WSR 25-17-089
PERMANENT RULES
DEPARTMENT OF HEALTH
(Pharmacy Quality Assurance Commission)
[Filed August 20, 2025, 8:28 a.m., effective September 20, 2025]

Effective Date of Rule: Thirty-one days after filing.

Purpose: Uniform facility enforcement frameworks for pharmacy. The pharmacy quality assurance commission (commission) is adopting new WAC 246-945-007 Civil fines, to implement a uniform process for fining pharmaceutical firms, which is required by ESSB 5271 (chapter 121, Laws of 2024). The adopted 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.

Citation of Rules Affected by this Order: New WAC 246-945-007.

Statutory Authority for Adoption: RCW 18.64.005, 18.64.024, 18.64.026, and ESSB 5271 (chapter 121, Laws of 2024).

Adopted under notice filed as WSR 25-10-089 on May 6, 2025.

Changes Other than Editing from Proposed to Adopted Version: On June 26, 2025, the commission adopted several clarifying and nonsubstantive revisions from the proposed to adopted version. The revisions include removing extraneous information for drug other controlled substances registrants in the title of Table 2 in WAC 246-945-007 (2)(c). In WAC 246-945-007 (2)(d)(i), "Analytical laboratories" was removed and in WAC 246-945-007 (2)(h)(i) and (ii), language was clarified from "patient or staff" to now say "patients, visitors, or staff."

A final cost-benefit analysis is available by contacting Julia Katz, P.O. Box 47852, Olympia, WA 98504-7852, phone 360-502-5058, fax 360-236-2260, TTY 711, email PharmacyRules@doh.wa.gov, website https://doh.wa.gov/licenses-permits-and-certificates/professions-new-renew-or-update/pharmacy-commission.

Number of Sections Adopted in Order to Comply with Federal Statute: New 0, Amended 0, Repealed 0; Federal Rules or Standards: New 0, Amended 0, Repealed 0; or Recently Enacted State Statutes: New 1, Amended 0, Repealed 0.

Number of Sections Adopted at the Request of a Nongovernmental Entity: New 0, Amended 0, Repealed 0.

Number of Sections Adopted on the Agency's own Initiative: New 0, Amended 0, Repealed 0.

Number of Sections Adopted in Order to Clarify, Streamline, or Reform Agency Procedures: New 1, Amended 0, Repealed 0.

Number of Sections Adopted using Negotiated Rule Making: New 0, Amended 0, Repealed 0; Pilot Rule Making: New 0, Amended 0, Repealed 0; or Other Alternative Rule Making: New 1, Amended 0, Repealed 0.

Date Adopted: August 19, 2025.

Hawkins DeFrance, PharmD, Chair
Pharmacy Quality Assurance Commission

RDS-6272.2

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, Drug Sample Distributor Registrant, Pharmaceutical Manufacturers, Pharmaceutical Wholesaler, Shopkeeper Registrants and Poison Distributors	
Operation Size - Small	<10 FTEs

Fine Amounts in Relation to the Severity of the Violation for Drug Other Controlled Substances Registrant, Drug Sample Distributor Registrant, Pharmaceutical Manufacturers, Pharmaceutical Wholesaler, Shopkeeper Registrants and Poison Distributors			
	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" under Table 2:

(A) Animal control/humane society registrants;

(B) Drug dog handlers registrants;

(C) Drug controlled substance researcher registrants;
(D) Drug itinerant vendor registrants;
(E) 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 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 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, 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.

(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.