

WSR 23-03-109

PROPOSED RULES

DEPARTMENT OF HEALTH

(Pharmacy Quality Assurance Commission)

[Filed January 18, 2023, 7:56 a.m.]

Supplemental Notice to WSR 22-20-100.

Preproposal statement of inquiry was filed as WSR 20-17-143.

Title of Rule and Other Identifying Information: New WAC

246-945-486 Return and reuse of unexpired medications—Department of corrections and 246-945-488 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 SSB 6526, an act relating to the reuse and donation of unexpired prescription drugs. The supplemental proposal removes a prescriber notification requirement from WAC 246-945-488 (2)(h)(i).

Hearing Location(s): On March 3, 2023, at 9:20 a.m., at Capital Region ESD 113, 6005 Tye Drive S.W., Tumwater, WA 98512; or virtual. Please download and import the following iCalendar (.ics) fields to your calendar system. Daily: <https://us02web.zoom.us/webinar/tZIsdu2hqzMuHNJh1lH4KKYkCjwBU5J0e2Ps/ics?icsToken=98tyKuGurzouE9GdtB-BRpwABYj4LPPwmFxbgo13lBPpK3R4Str9FehVEIcqOojV>. Topic: PQAC Business Meeting 2022. To access the meeting on March 3, 2023, 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. The access options include one-tap mobile: US: +12532158782,,86114958466# or +16699009128,,86114958466# or phone, 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/join>. The commission will provide a virtual and physical location for this hearing to promote social distancing and the safety of the citizens of Washington state.

Date of Intended Adoption: March 3, 2023.

Submit Written Comments to: Joshua Munroe, P.O. Box 47582, Olympia, WA 98504-7852, email <https://fortress.wa.gov/doh/policyreview>, fax 360-236-2901, by February 17, 2023.

Assistance for Persons with Disabilities: Contact Joshua Munroe, phone 360-236-2987, fax 360-236-2901, TTY 711, email PharmacyRules@doh.wa.gov, by February 24, 2023.

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 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.

Following the public rules hearing held on November 17, 2022, the commission determined that the proposed rule language required an amendment to WAC 246-945-488 (2)(h)(i) to remove a prescriber notification requirement that was deemed unnecessary in order to provide donated prescription drugs to patients with a valid standing prescription.

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.

The commission determined during the November 17, 2022, public rules hearing that the prescriber notification requirement found in WAC 246-945-488 (2)(h)(i) was superfluous if a patient already has a valid prescription for the drug donated via the prescription donation program. Furthermore, it was decided that any delay caused by notifying prescribers for a prescription they have already issued could be deleterious to the patient's health.

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

Statute Being Implemented: SSB 6526 (chapter 264, Laws of 2020) codified as RCW 18.64.610 and 69.70.110.

Rule is not necessitated by federal law, federal or state court decision.

Name of Proponent: Pharmacy quality assurance commission, governmental.

Name of Agency Personnel Responsible for Drafting and Implementation: Joshua Munroe, 111 Israel Road S.E., Tumwater, WA 98501, 360-236-2987; Enforcement: Marlee O'Neill, 111 Israel Road S.E., Tumwater, WA 98501, 360-480-9108.

A school district fiscal impact statement is not required under RCW 28A.305.135.

A cost-benefit analysis is required under RCW 34.05.328. A preliminary cost-benefit analysis may be obtained by contacting Joshua Munroe, P.O. Box 47852, Olympia, WA 98504-47852, phone 360-236-2987, fax 360-236-2901, TTY 711, email PharmacyRules@doh.wa.gov.

Scope of exemption for rule proposal from Regulatory Fairness Act requirements:

Is not exempt.

The proposed rule does not impose more-than-minor costs on businesses. Following is a summary of the agency's analysis showing how costs were calculated. 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 one percent of average annual payroll (\$6,639.73) or .3 percent 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.

It was further determined that the proposed amendment to WAC 246-945-488 (2)(h)(i) to remove the prescriber notification requirement would not affect existing cost estimates.

January 17, 2023
Teri Ferreira, RPh
Pharmacy Quality Assurance Chair

OTS-3189.3

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).

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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

(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.

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