



PROPOSED RULE MAKING

CR-102 (July 2022)
(Implements RCW 34.05.320)
Do NOT use for expedited rule making

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STATE OF WASHINGTON
FILED

DATE: September 02, 2022

TIME: 12:01 PM

WSR 22-18-076

Agency: Department of Health

Original Notice

Supplemental Notice to WSR _____

Continuance of WSR _____

Preproposal Statement of Inquiry was filed as WSR 21-21-008 ; or

Expedited Rule Making--Proposed notice was filed as WSR _____; or

Proposal is exempt under RCW 34.05.310(4) or 34.05.330(1); or

Proposal is exempt under RCW _____.

Title of rule and other identifying information: (describe subject) 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 Second Substitute House Bill (2SHB) 1148 (chapter 61, laws of 2021).

Hearing location(s):

Date:	Time:	Location: (be specific)	Comment:
10/11/2022	10:00 am	In response to the coronavirus disease 2019 (COVID-19), the Department of Health 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: 10/18/2022 (Note: This is **NOT** the effective date)

Submit written comments to:

Name: Julie Tomaro
Address: PO Box 47843, Olympia, WA 98504
Email: <https://fortress.wa.gov/doh/policyreview>
Fax: 360-236-2321
Other: None
By (date) 10/11/2022

Assistance for persons with disabilities:

Contact Julie Tomaro
Phone: 360-236-2937
Fax: 360-236-2321
TTY: 711
Email: julie.tomaro@doh.wa.gov
Other:
By (date) 10/04/2022

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 a new WAC section, 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; or (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

Is rule necessary because of a:

- Federal Law? Yes No
Federal Court Decision? Yes No
State Court Decision? Yes No

If yes, CITATION:

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters: None

Type of proponent: Private Public Governmental

Name of proponent: (person or organization) Washington State Department of Health

Name of agency personnel responsible for:

	Name	Office Location	Phone
Drafting:	Julie Tomaro	111 Israel Road SE, Tumwater, WA 98501	360-236-2937
Implementation:	Julie Tomaro	111 Israel Road SE, Tumwater, WA 98501	360-236-2937
Enforcement:	Julie Tomaro	111 Israel Road SE, Tumwater, WA 98501	360-236-2937

Is a school district fiscal impact statement required under [RCW 28A.305.135](#)? Yes No

If yes, insert statement here:

The public may obtain a copy of the school district fiscal impact statement by contacting:

Name:

Address:

Phone:

Fax:

TTY:

Email:

Other:

Is a cost-benefit analysis required under [RCW 34.05.328](#)?

Yes: A preliminary cost-benefit analysis may be obtained by contacting:

Name: Julie Tomaro

Address: PO Box 47843, Olympia, WA 98504

Phone: 360-236-2937

Fax:

TTY: 711

Email: julie.tomaro@doh.wa.gov

Other:

No: Please explain:

Regulatory Fairness Act and Small Business Economic Impact Statement

Note: The [Governor's Office for Regulatory Innovation and Assistance \(ORIA\)](#) provides support in completing this part.

(1) Identification of exemptions:

This rule proposal, or portions of the proposal, **may be exempt** from requirements of the Regulatory Fairness Act (see [chapter 19.85 RCW](#)). For additional information on exemptions, consult the [exemption guide published by ORIA](#). Please check the box for any applicable exemption(s):

This rule proposal, or portions of the proposal, is exempt under [RCW 19.85.061](#) because this rule making is being adopted solely to conform and/or comply with federal statute or regulations. Please cite the specific federal statute or regulation this rule is being adopted to conform or comply with, and describe the consequences to the state if the rule is not adopted.

Citation and description:

This rule proposal, or portions of the proposal, is exempt because the agency has completed the pilot rule process defined by [RCW 34.05.313](#) before filing the notice of this proposed rule.

This rule proposal, or portions of the proposal, is exempt under the provisions of [RCW 15.65.570\(2\)](#) because it was adopted by a referendum.

This rule proposal, or portions of the proposal, is exempt under [RCW 19.85.025\(3\)](#). Check all that apply:

- [RCW 34.05.310](#) (4)(b) (Internal government operations)
- [RCW 34.05.310](#) (4)(c) (Incorporation by reference)
- [RCW 34.05.310](#) (4)(d) (Correct or clarify language)
- [RCW 34.05.310](#) (4)(e) (Dictated by statute)
- [RCW 34.05.310](#) (4)(f) (Set or adjust fees)
- [RCW 34.05.310](#) (4)(g) ((i) Relating to agency hearings; or (ii) process requirements for applying to an agency for a license or permit)

This rule proposal, or portions of the proposal, is exempt under [RCW 19.85.025\(4\)](#) (does not affect small businesses).

This rule proposal, or portions of the proposal, is exempt under RCW _____.

Explanation of how the above exemption(s) applies to the proposed rule: 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.

(2) Scope of exemptions: *Check one.*

The rule proposal is fully exempt (*skip section 3*). Exemptions identified above apply to all portions of the rule proposal.

The rule proposal is partially exempt (*complete section 3*). The exemptions identified above apply to portions of the rule proposal, but less than the entire rule proposal. Provide details here (consider using [this template from ORIA](#)):

The rule proposal is not exempt (*complete section 3*). No exemptions were identified above.

(3) Small business economic impact statement: *Complete this section if any portion is not exempt.*

If any portion of the proposed rule is **not exempt**, does it impose more-than-minor costs (as defined by RCW 19.85.020(2)) on businesses?

No Briefly summarize the agency's minor cost analysis and how the agency determined the proposed rule did not impose more-than-minor costs. _____

Yes Calculations show the rule proposal likely imposes more-than-minor cost to businesses and a small business economic impact statement is required. Insert the required small business economic impact statement here:

The public may obtain a copy of the small business economic impact statement or the detailed cost calculations by contacting:

- Name:
- Address:
- Phone:
- Fax:
- TTY:
- Email:
- Other:

Date: September 2, 2022

Name: Todd Mountin, PMP for Umair A. Shah, MD, MPH

Title: Deputy Secretary of Operations for Secretary of Health

Signature:

A handwritten signature in black ink, appearing to read "Todd Mountin". The signature is written in a cursive style with a large initial "T" and "M".

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.