowledges the implementation of the new nursing home system was a good first step toward a more resident-centered and outcome-oriented survey process. However, the authors found the survey guidelines were often not used correctly or consistently. According to the report, many surveyors have difficulty assessing a large number of variables for each resident in their sample, stating that “The lack of explicit criteria to determine the frequency and/or severity of quality problems increases the difficulty of justifying citations.” The report also states that “insufficient consideration of case mix in outcome assessment for quality of care is evident, which appears to be related to the surveyors’ interpretation of sampling procedures, which results in over-representation of special care cases. If risk factors are not taken into consideration in outcome assessments, then nursing homes admitting residents at greatest risk for poor outcomes may be cited more frequently.”

- In 2000, the IOM published Improving the Quality of Long-Term Care, which concluded that while regulation had brought some limited improvements in nursing home care, further reform is still needed. This report is attached as Exhibit 6. With respect to the federal nursing home enforcement system, the IOM report recommends, inter alia: (1) greater focus on chronically poor performers by surveying them more frequently, increasing penalties for repeated violations of standards, and decertifying persistently substandard providers; (2) ensuring greater uniformity in state surveyor interpretation and application of survey regulations; and (3) more research into whether regulation enforcement had sufficient resources.
• In 2001, an academic researcher found that the nursing home enforcement system had made no positive changes in pressure sore, malnutrition, dehydration and bowel incontinence rates, while acknowledging improvements in some care indicators. (Walshe; see Exhibit 7.) The researcher also acknowledged that the changes in nursing home regulation may have resulted in the increasing domination of larger, multi-state corporations over smaller, single-site, owner-operated businesses and resulted in greater costs incurred by both nursing homes and enforcement agencies.

• In 2003, the U.S. Department of Health and Human Services, Office of Inspector General (OIG), issued a report, Nursing Home Deficiency Trends and Survey and Certification Process Consistency, attached as Exhibit 8. The OIG’s survey of state surveyors and survey and certification directors found that despite increasing number of assessed deficiencies, the majority of state surveyors and survey and certification directors reported that quality of care had stayed the same or declined over the last three years. The OIG found wide variations in state practices, including how each state determines both the number and type of deficiencies.

• In December 2005, the U.S. Government Accounting Office (GAO) published Nursing Homes: Despite Increased Oversight, Challenges Remain in Ensuring High-Quality Care and Resident Safety,” attached as Exhibit 9.8 GAO found inconsistency in how states conduct surveys and the understatement of serious quality problems by surveyors. In a series of reports, GAO has noted its key findings, including (1) a small proportion of nursing homes repeatedly caused actual harm to residents; (2) the result of state inspections understated the extent of serious quality-of-care and fire safety problems, reflecting weaknesses in the survey methodology and an inconsistent application of federal standards; (3) serious complaints alleging harm to residents remained uninvestigated for weeks and months; (4) when serious deficiencies were identified, federal and state enforcement policies did not ensure that deficiencies were addressed and remained corrected; and (5) federal oversight mechanisms of state monitoring were limited in their scope and effectiveness. GAO noted that there had been confusion among California surveyors as to what constituted “actual harm.” (p. 11.)

• In 2008, two professors from Brown University published a paper called “Balancing Regulatory Controls and Incentives: Toward Smarter and More Transparent Oversight in Long-Term Care,” attached as Exhibit 10. The professors analyzed the inconsistencies in the application and enforcement of regulations. Interestingly, the authors cited research that found that “most state regulators have not found monetary penalties to be effective in improving facilities’ responsiveness.” This article concludes that state-by-state differences

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8 This report is in the bill file for SB 1312.
in the patterns of deficiency citations could not be blamed on underlying differences in quality.

- In 2008, AAHSA issued its report, discussed above and attached as Exhibit 2. Its primary conclusion is that the current nursing home “survey and certification is broken and beyond repair.” AAHSA identified numerous flaws in the system, including (1) its emphasis on punishment, not quality improvement, (2) the adoption of extensive and highly detailed regulatory guidelines that has led to “an alarming inconsistency” in how surveyors interpret and apply requirements and cite deficiencies; (3) unrealistic expectations about how many recommended care processes can be measured and constrictive regulations that prevent innovation; (4) poor definitions of measures and methods of measurement; (5) confusing rules linking measures to deficiency statements; (6) a survey culture that depends on expert judgment; and (7) poor and increasingly strained communications between providers and surveyors. AAHSA proposed 31 short-term recommendations to help CMS improve the quality of survey teams; foster effective communication among regulators, surveyors and providers; better ensure consistent application of regulations; encourage providers to strive for excellence; facilitate accurate reporting to consumers; and improve the fairness of enforcement and dispute resolution.

Some of the many important themes to draw from this wealth of literature is that the nursing home enforcement system is not working well for nursing homes. The Legislature was aware of these shortcomings in the nursing home enforcement system as comments in the bill file identified them. (Exh. 11.) Again, it is with full knowledge of the nursing home enforcement system that the Legislature chose not to use that system as a model for the assessment of hospital administrative penalties.

If the model designed to improve quality of care in nursing homes is riddled with problems as applied to nursing homes, CHA believes that it is not an appropriate model for hospitals. This concern is heightened by the CMS-commissioned report that found that the nursing home enforcement system was less consistent when adjusted for case mix. Hospitals, by nature, have a more diverse case mix than nursing homes. **CHA emphasizes that the use of the nursing home system as a model for the assessment of penalties on hospitals is inappropriate. CDPH should follow the Legislature’s mandate by promulgating regulations that establish criteria for the fair and consistent assessment of administrative penalties.**

**D. The proposed rules selectively pick and choose from the federal nursing home model without any rationale.** If CDPH decides to continue using the nursing home enforcement system as a model, it should incorporate important protections for hospitals, such as the opportunity to correct and discount for waiving appeal rights.

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. **If CDPH decides to move forward with using**
the nursing home enforcement model, it should also import these important safeguards for providers.

For example, one important aspect of the federal nursing home enforcement system is the ability to correct violations before assessing penalties for most non-immediate jeopardy deficiencies. In the federal system, facilities may be given an opportunity to correct their non-immediate jeopardy deficiencies before remedies are imposed. (State Operations Manual, Sections 7304.1-7304.2.) This opportunity is not given to the facility if it has had deficiencies of actual harm or above in the current survey and in the previous standard survey or between the current survey and the last standard survey. CDPH should give hospitals an opportunity to correct non-immediate jeopardy deficiencies prior to the imposition of administrative penalties.

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, Title 42, Section 488.436.) CDPH should also reduce administrative penalties by a substantial amount if a hospital waives its right to appeal.

CHA recommends that the current proposed Section 70953 be renumbered subdivision 70953(a) and that the following subdivisions be added to proposed 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.

(c)(1) If a hospital waives its right to an appeal in accordance with Health and Safety Code Section 1280.3(f), any administrative penalty calculated pursuant to this article or Article 8 of Chapter 2 will be reduced by 35 percent.

(2) If the facility does not waive its right to an appeal in accordance with Health and Safety Code Section 1280.3(f), the administrative penalty is not reduced by 35 percent.

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 below, the “extent of noncompliance” scale is too vague for consistent application. 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 develop weightings for the initial penalty and adjustment factors that are arbitrary and capricious. CDPH should consult with CHA and other stakeholders to develop rational penalty factors.

A. The Initial Statement of Reasons provides no rationale for the weightings in the proposed regulations.

The Initial Statement of Reasons provides no rationale for the weightings for the matrix in proposed Section 70954 or for any of the proposed adjustment factors. For example, for the matrix in proposed Section 70954, the Initial Statement of Reasons only states that the penalty amounts are scaled from zero to 100 percent to result in increasingly higher initial penalties corresponding to the increasing seriousness of the deficiency. However, these assigned numbers do not appear to be tied to any rational benchmark or range. 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. For example:

- The assignment of adjustment factors for the patient’s physical and mental condition in Section 70955(a)(1) is arbitrary. This set of adjustment factors takes the impact of the alleged deficiency into account for a second time when it was considered in assessing the severity of the deficiency for the purposes of proposed Section 70954 and should be deleted.

- When factors beyond the hospital’s control restrict its ability to comply with licensure requirements, the adjustment figure in proposed Section 70955(a)(3) should be significantly more than 5 percent, and in the range of 75 percent. A hospital should not be held liable for deficiencies beyond its control.

- There is no rationale given for the downward adjustment of 20 percent if a hospital immediately corrects a violation while the federal nursing home system permits a downward adjustment of 50 percent under similar conditions. Proposed subdivision 70957(a) should be amended to provide a 50 percent reduction if the hospital immediately corrects the violation.

- CDPH also gives no rationale as to why an isolated incident for a facility that has demonstrated consistent regulatory compliance should only be subject to a five percent reduction pursuant to proposed Section 70957(b)(1). If a hospital has consistently complied with licensure requirements, it should be able to have its administrative penalty reduced by more than five percent, and in the range of 25 percent. CDPH should focus its efforts on “poor-performing” facilities.

Lastly, CDPH has presented no rationale as to how it established the penalties for violations of the hospital fair pricing policies requirements.
CHA requests that CDPH convene stakeholder meetings to establish rational benchmarks for the base penalty amounts and adjustment factors. Multiplying irrational base penalties by irrational adjustment factors can only lead to arbitrary and capricious results.

B. The overly prescriptive method of defining penalty amounts is out of line with other fines.

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:

### Minimum Penalty Amounts

<table>
<thead>
<tr>
<th>Severity Level:</th>
<th>Minimal</th>
<th>Moderate</th>
<th>Major</th>
</tr>
</thead>
<tbody>
<tr>
<td>6: Immediate jeopardy to patient health and safety – death</td>
<td>$53,437</td>
<td>$53,437</td>
<td>$53,437</td>
</tr>
<tr>
<td>5: Immediate jeopardy to patient health and safety – serious injury</td>
<td>$32,062</td>
<td>$37,406</td>
<td>$42,750</td>
</tr>
<tr>
<td>4: Immediate jeopardy to patient health and safety – likely to cause serious injury or death</td>
<td>$21,375</td>
<td>$26,718</td>
<td>$32,062</td>
</tr>
<tr>
<td>3: Actual harm that is not immediate jeopardy</td>
<td>$10,687</td>
<td>$14,250</td>
<td>$17,812</td>
</tr>
<tr>
<td>2: No actual harm but with potential for more than minimal harm, not immediate jeopardy</td>
<td>$3,562</td>
<td>$6,234</td>
<td>$8,906</td>
</tr>
</tbody>
</table>

By contrast, the federal nursing home enforcement system modeled by CDPH utilizes significantly lower penalty amounts. That system has two levels of types of civil monetary penalties: per day penalties that range from $50 to $10,000 per day of noncompliance, or per instance penalties that range from $1,000 to $10,000 per instance of noncompliance. (State
CDPH’s proposed minimum penalties are more than three times the amount of CMS’ minimum per instance penalties.

The proposed minimum fines are also excessive compared to the state nursing home enforcement system. The Long-Term Care, Health, Safety, and Security Act (Health and Safety Code Sections 1417, et seq.) governs long-term care providers and provides for issuance of citations for Class “AA,” Class “A” and Class “B” violations, and the imposition of civil penalties for regulatory violations. Class “B” violations are those that have a direct or immediate relationship to the health, safety or security of patients in a long-term health care facility, other than Class “A” violations. Class “A” violations are those which present an imminent danger or substantial probability that death or serious harm to the patients of a long-term care facility would result therefrom. Class “AA” violations are Class “A” violations that are a direct proximate cause of death of a patient in a long-term health care facility.9

The Long-Term Care, Health, Safety, and Security Act provides for heightened penalties to be levied against SNFs. A class “A” violation is analogous to a severity level 4 deficiency in the proposed regulations. While CDPH may only assess a $2,000 to $20,000 penalty for a class “A” violation, the proposed regulations would mandate that CDPH assess a penalty of at least $21,375 for a severity level 4 deficiency:

<table>
<thead>
<tr>
<th>State Nursing Home Citation Level</th>
<th>Fine Range for Skilled Nursing Facility</th>
<th>Proposed Rule Equivalent Severity Level</th>
<th>Proposed Fine Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>“AA” Violation</td>
<td>$25,000-$100,000</td>
<td>Severity Level 6</td>
<td>$53,437-$125,000</td>
</tr>
<tr>
<td>“A” Violation</td>
<td>$2,000-$20,000</td>
<td>Severity Levels 4-5</td>
<td>$21,375-$125,000</td>
</tr>
<tr>
<td>“B” Violation</td>
<td>$100-$2,000</td>
<td>Severity Levels 2-3</td>
<td>$3,562-$25,000</td>
</tr>
</tbody>
</table>

Administrative penalties assessed by other states also tend to be in a much smaller dollar amount than those proposed by CDPH and typically do not establish mandatory minimum penalties. For example:

<table>
<thead>
<tr>
<th>State</th>
<th>Penalty Amounts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Florida</td>
<td>Up to $1,000 per violation, per day, no minimum.</td>
</tr>
<tr>
<td>New Mexico</td>
<td>Assessed based on initial base penalty ($100-$5,000) plus per day penalty (not to exceed</td>
</tr>
</tbody>
</table>

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9 Health and Safety Code Section 1424.
<table>
<thead>
<tr>
<th>State</th>
<th>Penalties</th>
</tr>
</thead>
<tbody>
<tr>
<td>New York</td>
<td>Up to $2,000 per violation, up to $5,000 per subsequent violation, and up to $10,000 if the violation directly results in serious physical harm to any patient or patients, no minimum</td>
</tr>
<tr>
<td>Pennsylvania</td>
<td>Up to $500 for each deficiency per day, no minimum</td>
</tr>
<tr>
<td>Texas</td>
<td>Up to $1,000 per violation, no minimum</td>
</tr>
</tbody>
</table>

The establishment of minimum administrative penalties is problematic, especially since the proposed regulations could permit a single incident to give rise to multiple deficiencies, without limit. This could result in excessive fines for hospitals, which are already suffering financial strain, and result in more resources being diverted from patient care.

CDPH has established very high minimum administrative penalties, despite any authority from the Legislature and without regard to the fines permitted by similar enforcement systems. CHA urges CDPH to reconsider these minimum administrative penalties to establish penalty amounts in line with other similar monetary penalty systems.

IV. The criteria to determine penalties needs to provide details that clarify how each of the eight statutory criteria are weighted, and give equal value and attention to the factors that would lessen the penalty amount for deficient practices above minor violations. The regulations do not address, clarify or specify how each of the eight statutory factors are weighted.

As discussed above, the proposed regulations give significant consideration to only one set of criteria enunciated by the Legislature: the nature, scope, and severity of the violation. The proposed regulations fail to give any significant consideration to the other seven criteria, such as:

- The patient’s physical and mental condition. Although proposed Section 70954(b)(2) states that evaluators should consider a patient’s physical and mental condition when determining the level of severity using the matrix in Section 70954(d), it provides no guidance regarding how an evaluator may do that. Pursuant to the matrix, the severity levels are assigned based on the level of actual or potential harm and the amount of that actual or potential harm. The proposed regulations provide no flexibility for consideration of the patient’s physical and mental condition. Proposed Section 70955(a)(1) creates an initial penalty

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10 The matrix considers only the scope and severity of the violation and does not properly consider the nature of the violation.
adjustment factor for the patient’s physical and mental condition that looks only at the patient’s condition after an alleged violation, but does not consider the patient’s condition before the violation. 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, as follows:

(a)(1) Patient’s physical and mental condition. The initial penalty may be adjusted downward by up to 75 percent based upon the patient’s physical and mental condition.

(A) The initial penalty shall be adjusted upward by 10 percent, if the violation caused actual harm to the patient at severity level 3 or 5 resulting in a physical or mental impairment that substantially limits one or more of the major life activities of a patient, or the loss of bodily function, if the impairment or loss lasts more than seven days or is still present at the time of discharge from the hospital, or the loss of a body part, or

(B) The initial penalty shall be adjusted upward by 5 percent, if the violation caused actual harm to the patient at severity level 3 or 5 resulting in a physical or mental impairment that substantially limits one or more of the major life activities of a patient, or the loss of bodily function, if the impairment or loss lasts more than three days.

The probability and severity of the risk that the violation presents to the patient. 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. 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, attached as Exhibit 12. 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 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.
The facility’s history of compliance with related state and federal statutes and regulations. Proposed Section 70957 permits a reduction of five percent if hospital inspections within the last three years noted no state or federal deficiencies that resulted in patient harm or immediate jeopardy. It also permits an increase of five percent if the hospital has three or more repeat deficiencies that pose a risk of more than minimal harm to patient health or safety within the three year period immediately prior to the date of the violation. Proposed Section 70953 should be amended as discussed above to provide hospitals with an opportunity to correct. 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** 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).

Factors beyond the facility’s control that restrict the facility’s ability to comply with this chapter or the rules and regulations promulgated thereunder. 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 not continue to penalize facilities in situations when the outcome is not in their control. 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 hospital’s control that restrict the hospital’s ability to comply with licensure requirements, the initial penalty may be adjusted downward by up to **75 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.

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, that 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 nondelegable 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 that 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.

- 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 percent, provided that all of the following apply . . . .

In conclusion, the proposed regulations need to give equal attention or weight to factors that would reduce the penalty amount, those being the history of compliance (not noncompliance), circumstances beyond a hospital’s control, or demonstrated willfulness of the violation.

V. 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.

A. The exception for minor violations is not properly defined in the proposed regulations.

Health and Safety Code Section 1280.3 as initially proposed by the Legislature did not include an exception for “minor violations.” However, in response to CHA advocacy, the Legislature added the exception in Health and Safety Code Section 1280.3(c) prohibiting CDPH from assessing penalties for “minor violations.” That term was not defined in SB 1312.

CHA’s intent in negotiating this amendment was to ensure that CDPH did not assess administrative penalties for mere technical violations that do not reasonably lead to a risk of harm to patients. CHA advocated for this exception in part because hospital licensure requirements are often technical and outdated. For example, an acute psychiatric hospital could be cited for violation of California Code of Regulations, Title 22, Section 71647(c), for failing to render a needle unusable prior to discarding it into a waste container, even if the hospital complied with the current standard of care by disposing the intact needle in a rigid, puncture proof container with a special one-way opening. As another example, a hospital could be cited for failing to post a hospital’s new license after the expiration of the prior license. However, a reasonable person would not foresee that either of these violations would lead to any material risk to patients.

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.” 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.11

B. 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.”12 Moreover, the reliance of a “likelihood” standard necessitates expert medical opinion to determine whether the probability of serious injury or death is high enough to constitute an immediate jeopardy. CHA recommends that CDPH clarify the definition of the phrase “is likely to cause” within the definition of “immediate jeopardy” to mean “presents an

11 CHA proposes a definition for the term “actual patient harm” below.

12 South Ridge Nursing and Rehab. Center, DAB No. 1778 (2001); see also Grace Healthcare of Benton v. U.S. Dept. of Health and Human Servs., 603 F.3d 412, 421 (overturning Departmental Appeals Board (“DAB”) affirmation of immediate jeopardy finding as contrary to interpretation of “immediate jeopardy” in prior DAB decisions).
imminent danger or substantial probability that death or serious harm would result therefrom.”

- 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.

- “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.” **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.

- There is no meaningful distinction between “actual patient harm” (severity level 3) and “serious injury” (severity level 5). 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. **CHA recommends that severity level 5 be clarified to mean serious injury that substantially limits one or more of the activities of daily living, or the loss of bodily function, if the impairment or loss lasts more than seven days.**

- There is likewise 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.**

- 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

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13 This language is comparable to the language used in Health and Safety Code section 1424(d) with respect to nursing home citations.

14 In the matrix, the term “actual harm” is used. The terminology “actual patient harm” should consistently be used to avoid confusion.
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.”

C. 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[] somewhat from the requirement,” “but not as well as if all provisions had been met,” (2) “deviate[] from the requirement, but. . . compl[y] to some extent, although not all of its important provisions are complied with,” or (3) “deviate[] 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. Moreover, as discussed above, CDPH has provided no rationale for constructing this confusing scale; these definitions are not required by the statute. CHA requests that CDPH withdraw the “extent of noncompliance” scale as it is too vague for consistent implementation.

D. CDPH should clarify the definition of the word “deficiency” so that only one deficiency may be assessed per type of violation per incident.

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. CHA urges CDPH to revise paragraph 70952(a)(2) to read:

(2) “Deficiency” means a licensee’s failure to comply with any law relating to the operation or maintenance of a hospital as a requirement of licensure under Health and Safety Code or this division. The department will assess only one deficiency and one administrative penalty if:

(A) a violation of a single requirement of licensure occurred, even though numerous patients were exposed to the potential for harm, or

(B) a violation occurred of more than one requirement of licensure creating a situation directly affecting patient health, safety or security, and each violation does not independently
meet the necessary criteria for the assessment of an administrative penalty.

The department may issue more than one deficiency and one administrative penalty if:

(A) a violation occurred of more than one requirement of licensure or the violation had the potential to cause or caused harm to more than one patient, and

(B) each violation can independently meet the necessary criteria for the assessment of an administrative penalty.

E. 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. 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.

This practice would conflict with the Legislature’s intent behind Health and Safety Code Section 1280.3(a). A Senate Health Statement drafted by the author of SB 1312 from August 30, 2006, attached as Exhibit 13, specifically describes CHA’s request that the Senate “[a]dopt amendments that would prevent double fines for a single incident.” In response, the author offered to “place a letter in the journal assuring that single incidents of immediate jeopardy are not dually fined by separate agencies, if necessary.” Proposed subdivision 70954(d) should clarify that single incidents of immediate jeopardy will not be counted as multiple immediate jeopardy deficiencies for the purposes of assessing administrative penalties:

... An immediate jeopardy penalty shall be considered a first administrative penalty if the date the violation occurred is more than three years from the date of violation of the last state-issued immediate jeopardy penalty, the hospital has not received additional state-issued immediate jeopardy violations, and the department finds that the hospital has been in substantial compliance for more than three years prior to the date of the violation that is the subject of the penalty calculation.

F. Proposed subparagraph 70957(a)(1)(C) is vague and should be clarified.
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, met 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.”**

G. 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 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.”**

- 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.”**

**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 H&SC 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, or

(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.

VI. The proposed regulations need to be based on principles of due process and fundamental fairness, and facilitate the benefits highlighted in the Initial Statement of Reasons to more effectively enforce compliance, deter less serious violations, and promote statewide consistency. To ensure fairness, the proposed regulations should establish procedural safeguards.

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 recalculated.

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
of deficiencies, but CDPH delays can run into years. This delay compounds the long, sometimes years-long, delays by CDPH to investigate deficiencies. Currently, many hospitals have appeals that have been outstanding for years and hearings have not yet been scheduled. When CDPH fails to respond in a timely manner to a request for an appeal, the appeal should be deemed to be granted.

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.

VII. The proposed regulations unlawfully seek to impose retroactive effects. CDPH should amend these regulations so that they are only effective prospectively.

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 proposed subdivision 70951(b) to clarify that immediate jeopardy penalties pursuant to Health and Safety Code

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15 People v. Grant (1999) 20 Cal.4th 150, 157, citing Landgraf v. USI Film Products (1994) 511 U.S. 244, 269 [emphasis in original].


18 Myers, 28 Cal.4th at 840; see Cal. Civil Code § 3.
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).

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CHA appreciates the opportunity to submit comments on the proposed rule. We urge CDPH to give careful consideration to our comments and recommendations and make the necessary changes to ensure that hospitals are treated fairly under the proposed rules. If you have questions, please do not hesitate to contact me at (916) 552-7574 or Jana DuBois, CHA vice president and legal counsel, at (916) 552-7636.

Very truly yours, David Perrott, MD, DDS
Senior Vice President & Chief Medical Officer