PROPOSED RULE MAKING

CR-102 (June 2024)
(Implements RCW 34.05.320)
Do **NOT** use for expedited rule making

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FILED

DATE: May 06, 2025
TIME: 2:30 PM

WSR 25-10-089

Agency: Department of Health – Pharmacy Quality Assurance Commission

☒ **Original Notice**

☐ **Supplemental Notice to WSR**

☐ **Continuance of WSR**

☒ **Preproposal Statement of Inquiry was filed as WSR 24-15-057; 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: Uniform Facility Enforcement Framework for Pharmacy. The Pharmacy Quality Assurance Commission (commission) is proposing to implement a uniform process for fining pharmaceutical firms in a new section of rule, WAC 246-945-007 Civil Fines. The proposed rules implement Engrossed Substitute Senate Bill (ESSB) 5271 (chapter 121, Laws of 2024).

Hearing location(s):

Date:	Time:	Location:	Comment:
June 26, 2025	1:00 pm	**Physical Location:** Capital Region ESD 113 6005 Tyee Dr. SW Tumwater, WA 98512 **Virtual Location:** Virtual: To access the meeting on June 26, 2025 at 1:00 pm, go to https://us02web.zoom.us/j/86309299195 or https://zoom.us/join and use the Webinar ID 863 0929 9195 The access options include one tap mobile: +12532158782,,86309299195# US (Tacoma) +12532050468,,86309299195# US Or Telephone: Dial (for higher quality, dial a number based on your current location): +1 253 215 8782 US (Tacoma) +1 253 205 0468 US	The commission will hold a hybrid hearing. Attendees are welcome to attend either in-person at the physical location or virtual via Zoom.

Date of intended adoption: 06/26/2025 (Note: This is **NOT** the **effective** date)

Submit written comments to:	**Assistance for persons with disabilities:**
Name: Julia Katz	Contact: Julia Katz
Address: PO Box 47852, Olympia, WA 98504-7852	Phone: 360-236-4946
Email: None	Fax: 360-236-2260
Fax: 360-236-2260	TTY: 711
Other: https://fortress.wa.gov/doh/policyreview/	Email: PharmacyRules@doh.wa.gov
Beginning (date and time): The date and time of this filing	Other: None
By (date and time): June 12, 2025 at 11:59 p.m.	By (date): June 12, 2025

Purpose of the proposal and its anticipated effects, including any changes in existing rules:
The commission is proposing to implement a fine matrix for pharmaceutical firms as part of a uniform facility enforcement framework in a new section of rule, WAC 246-945-007 Civil fines for pharmaceutical firms. The enforcement framework delineates how the commission will impose civil fines upon pharmaceutical firm licensees, registrants, permit holders, or other pharmaceutical firm credential holders when the commission determines the licensee has previously been subject to an enforcement action for the same or similar type of violation of the same or similar statute or rule, or 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 when a licensee failed to correct noncompliance with a statute or rule by a date established or agreed to by the commission. The proposed rule establishes civil fines in relation to the severity and scope of the noncompliance and operation size of the licensee. The anticipated effect is to increase patient safety by ensuring that pharmaceutical firms licensed in Washington state comply with regulations.

Reasons supporting proposal: The proposed rule is necessary to implement ESSB 5271 as it pertains to pharmaceutical firms and codified in RCW 18.64.024 and RCW 18.64.026. ESSB 5271 was enacted during the 2024 regular legislative session with an effective date of June 6, 2024. ESSB 5271 directed the commission to adopt rules to establish specific fine amounts. On May 2, 2024, the commission authorized rulemaking to establish a fine severity framework and related mechanisms permitted by ESSB 5271.

Statutory authority for adoption: RCW 18.64.005, 18.64.024, 18.64.026, and ESSB 5271 (chapter 121, Laws of 2024)

Statute being implemented: RCW 18.64.024 and 18.64.026

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

Name of proponent: (person or organization) Pharmacy Quality Assurance Commission
Type of proponent: ☐ Private. ☐ Public. ☒ Governmental.

Name of agency personnel responsible for:

	Name	Office Location	Phone
Drafting	Julia Katz	111 Israel Rd SE, Tumwater, WA 98501	360-236-4946
Implementation	Julia Katz	111 Israel Rd SE, Tumwater, WA 98501	360-236-4946
Enforcement	Marlee B. O'Neill	111 Israel Rd SE, Tumwater, WA 98501	360-480-9108

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: Julia Katz
Address: PO Box 47852, Olympia, WA 98504-7852
Phone: 360-236-4946
Fax: 360-236-2260
TTY: 711
Email: PharmacyRules@doh.wa.gov
Other: None

☐ 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:

(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.

There are no costs imposed by the proposed rule, the cost is less than the minor cost threshold ($19,161.74 for pharmacies and drug stores, $10,305.83 for drugs and druggists' sundries merchant wholesalers).

The minor cost analysis demonstrated that there is no estimated cost to pharmaceutical firms. Using the Governor's Office for Regulatory Innovation and Assistance's Minor Cost Threshold Calculator with NAICS Code Titles 446110 Pharmacies and Drug Stores and 424210 Drugs and Druggists' Sundries Merchant Wholesalers, the minor cost threshold is not met per RCW 19.85.020. A full SBEIS may not be required since the minor cost threshold is not met.

The following is a brief description of the proposed rule including the current situation/rule, followed by the history of the issue and why the proposed rule is needed. A description of the probable compliance requirements and the kinds of professional services that a small business is likely to need in order to comply with the proposed rule.
The commission is proposing to implement a uniform process for fining pharmaceutical firms in a new section of rule WAC 246-945-007, Civil Fines. The proposed rule is necessary to implement ESSB 5271 in chapter 246-945 WAC.

ESSB 5271 was enacted during the 2024 regular legislative session with an effective date of June 6, 2024. Codified in RCW 18.64.024 and RCW 18.64.026 the statute allows the commission to impose conditions and civil fines upon pharmaceutical firm licensees, registrants, permit holders, or other pharmaceutical firm credential holders when the commission determines the licensee has previously been subject to an enforcement action for the same or similar type of violation of the same or similar statute or rule, or 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 when a licensee failed to correct noncompliance with a statute or rule by a date established or agreed to by the commission. The statutes also authorizes the commission to impose a limited stop service for statute or rule violations, if the commission finds that the violation results in immediate jeopardy.

RCW 18.64.024 requires the commission to adopt a civil fine severity matrix in rule. The matrix must establish specific fine amounts in relation to the severity of the pharmaceutical firm licensee's noncompliance, operation size of the licensee, and at an adequate level to be a deterrence for future noncompliance. Civil fines may be assessed by the commission up to $10,000 per violation, not to exceed a total amount of $1,000,000, for repeat violations of the same or similar statute or rule.

The proposed rule establishes a process for the commission to assess civil fines on pharmaceutical firm licensees, registrants, permit holders, or other pharmaceutical firm credential holders issued by the commission who are subject to a repeat violation or fail to comply with statute or rule. Civil fines will be determined in relation to the severity, scope, and operation size of the licensee with established laws and rules by pharmaceutical firms. The proposed rule defines and categorizes scope, severity, and operation size metrics, and establishes the fine amounts.

The proposed rule does not impose new compliance requirements nor professional services of small businesses in order to be compliant.

Identification and summary of which businesses are required to comply with the proposed rule using the North American Industry Classification System (NAICS).

SBEIS Table 1. Summary of Businesses Required to comply to the Proposed Rule

NAICS Code (4, 5 or 6 digit)	NAICS Business Description	Number of businesses in Washington State	Minor Cost Threshold
325412	Pharmaceutical Preparation Manufacturing	101*	$10,463.92
446110	Pharmacies and Drug Stores	267**	$19,161.74
424210	Drugs and Druggists' Sundries Merchant Wholesalers	388***	$10,305.83****

*The Employment Security Department (ESD) reported 101 businesses categorized as Pharmaceutical Preparation Manufacturing, but Department of Health (department) staff reported the number of pharmaceutical manufacturers as of October 2024 as 38 manufacturers.
**The ESD reported 267 businesses categorized as Pharmacies and Drug Stores, but department staff reported the number of pharmacies as of April 2024, with 1,283 facilities being standalone pharmacies and 110 facilities being hospital pharmacies.
***The ESD reported 388 businesses categorized as Drugs and Druggists' Sundries Merchant Wholesalers, but department staff reported the number of pharmaceutical wholesalers as of October 2024 with 1,434 facilities.
****No codes were found for the remaining pharmaceutical firm licensees, registrants, permit holders, and credential holders issued by the commission, but department staff reported them as of October 2024 as Drug Animal Control/Humane Society Registration Sodium Pentobarbital as 32 registrants, Drug Controlled Substance Researcher Registration as 343 registrants, Drug Dog Handlers K9 Registration as 13 registrants, Drug Itinerant Vendor Registration as 1 registrant, Drug Other Controlled Substances Registration as 88 registrants, Drug Precursor Chemicals Registration as 5 registrants, Drug Sample

Distributor Registration as 155 registrants, Hospital Pharmacy Associated Clinic as 435 licensees, Pharmacy Health Care Entity License as 692 licensees, Pharmacy Non Resident License as 9,456 licensees, Poison Distributor License as 3 licensees, Pharmacy Technician Formal Training Program as 17 permit holders, Training Program Pharmacy as 940 permit holders, and Wildlife Chemical Capture Drug Registration as 15 registrants.

Analysis of probable costs of businesses in the industry to comply with the proposed rule and includes the cost of equipment, supplies, labor, professional services, and administrative costs. The analysis considers if compliance with the proposed rule will cause businesses in the industry to lose sales or revenue.

WAC 246-945-007 CIVIL FINES FOR PHARMACEUTICAL FIRMS.

Description: The proposed rule establishes a process for the commission to assess civil fines on pharmaceutical firm licensees, registrants, permit holders, or other pharmaceutical firm credential holders issued by the commission who are subject to a repeat violation or fail to comply with statute or rule. Civil fines will be determined in relation to the severity, scope, and operation size of the licensee with established laws and rules by pharmaceutical firms. The proposed rule defines and categorizes scope, severity, and operation size metrics, and establishes the fine amounts.

Cost(s): This rule does not require a licensed pharmaceutical firm to implement any new requirements or make changes to their policies or procedures. No new costs will be imposed on licensed pharmaceutical firms unless they violate established laws and rules, and the commission has determined:

- The licensed pharmaceutical firm has previously been subject to an enforcement action for the same or similar type of violation of the same statute or rule, or
- The licensed pharmaceutical firm has been given any previous statement of deficiency that included the same or similar type of violation of the same statute or rule, or
- The licensed pharmaceutical firm failed to correct noncompliance with a statute or rule by a date established or agreed to by the department.

Summary of all Cost(s)

SBEIS Table 2. Summary of Section 3 probable cost(s)

WAC Section and Title	Probable Cost(s)
WAC 246-945-007 Civil Fines	$0

Analysis on if the proposed rule may impose more than minor costs for businesses in the industry. Includes a summary of how the costs were calculated.

No, since there are no costs imposed by the proposed rule, the cost is less than the minor cost threshold ($10,463.92 for pharmaceutical preparation manufacturing, $19,161.74 for pharmacies and drug stores, $10,305.83 for drugs and druggists' sundries merchant wholesalers).

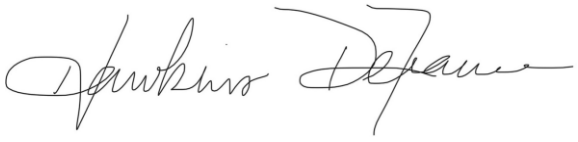
Summary of how the costs were calculated

The proposed rule does not require a licensed pharmaceutical firm to implement any new requirements or make changes to their policies or procedures. The proposed rules outline fines that may be imposed on licensed pharmaceutical firms if they violate established laws and rules, and the commission has determined fines are necessary to deter future noncompliance.

☐ 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: Julia Katz
Address: PO Box 47852, Olympia, WA 98504-7852
Phone: 360-236-4946
Fax: 360-236-2260
TTY: 711
Email: PharmacyRules@doh.wa.gov
Other: None

Date: May 5, 2025 **Name:** Hawkins DeFrance, PharmD **Title:** Pharmacy Quality Assurance Commission Chair	**Signature:** 

NEW SECTION

WAC 246-945-007 Civil fines for pharmaceutical firms. (1) This section does not govern actions taken under chapter 18.130 RCW.

(2) The commission may assess civil fines on pharmaceutical firm licensees pursuant to RCW 18.64.024 and 18.64.026, and these rules.

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

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

(ii) The licensee 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 licensee has failed to correct noncompliance with a statute or rule by a date established or agreed to by the commission.

(b) The commission may assess a civil fine that is higher than the maximum fine amounts in Table 1, Table 2, or Table 3, not to exceed $10,000 per violation, if it determines that the maximum fine amounts would not be sufficient to deter future noncompliance.

(c) The commission shall determine the amount of a civil fine in accordance with Table 1, Table 2, Table 3, or (d)(i) of this subsection:

Table 1

Fine Amounts in Relation to the Severity of the Violation for Remote Opioid Use Disorder (OUD) Dispensing Sites and Pharmacies (including HPACs, Nuclear Pharmacies, and Nonresident Pharmacies)			
Operation Size - Small	<30,000 prescriptions dispensed annually		
	Impact of Potential or Actual Harm		
Scope	**Low**	**Moderate**	**High**
Limited	$100 - $500	$1,750 - $2,750	$3,000 - $6,000
Pattern	$500 - $1,500	$2,750 - $3,750	$4,000 - $7,000
Widespread	$1,500 - $2,500	$3,750 - $4,750	$5,000 - $8,000
Operation Size - Medium	30,000 - 69,999 prescriptions dispensed annually		
	Impact of Potential or Actual Harm		
Scope	**Low**	**Moderate**	**High**
Limited	$250 - $750	$1,125 - $3,125	$4,000 - $7,000
Pattern	$750 - $1,750	$2,125 - $4,125	$5,000 - $8,000
Widespread	$1,750 - $2,750	$3,125 - $5,125	$6,000 - $9,000
Operation Size - Large	70,000+ prescriptions dispensed annually		
	Impact of Potential or Actual Harm		
Scope	**Low**	**Moderate**	**High**
Limited	$500 - $1,000	$1,500 - $3,500	$5,000 - $8,000
Pattern	$1,000 - $2,000	$2,400 - $4,500	$6,000 - $9,000
Widespread	$2,000 - $3,000	$3,500 - $5,500	$7,000 - $10,000

Table 2

Fine Amounts in Relation to the Severity of the Violation for Drug Other Controlled Substances Registrant (Opioid Treatment Programs and Precursor Chemical Registrants), Drug Sample Distributor Registrant, Pharmaceutical Manufacturers, Pharmaceutical Wholesaler, Shopkeeper Registrants and Poison Distributors			
Operation Size - Small	<10 FTEs		
	Impact of Potential or Actual Harm		
Scope	**Low**	**Moderate**	**High**
Limited	$100 - $500	$1,750 - $2,750	$3,000 - $6,000
Pattern	$500 - $1,500	$2,750 - $3,750	$4,000 - $7,000
Widespread	$1,500 - $2,500	$3,750 - $4,750	$5,000 - $8,000
Operation Size - Medium	10 - 24 FTEs		
	Impact of Potential or Actual Harm		
Scope	**Low**	**Moderate**	**High**
Limited	$250 - $750	$1,125 - $3,125	$4,000 - $7,000
Pattern	$750 - $1,750	$2,125 - $4,125	$5,000 - $8,000
Widespread	$1,750 - $2,750	$3,125 - $5,125	$6,000 - $9,000
Operation Size - Large	25+ FTEs		
	Impact of Potential or Actual Harm		
Scope	**Low**	**Moderate**	**High**
Limited	$500 - $1,000	$1,500 - $3,500	$5,000 - $8,000
Pattern	$1,000 - $2,000	$2,400 - $4,500	$6,000 - $9,000
Widespread	$2,000 - $3,000	$3,500 - $5,500	$7,000 - $10,000

Table 3

Fine Amounts in Relation to the Severity of the Violation for Health Care Entities (HCEs)			
Operation Size - Small	<5,000 drug orders dispensed and administered or delivered to the patient annually		
	Impact of Potential or Actual Harm		
Scope	**Low**	**Moderate**	**High**
Limited	$100 - $500	$1,750 - $2,750	$3,000 - $6,000
Pattern	$500 - $1,500	$2,750 - $3,750	$4,000 - $7,000
Widespread	$1,500 - $2,500	$3,750 - $4,750	$5,000 - $8,000
Operation Size - Medium	5,000 - 19,999 drug orders dispensed and administered or delivered to the patient annually		
	Impact of Potential or Actual Harm		
Scope	**Low**	**Moderate**	**High**
Limited	$250 - $750	$1,125 - $3,125	$4,000 - $7,000
Pattern	$750 - $1,750	$2,125 - $4,125	$5,000 - $8,000
Widespread	$1,750 - $2,750	$3,125 - $5,125	$6,000 - $9,000
Operation Size - Large	20,000+ drug orders dispensed and administered or delivered to the patient annually		
	Impact of Potential or Actual Harm		
Scope	**Low**	**Moderate**	**High**
Limited	$500 - $1,000	$1,500 - $3,500	$5,000 - $8,000
Pattern	$1,000 - $2,000	$2,400 - $4,500	$6,000 - $9,000
Widespread	$2,000 - $3,000	$3,500 - $5,500	$7,000 - $10,000

(d) The "operation size" of a licensee will be considered when calculating fine amounts. Licensee operation sizes are categorized as small, medium, and large.

(i) The following licensees are categorized as "small":

(A) Animal control/humane society registrants;

(B) Drug other controlled substance registrants (drug dog handlers K9 registrants;
(C) Drug controlled substance researcher registrants;
(D) Analytical laboratories;
(E) Drug itinerant vendor registrants;
(F) Wildlife chemical capture drug registrants;
(F) Ancillary utilization pharmacies; and
(G) Technician training programs.

(ii) "Prescriptions" in Table 1 and "drug orders" in Table 3 includes prescriptions and drug orders for "legend drugs" as defined in RCW 69.41.010 and "controlled substances" as defined in RCW 69.50.101.

(e) The licensee shall assist the commission with determining their operation size, including providing information necessary to determine a licensee's operation size. A licensee who fails to assist the commission will be deemed a large operation size.

(f) The "severity of the violation" will be considered when determining fines. Levels of severity are categorized as low, moderate, or high, and defined as:

(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.

(g) Factors the commission will consider when determining the severity of the violation include, but are not limited to:

(i) Whether harm to the patient has occurred, or could occur including, but not limited to, a violation of patient's rights;

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

(iii) The degree to which the licensee failed to meet the patient's highest practicable physical, mental, and psychosocial well-being;

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

(v) Whether the licensee has been offered, or requested, and received and implemented technical assistance from the commission.

(h) 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 patient 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 deficient practice 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 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.

(i) When determining the scope of the violation, the commission will also consider the duration of time that has passed between violations that relate to the same or similar circumstances.

(j) A licensee may appeal the commission's action of assessing civil fines under RCW 18.64.024.