

WSR 25-07-093

PERMANENT RULES

DEPARTMENT OF HEALTH

(Pharmacy Quality Assurance Commission)

[Filed March 18, 2025, 1:13 p.m., effective April 18, 2025]

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

Purpose: Dialysate and dialysis device manufacturers and wholesalers in home dialysis programs. The pharmacy quality assurance commission (commission) adopted amendments to WAC 246-945-090, 246-945-091, 246-945-092, and 246-945-093 to include manufacturers and wholesalers of dialysis devices and approved legend drugs, including dialysate, in home dialysis program rules under the commission's jurisdiction. The adopted rule is necessary to implement SHB 1675 (chapter 23, Law of 2022), as well as implement safeguards and quality assurance measures for patients receiving dialysate, dialysis devices, and approved legend drugs from manufacturers and wholesalers.

The commission is adopting the rules as proposed under WSR 24-24-028. This was a supplemental CR-102 which, in response to public comments, differed from the initial proposal under WSR 24-14-140 by proposing to amend WAC 246-945-090 to add the word "may" and list the dialysis devices manufacturers and wholesalers may sell, deliver, possess, or dispense to home dialysis patients; and to amend WAC 246-945-091, 246-945-092, and 246-945-093 to conform to the list of dialysis devices.

Citation of Rules Affected by this Order: Amending WAC 246-945-090, 246-945-091, 246-945-092, and 246-945-093.

Statutory Authority for Adoption: RCW 18.64.005, 18.64.257, and 69.41.032.

Adopted under notice filed as WSR 24-24-028 on November 22, 2024.

A final cost-benefit analysis is available by contacting Julia Katz, P.O. Box 47852, Olympia, WA 98504-7852, phone 360-236-4946, fax 360-236-2260, 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Number of Sections Adopted in Order to Comply with Federal Statute: New 0, Amended 0, Repealed 0; Federal Rules or Standards: New 0, Amended 0, Repealed 0; or Recently Enacted State Statutes: New 0, Amended 4, Repealed 0.

Number of Sections Adopted at the Request of a Nongovernmental Entity: New 0, Amended 0, Repealed 0.

Number of Sections Adopted on the Agency's own Initiative: New 0, Amended 0, Repealed 0.

Number of Sections Adopted in Order to Clarify, Streamline, or Reform Agency Procedures: New 0, Amended 0, Repealed 0.

Number of Sections Adopted using Negotiated Rule Making: New 0, Amended 0, Repealed 0; Pilot Rule Making: New 0, Amended 0, Repealed 0; or Other Alternative Rule Making: New 0, Amended 4, Repealed 0.

Date Adopted: March 14, 2025.

Hawkins DeFrance, PharmD, Chair  
Pharmacy Quality Assurance Commission

OTS-5459.2

AMENDATORY SECTION (Amending WSR 20-12-072, filed 6/1/20, effective 7/1/20)

**WAC 246-945-090 Home dialysis programs, manufacturers, and wholesalers—Legend drugs and dialysis devices.** Pursuant to RCW 18.64.257 and 69.41.032, a medicare-approved dialysis center (~~(or)~~), a facility operating a medicare-approved home dialysis program (~~(may)~~), a manufacturer, or a wholesaler may sell, deliver, possess, or dispense directly to its home dialysis patients, in case(~~(s)~~) or full shelf (~~(package)~~) lots, and if prescribed by a (~~(physician)~~) practitioner, the following:

(1) Legend drugs:

- ~~((1))~~ (a) Sterile heparin, 1000 u/mL, in vials;
- ~~((2))~~ (b) Sterile potassium chloride, 2 mEq/mL, for injection;
- ~~((3))~~ (c) Commercially available dialysate; and
- ~~((4))~~ (d) Sterile sodium chloride, 0.9%, for injection in containers of not less than 150 mL.

(2) Dialysis devices:

- (a) Class II medical devices that are manufactured and marketed in compliance with the Federal Food, Drug, and Cosmetic Act and indicated for acute and chronic dialysis therapy in the home; and
- (b) Related supplies and accessories of the dialysis device.

AMENDATORY SECTION (Amending WSR 20-12-072, filed 6/1/20, effective 7/1/20)

**WAC 246-945-091 Home dialysis programs, manufacturers, and wholesalers—Pharmacist consultant.** (~~Home dialysis programs involved in the distribution of legend drugs as~~) A medicare-approved dialysis center, a facility operating a medicare-approved home dialysis program, a manufacturer, or a wholesaler who sells, delivers, possesses, or dispenses dialysis devices and legend drugs directly to its home dialysis patients permitted by RCW 18.64.257 and 69.41.032(~~(r)~~) shall have an agreement with a pharmacist which provides for consultation as necessary. This agreement shall include advice on the drug (~~(distribution)~~) and device shipment and delivery process to home dialysis patients and on the location used for storage and (~~(distribution)~~) shipment of the authorized drugs and devices, which shall be reasonably separated from other activities and shall be secure.

AMENDATORY SECTION (Amending WSR 20-12-072, filed 6/1/20, effective 7/1/20)

**WAC 246-945-092 Home dialysis programs, manufacturers, and wholesalers—Records.** (1) A medicare-approved dialysis center, a facility operating a medicare-approved home dialysis program, a manufacturer, or a wholesaler who sells, delivers, possesses, or dispenses dialysis devices and legend drugs directly to its home dialysis patients permitted by RCW 18.64.257 and 69.41.032 shall attach a record of shipment (~~(shall be attached)~~) to the (~~(prescriber's)~~) practitioner's order (~~(and)~~). The record of shipment shall include:

- (a) The name of the patient;

- (b) Strengths and quantities of drugs, if applicable;
  - (c) Device name, if applicable;
  - (d) The name of the drug manufacturer((s' names)), if applicable;
  - ~~((d))~~ (e) The name of the device manufacturer, if applicable;
  - (f) Date of shipment;
  - ~~((e))~~ (g) Names of persons who selected, assembled and packaged for shipment; and
  - ~~((f))~~ (h) The name of the pharmacist or designated individual responsible for the ((distribution)) shipment.
- (2) Prescription records, and drug ((distribution)) and device shipment records shall be maintained in accordance with WAC 246-945-020.

AMENDATORY SECTION (Amending WSR 20-12-072, filed 6/1/20, effective 7/1/20)

**WAC 246-945-093 Home dialysis programs, manufacturers, and wholesalers—Quality assurance.** ~~((Home dialysis programs involved in the distribution of legend drugs as))~~ A medicare-approved dialysis center, a facility operating a medicare-approved home dialysis program, a manufacturer, or a wholesaler who sells, delivers, possesses, or dispenses dialysis devices and legend drugs directly to its home dialysis patients permitted by RCW 18.64.257 and 69.41.032((r)) shall develop a quality assurance program for drug ((distribution)) and device shipment and delivery, and shall maintain records of drug ((distribution)) and device shipment and delivery errors and other problems, including loss due to damage or theft.