



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: October 04, 2022
TIME: 1:48 PM

WSR 22-20-100

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 20-17-143 ; 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 246-945-486 (New) Return and reuse of unexpired medications – Department of corrections and WAC 246-945-488 (New) Safe donation of unexpired prescription drugs. The Pharmacy Quality Assurance Commission (commission) is proposing new sections in chapter 246-945 WAC for the implementation of Substitute Senate Bill (SSB) 6526, an act relating to the reuse and donation of unexpired prescription drugs.

Hearing location(s):

Date:	Time:	Location: (be specific)	Comment:
11/17/2022	9:20 a.m.	<p>The Pharmacy Quality Assurance Commission will provide a virtual and a physical location for this hearing to promote social distancing and the safety of the citizens of Washington State.</p> <p>Physical location: Capital Region ESD 113 6005 Tyee Dr SW Tumwater, WA 98512 Lewis Room</p> <p>Virtual: Please download and import the following iCalendar (.ics) files to your calendar system. Daily: https://us02web.zoom.us/webinar/tZlSdu2hqzMuHNJhllH4KKYkCjwBU5J0e2Ps/ics?icsToken=98tyKuGurzouE9GdtB-BRpwABYj4LPPwmFxbgo13BPpK3R4STr9FehVElCqOojV Topic: PQAC Business Meeting 2022</p> <p>To access the meeting on November 17 at 9 a.m., go to https://zoom.us/join or https://us02web.zoom.us/j/86114958466 and use the Webinar ID 861 1495 8466</p>	

	<p>The access options include one tap mobile: US: +12532158782,,86114958466# or +16699009128,,86114958466# Or Telephone: Dial(for higher quality, dial a number based on your current location): US: +1 253 215 8782 or +1 669 900 9128 or +1 346 248 7799 or +1 669 444 9171 or +1 386 347 5053 or +1 564 217 2000 or +1 646 558 8656 or +1 646 931 3860 or +1 301 715 8592 or +1 312 626 6799 Webinar ID: 861 1495 8466 International numbers available: https://us02web.zoom.us/j/86114958466</p>	
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Date of intended adoption: 11/17/2022 (Note: This is **NOT** the effective date)

<p>Submit written comments to: Name: Joshua Munroe Address: PO Box 47582 Olympia, WA 98504-7852 Email: https://fortress.wa.gov/doh/policyreview Fax: 360-236-2901 Other: N/A By (date) <u>11/03/2022</u></p>	<p>Assistance for persons with disabilities: Contact <u>Joshua Munroe</u> Phone: 360-236-2987 Fax: 360-236-2901 TTY: 711 Email: PharmacyRules@doh.wa.gov Other: N/A By (date) <u>11/10/2022</u></p>
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Purpose of the proposal and its anticipated effects, including any changes in existing rules: The 2020 Washington state legislature passed SSB 6526, an act relating to the reuse and donation of unexpired prescription drugs. SSB 6526 permits the Department of Corrections (DOC) pharmacy to accept returns of unit dose packages. The law also allows the commission to adopt rules to allow the safe donation of prescription drugs under chapter 69.70 RCW including, but not limited to, allowing pharmacy to pharmacy donation of unexpired prescription drug stock.

The proposed WAC 246-945-486 specifically allows the DOC pharmacy to accept for return and reuse noncontrolled unexpired legend drugs in unit dose packages, or full or partial multiple dose medication cards from the facilities it serves. The DOC pharmacy must ensure product integrity by adhering to RCW 69.70.050(1), (2), and (5).

The proposed language in WAC 246-945-488 adopts the required conditions for donated prescription drugs outlined in chapter 69.70 RCW, but also adds a requirement that participating pharmacies must submit an additional form to the commission as notification of participation in the program. They must also notify the commission when terminating participation in the program. The proposed rule also directs participating pharmacies to develop policies and procedures that facilitate compliance with the statutory requirements. The policies and procedures must also include an additional requirement to notify the prescriber when donated medications are dispensed to a patient.

In addition, WAC 246-945-488 contains measures to ensure patient safety and product integrity such as separating the donated drugs from the rest of the pharmacy’s drug stock and maintaining a separate inventory. Finally, the rule also adds the clarification that practitioners, pharmacists, medical facilities, manufacturers, wholesalers, or persons to whom a prescription drug was prescribed are not required to obtain a wholesaler license when donating drugs to a pharmacy.

Reasons supporting proposal: SSB 6526 requires the commission to adopt rules allowing the DOC pharmacy to accept returns of unit dose packages or full or partial multiple dose medication cards from the facilities it serves and reuse the unexpired medication. The bill also allows the commission to adopt rules allowing the safe donation of prescription drugs under chapter 69.70 RCW including, but not limited to, allowing pharmacy to pharmacy donations of unexpired prescription

drug stock. The proposed rules improve accessibility and visibility of the drug donation program under chapter 69.70 RCW while ensuring optimal patient safety and product integrity.

Statutory authority for adoption: RCW 18.64.005; SSB 6526 (chapter 264, Laws of 2020) codified as RCW 18.64.610 and RCW 69.70.110

Statute being implemented: SSB 6526 (chapter 264, Laws of 2020) codified as RCW 18.64.610 and RCW 69.70.110

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 Pharmacy Quality Assurance Commission

Name of agency personnel responsible for:

	Name	Office Location	Phone
Drafting:	Joshua Munroe	111 Israel Rd SE, Tumwater, WA 98501	360-236-2987
Implementation:	Joshua Munroe	111 Israel Rd SE, Tumwater, WA 98501	360-236-2987
Enforcement:	Marlee 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: Joshua Munroe

Address: PO Box 47852
Olympia, WA 98504-47852

Phone: 360-236-2987

Fax: 360-236-2901

TTY: 711

Email: PharmacyRules@doh.wa.gov

Other: N/A

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)(e)
(Dictated by statute)

[RCW 34.05.310](#) (4)(c)
(Incorporation by reference)

[RCW 34.05.310](#) (4)(f)
(Set or adjust fees)

[RCW 34.05.310](#) (4)(d)
(Correct or clarify language)

[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.

The proposed rule does not require changes to a licensee's or a pharmacy's existing practices or infrastructure. For pharmacies that choose to participate in the prescription donation program, costs are limited to one-time costs—procuring additional shelving/storage, time taken creating policies and procedures, and time taken to fill out the necessary registration form—and the recurring cost of maintaining a separate inventory for donated items. The agency estimates that the probable one-time cost to comply with the optional program could be as high as \$733.50 which is significantly less than the minor cost threshold of either 1% of average annual payroll (\$6,639.73) or .3% of average annual gross business income (\$53,119.28). The agency determined that the requirements to comply with the optional program did not impose more-than-minor costs on small businesses.

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: Joshua Munroe
Address: PO Box 47852
Olympia, WA 98504-7852
Phone: 360-236-2987
Fax: 360-236-2901
TTY: 711
Email: PharmacyRules@doh.wa.gov
Other: N/A

Date: October 4, 2022	Signature: 
Name: Teri Ferreira, RPh	
Title: Pharmacy Quality Assurance Chair	

NEW SECTION

WAC 246-945-486 Return and reuse of unexpired medications—Department of corrections. (1) For the purposes of this section, the term "facilities" includes all facilities served by the Washington state department of corrections pharmacy.

(2) The Washington state department of corrections pharmacy may accept for return and reuse noncontrolled legend drugs in unit dose packages, or full or partial multiple dose medication cards from the facilities it serves, if product integrity can be assured and the Washington state department of corrections pharmacy complies with RCW 69.70.050 (1), (2), and (5).

NEW SECTION

WAC 246-945-488 Safe donation of unexpired prescription drugs.

(1) For the purposes of this section, the definitions in RCW 69.70.010 apply.

(2) A pharmacy that accepts, distributes, or dispenses prescription drugs and supplies under WAC 246-945-485 (1)(b) that are donated shall:

(a) Comply with the requirements in RCW 69.70.020, 69.70.030, 69.70.040, and 69.70.050, when applicable;

(b) Complete and return an attestation form developed and supplied by the commission attesting to participation in the drug donation program;

(c) Notify the commission in writing if it is no longer accepting donated prescription drugs and supplies. This notification must occur within thirty calendar days of the pharmacy no longer accepting donated prescription drugs and supplies;

(d) Not accept donations of prescription drugs and supplies via a drop box;

(e) Ensure that prescription drugs and supplies donated by the person to whom the prescription drug was prescribed or the person's representative are accompanied by the department's drug donation form in accordance with RCW 69.70.020(2);

(f) Ensure clear separation of the pharmacy's donated prescription drug stock from the rest of the pharmacy's drug stock;

(g) Maintain a separate inventory of all prescription drugs and supplies donated to the pharmacy; and

(h) Develop and implement policies and procedures addressing:

(i) When prescription drugs or supplies may be accepted and dispensed. The policy and procedure shall require a pharmacist to inspect the donated prescription drugs and supplies and to notify the prescriber when delivering donated prescription drugs and supplies to a patient; and

(ii) How the pharmacy will respond when it is informed of a recall for donated prescription drugs and supplies.

(3) Practitioners, pharmacists, medical facilities, drug manufacturers, drug wholesalers, persons to whom a prescription drug was prescribed, or the person's representative, are not required to obtain a wholesaler license when donating prescription drugs to a pharmacy.