



RULE-MAKING ORDER PERMANENT RULE ONLY

CR-103P (December 2017) (Implements RCW 34.05.360)

CODE REVISER USE ONLY

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STATE OF WASHINGTON
FILED

DATE: December 20, 2022

TIME: 4:11 PM

WSR 23-01-131

Agency: Department of Health

Effective date of rule:

Permanent Rules

31 days after filing.

Other (specify) _____ (If less than 31 days after filing, a specific finding under RCW 34.05.380(3) is required and should be stated below)

Any other findings required by other provisions of law as precondition to adoption or effectiveness of rule?

Yes No If Yes, explain:

Purpose: WAC 246-320-011 Department responsibilities - Licensing - Adjudicative proceeding and new WAC 246-320-013 Department responsibilities - Enforcement. The Department of Health (department) is adopting a severity matrix for civil fines related to acute care hospital enforcement in order to implement Second Substitute House Bill (2SHB) 1148 (chapter 61, laws of 2021).

Citation of rules affected by this order:

New: WAC 246-320-013

Repealed: None

Amended: WAC 246-320-011

Suspended: None

Statutory authority for adoption: RCW 70.41.030

Other authority: 2SHB 1148 (chapter 61, laws of 2021)

PERMANENT RULE (Including Expedited Rule Making)

Adopted under notice filed as WSR 22-18-076 on 09/02/2022.

Describe any changes other than editing from proposed to adopted version: There were no changes to the proposed rule.

If a preliminary cost-benefit analysis was prepared under RCW 34.05.328, a final cost-benefit analysis is available by contacting:

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Other:

**Note: If any category is left blank, it will be calculated as zero.
No descriptive text.**

**Count by whole WAC sections only, from the WAC number through the history note.
A section may be counted in more than one category.**

The number of sections adopted in order to comply with:

Federal statute:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Federal rules or standards:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Recently enacted state statutes:	New	<u>1</u>	Amended	<u>1</u>	Repealed	<u>0</u>

The number of sections adopted at the request of a nongovernmental entity:

New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
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The number of sections adopted on the agency's own initiative:

New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
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The number of sections adopted in order to clarify, streamline, or reform agency procedures:

New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
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The number of sections adopted using:

Negotiated rule making:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Pilot rule making:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Other alternative rule making:	New	<u>1</u>	Amended	<u>1</u>	Repealed	<u>0</u>

Date Adopted: December 20, 2022

Name: Kristin Peterson, JD for Umair A. Shah, MD, MPH

Title: Chief of Policy for Secretary of Health

Signature:



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.))~~

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.