ConsumersUnion
POLICY & ACTION FROM CONSUMER REPORTS

December 10, 2012

Ron Chapman, MD, MPH
Director, Department of Public Health
Office of Regulations
MS 0507
P.O. Box 997377
Sacramento, CA 95899-7377

Re: Administrative Penalties: General Acute Care Hospitals: DPH-09-012

Dear Dr. Chapman,

Consumers Union, the advocacy and policy division of Consumer Reports, along with our Safe Patient Project and California's Niles Project, write to comment on the proposed regulations on hospital administrative penalties, specifically focusing on fines assessed due to a hospital's noncompliance with laws that has caused or is likely to cause serious injury or death to a patient.

The proposed regulations leave several gaps in effectively implementing these fines and we urge that they be revised to provide clarity and to more appropriately fine the worst violators. We believe making these changes will result in achieving the intended effect of ensuring that acute care hospitals fully comply with licensing standards, while giving the department powerful sanctions to enforce the laws and regulations governing the safety of patients in acute care hospitals.

The Effect of "Actual and Potential Patient Harm"

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 following:

> T*he criteria shall include, but need not be limited to, 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 this chapter or the rules and regulations promulgated thereunder.*
> *(7) The demonstrated willfulness of the violation.*

(8) The extent to which the facility detected the violation and took steps to immediately correct the violation and prevent the violation from recurring.

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:

- 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.
- 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.
- 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.

Immediate Jeopardy Violations: Serious Injury, likely to cause serious injury or death

While the statute gives the department some discretion in assessing fines, we do not find statutory authority for giving a different status for violations that cause serious injury and those that 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 these regulations propose that a violation 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). We oppose the proposed diminution of immediate jeopardy violations in the manner proposed by the department. In other words, the fines for Severity level 5 and 4 should be the same as Severity level 6 – that is, 100% of the fines allowed.

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, addressed below in order of importance:

Willful violation. 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.

Financial harm. The proposed adjustment for actual financial harm is not consistent with the statute, which makes this one of the specific criteria that must be applied. The proposed one percent increase in the penalty is seriously insufficient, when one considers the *actual financial harm* to patients from a preventable readmissions or longer hospital stays. This proposed adjustment for a Severity Level 2 minimal fine of 20% of $25,000 amounts to $50. This adjustment should be raised. Further, limiting the adjustment to "information discovered by the department during the normal course of an investigation" has no basis in statute and undermines the Administration's efforts to reduce preventable readmissions and hospital infections. We note that Medicare has begun reducing hospital payments for preventable readmissions and has reduced payments to *three quarters* of American hospitals on this basis, including many in California. This information is available to the department, but may not be during the normal course of an investigation.

Factors beyond the hospital's control. The downward adjustment appears to be limited to those situations which constitute disasters and emergencies. We do not object to this, but suggest that the current language is unclear and minor amendments to this section could clarify that the department's intent is to limit this adjustment to only these situations.

Further, we urge that additional adjustments be considered:

Multiple Violations in the Same Hospital. 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.

Number of patients affected, Duration of violation. 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. The proposed regulation needs to be amended for clarity and to ensure the department has a range of sanctions to address both isolated incidents quickly identified and cured, as well as longer term, larger scale violations. As currently drafted, the adjustments to the base penalty do not accomplish this.

Penalties for Violations of Hospital Fair Pricing Policy Requirements

In a separate letter, we note, we joined with Health Access California, Western Center on Law and Poverty and other consumer advocates in opposing the proposed regulation on penalties for violations of the hospital fair pricing requirements as inconsistent with the statute requiring that penalties be based on actual financial harm.

Conclusion

The proposed regulations, in several areas, miss the mark to clearly create fines that focus on the worse situations that put patient safety at risk. We urge you to address the issues we have raised in these comments. We have not provided alternative language to the sections we are urging the department to change, but will be happy to work with department staff on the needed revisions.

Sincerely,

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