

WSR 22-18-076

PROPOSED RULES

DEPARTMENT OF HEALTH

[Filed September 2, 2022, 12:01 p.m.]

Original Notice.

Preproposal statement of inquiry was filed as WSR 21-21-008.

Title of Rule and Other Identifying Information: WAC 246-320-011 Department responsibilities—Licensing—Adjudicative proceeding; and new WAC 246-320-013 Department responsibilities—Enforcement. The department of health (department) is proposing a severity matrix for civil fines related to acute care hospital enforcement in order to implement 2SHB 1148 (chapter 61, Laws of 2021).

Hearing Location(s): On October 11, 2022, at 10:00 a.m. In response to the coronavirus disease 2019 (COVID-19), the department of health (DOH) will not provide a physical location for this hearing. This promotes social distancing and the safety of the citizens of Washington state. A virtual public hearing, without a physical meeting space, will be held instead. Register in advance for this webinar https://us02web.zoom.us/webinar/register/WN_KqecnygxTg-ZJ4kaojdQzg. After registering, you will receive a confirmation email containing information about joining the webinar.

Date of Intended Adoption: October 18, 2022.

Submit Written Comments to: Julie Tomaro, P.O. Box 47843, Olympia, WA 98504, email <https://fortress.wa.gov/doh/policyreview>, fax 360-236-2321, by October 11, 2022.

Assistance for Persons with Disabilities: Contact Julie Tomaro, phone 360-236-2937, fax 360-236-2321, TTY 711, email julie.tomaro@doh.wa.gov, by October 4, 2022.

Purpose of the Proposal and Its Anticipated Effects, Including Any Changes in Existing Rules: The department is proposing to amend WAC 246-320-011 and create new WAC 246-320-013 to establish a severity matrix for civil fines for licensed acute care hospitals. Section 2 of 2SHB 1148 allows the department, under RCW 43.70.095, to assess a civil fine of up to \$10,000 per violation, not to exceed a total fine of \$1,000,000, on a hospital licensed under chapter 70.41 RCW, when the department determines: (1) The hospital has previously been subject to an enforcement action for the same or similar type of violation of the same statute or rule; (2) the hospital has been given any previous statement of deficiency that included the same or similar type of violation of the same or similar statute or rule; or (3) the hospital failed to correct noncompliance with a statute or rule by a date established or agreed to by the department. The proposed rule sets these fine amounts and establishes a matrix of severity and process by which they will be applied.

Reasons Supporting Proposal: In 2021, 2SHB 1148 was passed, which requires the department to adopt rules establishing specific fine amounts for licensed acute care hospitals in relation to: (1) The severity of the noncompliance and at an adequate level to be a deterrent to future noncompliance; and (2) the number of licensed beds and the operation size of the hospital. The department conducted workshops and solicited input from interested parties in order to create a fair yet binding regulation that addresses the intent of the bill.

Statutory Authority for Adoption: RCW 70.41.030.

Statute Being Implemented: 2SHB 1148 (chapter 61, Laws of 2021); RCW 70.41.130.

Rule is not necessitated by federal law, federal or state court decision.

Name of Proponent: DOH, governmental.

Name of Agency Personnel Responsible for Drafting, Implementation, and Enforcement: Julie Tomaro, 111 Israel Road S.E., Tumwater, WA 98501, 360-236-2937.

A school district fiscal impact statement is not required under RCW 28A.305.135.

A cost-benefit analysis is required under RCW 34.05.328. A preliminary cost-benefit analysis may be obtained by contacting Julie Tomaro, P.O. Box 47843, Olympia, WA 98504, phone 360-236-2937, TTY 711, email julie.tomaro@doh.wa.gov.

This rule proposal, or portions of the proposal, is exempt from requirements of the Regulatory Fairness Act because the proposal:

Is exempt under RCW 19.85.025(4).

Explanation of exemptions: This proposed rule only applies to licensed acute care hospitals; these do not meet the definition of "small business" in RCW 18.85.020. Additionally, the proposed rule establishes fine amounts in relation to the severity of noncompliance that would only be assessed on an acute care hospital that repeatedly did not comply with regulations; the rule does not impose costs for compliance with regulations.

Scope of exemption for rule proposal:

Is fully exempt.

September 2, 2022
 Todd Mountin, PMP
 Deputy Secretary of Operations
 for Umair A. Shah, MD, MPH
 Secretary

OTS-3896.2

AMENDATORY SECTION (Amending WSR 09-07-050, filed 3/11/09, effective 4/11/09)

WAC 246-320-011 Department responsibilities—Licensing—Adjudicative proceeding. This section identifies the actions and responsibilities of the department for licensing hospitals.

(1) Before issuing an initial license, the department will verify compliance with chapter 70.41 RCW and this chapter which includes, but is not limited to:

- (a) Approval of construction documents;
- (b) Receipt of a certificate of need as provided in chapter 70.38 RCW;
- (c) Approval by the local jurisdiction of all local codes and ordinances and the permit to occupy;
- (d) Approval of the initial license application;
- (e) Receipt of the correct license fee;
- (f) Compliance with the on-site survey conducted by the state fire marshal required in RCW 70.41.080; and
- (g) Conduct an on-site licensing survey in accordance with WAC 246-320-016.

(2) The department may issue a license to include two or more buildings, if the applicant:

(a) Meets the requirements listed in subsection (1) of this section;

(b) Operates the buildings as an integrated system with:

(i) Governance by a single authority over all buildings or portions of buildings;

(ii) A single medical staff for all hospital facilities; and

(iii) Use all policies and procedures for all facilities and departments.

(c) Arranges for safe and appropriate transport of patients between all facilities and buildings.

(3) Before reissuing a license, the department will:

(a) Verify compliance with the on-site survey conducted by the state fire marshal required in RCW 70.41.080;

(b) Review and accept the annual hospital update information documentation;

(c) Assure receipt of the correct annual fee; and

(d) Reissue licenses as often as necessary each calendar year so that approximately one-third of the hospital licenses expire on the last day of the calendar year.

(4) The department may issue a provisional license to allow the operation of a hospital, if the department determines that the applicant or licensed hospital failed to comply with chapter 70.41 RCW or this chapter.

~~((5) The department may deny, suspend, modify, or revoke a license when it finds an applicant or hospital has failed or refused to comply with chapter 70.41 RCW or this chapter. The department's notice of a license denial, suspension, modification, or revocation will be consistent with RCW 43.70.115. The proceeding is governed by the Administrative Procedure Act chapter 34.05 RCW, this chapter, and chapters 246-08 and 246-10 WAC. If this chapter conflicts with chapter 246-08 or 246-10 WAC, this chapter governs.))~~

[Statutory Authority: Chapter 70.41 RCW and RCW 43.70.040. WSR 09-07-050, § 246-320-011, filed 3/11/09, effective 4/11/09.]

NEW SECTION

WAC 246-320-013 Department responsibilities—Enforcement. (1)

The department may deny, suspend, modify, or revoke a license when it finds an applicant or hospital has failed or refused to comply with chapter 70.41 RCW or this chapter. The department's notice of a license denial, suspension, modification, or revocation will be consistent with RCW 43.70.115. The proceeding is governed by the Administrative Procedure Act chapter 34.05 RCW, this chapter, and chapters 246-08 and 246-10 WAC. If this chapter conflicts with chapter 246-08 or 246-10 WAC, this chapter governs.

(2) The department may assess civil fines on a hospital according to RCW 70.41.130.

(a) The department may assess a civil fine of up to \$10,000 per violation, not to exceed a total fine of \$1,000,000, on a hospital when:

(i) The hospital has previously been subject to an enforcement action for the same or similar type of violation of the same statute or rule; or

(ii) The hospital has been given any previous statement of deficiency that included the same or similar type of violation of the same or similar statute or rule; or

(iii) The hospital failed to correct noncompliance with a statute or rule by a date established or agreed to by the department.

(b) The department will assess civil fine amounts based on the scope and severity of the violation(s) and in compliance with (g) and (h) of this subsection:

(c) The "severity of the violation" will be considered when determining fines. Levels of severity are categorized as follows:

(i) "**Low**" means harm could happen but would be rare. The violation undermines safety or quality or contributes to an unsafe environment but is very unlikely to directly contribute to harm;

(ii) "**Moderate**" means harm could happen occasionally. The violation could cause harm directly but is more likely to cause harm as a continuing factor in the presence of special circumstances or additional failures. If the deficient practice continues, it would be possible that harm could occur but only in certain situations or patients;

(iii) "**High**" means harm could happen at any time or did happen. The violation could directly lead to harm without the need for other significant circumstances or failures. If the deficient practice continues, it would be likely that harm could happen at any time to any patient.

(d) Factors the department will consider when determining the severity of the violation include:

(i) Whether harm to the patient(s) has occurred, or could occur;

(ii) The impact of the actual or potential harm on the patient(s);

(iii) The degree to which the hospital demonstrated noncompliance with requirements, procedures, policies or protocols;

(iv) The degree to which the hospital failed to meet the patient's physical, mental, and psychosocial well-being; and

(v) Whether a fine at a lower severity has been levied and the condition or deficiency related to the violation has not been adequately resolved.

(e) The scope of the violation is the frequency, incidence, or extent of the occurrence of the violation(s). The levels of scope are defined as follows:

(i) "**Limited**" means a unique occurrence of the deficient practice that is not representative of routine or regular practice and has the potential to impact only one or a very limited number of patients, visitors, or staff. It is an outlier. The scope of the violation is limited when one or a very limited number of patients are affected or one or a very limited number of staff are involved, or the deficiency occurs in a very limited number of locations.

(ii) "**Pattern**" means multiple occurrences of the deficient practice, or a single occurrence that has the potential to impact more than a limited number of patients, visitors, or staff. It is a process variation. The scope of the violation becomes a pattern when more than a very limited number of patients are affected, or more than a very limited number of staff are involved, or the situation has occurred in several locations, or the same patient(s) have been affected by repeated occurrences of the same deficient practice.

(iii) **"Widespread"** means the deficient practice is pervasive in the facility or represents a systemic failure or has the potential to impact most or all patients, visitors, or staff. It is a process failure. Widespread scope refers to the entire organization, not just a subset of patients or one unit.

(f) When determining the scope of the violation, the department will also consider the duration of time that has passed between repeat violations, up to a maximum of two prior survey cycles.

(g) The department will consider the operation size of the hospital and the number of licensed beds when assessing a civil fine based on the following tables:

Table 1: 0-25 and 26-99 licensed beds

Fine Amounts in Relation to the Scope and Severity of the Violation			
Scope	Severity		
	Low	Moderate	High
Limited	\$500 - \$550	\$1,000 - \$1,100	\$2,000 - \$2,200
Pattern	\$1,000 - \$1,100	\$2,000 - \$2,200	\$4,000 - \$4,400
Widespread	\$1,500 - \$1,650	\$3,000 - \$3,300	\$5,000 - \$5,500

Table 2: 100-299 licensed beds

Fine Amounts in Relation to the Scope and Severity of the Violation			
Scope	Severity		
	Low	Moderate	High
Limited	\$500 - \$650	\$1,000 - \$1,300	\$2,000 - \$2,600
Pattern	\$1,000 - \$1,300	\$2,000 - \$2,600	\$4,000 - \$5,200
Widespread	\$1,500 - \$1,950	\$3,000 - \$3,900	\$5,000 - \$6,500

Table 3: 300+ licensed beds

Fine Amounts in Relation to the Scope and Severity of the Violation			
Scope	Severity		
	Low	Moderate	High
Limited	\$500 - \$1,000	\$1,000 - \$2,000	\$2,000 - \$4,000
Pattern	\$1,000 - \$2,000	\$2,000 - \$4,000	\$4,000 - \$8,000
Widespread	\$1,500 - \$3,000	\$3,000 - \$6,000	\$5,000 - \$10,000

(h) The department may assess a civil fine that is higher than the maximum fine amounts in (g) of this subsection, not to exceed \$10,000 per violation, if it determines that the maximum fine amounts listed in (g) of this subsection would not be sufficient to deter future noncompliance.

(i) A hospital may appeal the department's action of assessing civil fines under RCW 43.70.095.

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