

WSR 23-11-088

PERMANENT RULES

DEPARTMENT OF HEALTH

(Pharmacy Quality Assurance Commission)

[Filed May 17, 2023, 9:17 p.m., effective June 17, 2023]

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

Purpose: The pharmacy quality assurance commission (commission) adopted new sections in chapter 246-945 WAC for the implementation of SSB 6526 (chapter 264, Laws of 2020), an act relating to the reuse and donation of unexpired prescription drugs passed by the 2020 Washington state legislature. SSB 6526 permits the department of corrections (DOC) pharmacy to accept returns of prescription drugs in 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.

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).

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 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.

Citation of Rules Affected by this Order: New WAC 246-945-486 and 246-945-488.

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.

Adopted under notice filed as WSR 23-03-109 on January 18, 2023.

Changes Other than Editing from Proposed to Adopted Version:

None. The rules were originally proposed under notice filed as WSR 22-20-100 on October 4, 2022. 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. The commission repropoed the rules under notice filed as WSR 23-03-109 on January 18, 2023, and there were no changes made between this supplemental proposed rule and the final rule.

A final cost-benefit analysis is available by contacting Joshua Munroe, P.O. Box 47852, Olympia, WA 98504-7852, phone 360-502-5058, TTY 711, email pharmacyrules@doh.wa.gov.

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 0, 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 2, Amended 0, Repealed 0.

Number of Sections Adopted in Order to Clarify, Streamline, or Reform Agency Procedures: New 0, 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 2, Amended 0, Repealed 0.

Date Adopted: May 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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