



PREPROPOSAL STATEMENT OF INQUIRY

CR-101 (October 2017) (Implements RCW 34.05.310)

Do NOT use for expedited rule making

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STATE OF WASHINGTON
FILED

DATE: July 16, 2024

TIME: 12:25 PM

WSR 24-15-057

Agency: Department of Health – Pharmacy Quality Assurance Commission

Subject of possible rule making: Uniform Facility Enforcement Framework for Pharmacy. The Pharmacy Quality Assurance Commission (commission) is considering amending and establishing a new section in chapter 246-945 WAC to implement a uniform enforcement tool for pharmaceutical firms provided by Engrossed Substitute Senate Bill (ESSB) 5271 (chapter 121, Laws of 2024). Other amendments to sections in chapter 246-945 WAC to implement ESSB 5271 may also be considered.

Statutes authorizing the agency to adopt rules on this subject: RCW 18.64.005, ESSB 5271 (chapter 121, Laws of 2024)

Reasons why rules on this subject may be needed and what they might accomplish:

ESSB 5271 was enacted during the 2024 regular legislative session with an effective date of June 6, 2024. The law authorizes the commission to impose civil fines upon facility licensees, registrants, permit holders, or other credential holders issued by the commission who fail or refuse to comply with state or federal statute or administrative rule. The commission may assess a civil fine up to \$10,000 per violation and a total fine of \$1,000,000 when a facility licensee, registrant, permit holder, or other credential holder is found to subsequently be in violation of the same or similar statute or rule. Section 33(1)(b)(iii) of ESSB 5271 requires the commission to adopt a rule to establish the fines, for pharmaceutical firms, according to the severity of the noncompliance and the size of the operation.

Identify other federal and state agencies that regulate this subject and the process coordinating the rule with these agencies: None.

Process for developing new rule (check all that apply):

- Negotiated rule making
- Pilot rule making
- Agency study
- Other (describe) Collaborative rulemaking


Interested parties can participate in the decision to adopt the new rule and formulation of the proposed rule before publication by contacting:

Name: Julia Katz	(If necessary) Name:
Address: PO Box 47852, Olympia, WA 98504-7852	Address:
Phone: 360-791-1167	Phone:
Fax:	Fax:
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Email: PharmacyRules@doh.wa.gov	Email:
Web site:	Web site:
Other:	Other:

Additional comments:

Interested parties can participate in the drafting of the proposed rules. The department will conduct a series of rules workshops. Rulemaking notices will be delivered via the GovDelivery list. To receive notices, please go to:

<https://public.govdelivery.com/accounts/WADOH/subscriber/new>. After signing in, please click open the box labeled "Health Systems Quality Assurance." Next click open the box labeled "Health Professions" and then click again on "Pharmacy Commission Newsletter." You may also check the box next to one or more of the other professions or facilities listed to receive information related to that specific topic.

Date: July 10, 2024	Signature: 
Name: Hawkins DeFrance, PharmD	
Title: Pharmacy Quality Assurance Commission Chair	