

WSR 24-14-140

PROPOSED RULES

DEPARTMENT OF HEALTH

(Pharmacy Quality Assurance Commission)

[Filed July 3, 2024, 8:45 a.m.]

Original Notice.

Preproposal statement of inquiry was filed as WSR 23-21-010.

Title of Rule and Other Identifying Information: Dialysate and dialysis device manufacturers and wholesalers in home dialysis programs. The pharmacy quality assurance commission (commission) is proposing to amend 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 proposed amendments are in response to statutory changes made by SHB 1675 (chapter 23, Laws of 2022).

Hearing Location(s): On August 22, 2024, at 9:30 a.m., at the Department of Labor and Industries, Room S117/118, 7273 Linderson Way S.W., Tumwater, WA 98501; virtually via Zoom # 871 4349 5001. Please download and import the following iCalendar (.ics) fields to your calendar system https://us02web.zoom.us/webinar/tZwvcu-orjooGdL0ucE3WWkJLsRorLzko_bx/ics?icsToken=98tyKuGgrD4sGtSUSHqBRpw-AI_4M_TziH5BjadxzArmJnNkVQj_cGvFwPaBTCTPf. Topic: PQAC business meeting 2024. To access the meeting on August 22, 2024, at 9 a.m., go to <https://us02web.zoom.us/j/87143495001> and use the Webinar ID 871 4349 5001. 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/u/kdLNo6unOZ>. The commission will hold a hybrid hearing. Attendees are welcome to attend either in person at the physical location or virtual via Zoom.

Date of Intended Adoption: August 22, 2024.

Submit Written Comments to: Julia Katz, P.O. Box 47852, Olympia, WA 98504-7852, email <https://fortress.wa.gov/doh/policyreview/>, fax 360-236-2901, beginning the date and time of this filing, by August 8, 2024, at midnight.

Assistance for Persons with Disabilities: Contact Julia Katz, phone 360-502-505 [5058], fax 360-236-2901, TTY 711, email PharmacyRules@doh.wa.gov, by August 15, 2024.

Purpose of the Proposal and Its Anticipated Effects, Including Any Changes in Existing Rules: The purpose of the proposal is to allow manufacturers and wholesalers to sell, deliver, possess, and dispense prescribed approved legend drugs, including commercially available dialysate, and dialysis devices directly to home dialysis patients. RCW 16.64.257 and 69.41.032, amended by SHB 1675, direct the commission to adopt rules to implement the statutes.

Reasons Supporting Proposal: The amended rules are needed to implement SHB 1675, which amended RCW 16.64.257 and 69.41.032 to ensure manufacturers and wholesalers may distribute approved legend drugs and dialysis devices directly to dialysis patients and granted the commission authority to adopt rules. Additionally, the proposed rules establish important quality assurance measures for wholesalers and manufac-

turers dispensing approved legend drugs and dialysis devices directly to home dialysis patients.

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

Statute Being Implemented: RCW 18.64.257 and 69.41.032.

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, Implementation, and Enforcement: Julia Katz, 111 Israel Road S.E., Tumwater, WA 98501, 360-502-5058.

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 Julia Katz, P.O. Box 47852, Olympia, WA 98504-7852, phone 360-502-5058, fax 360-236-2901, 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 costs of the proposed rule (\$1,669) are **less than** the minor cost threshold (\$10,305.83).

The minor cost analysis demonstrated that the estimated cost to manufacturers and wholesalers choosing to dispense approved legend drugs and dialysis devices to patient homes is \$1,669. Using the Governor's Office for Regulatory Innovation and Assistance's Minor Cost Threshold Calculator with NAICS Code Title, 424210 Drugs and Drug-gists' Sundries Merchant Wholesalers, the minor cost threshold is not met per RCW 19.85.020. A full small business economic impact statement (SBEIS) may not be required since the minor cost threshold is not met. Excerpts of an SBEIS are provided herein.

The following is a brief description of the proposed rule including the current situation/rule, followed by the history of the issue and why the proposed rule is needed. A description of the probable compliance requirements and the kinds of professional services that a small business is likely to need in order to comply with the proposed rule.

The commission is proposing this rule to regulate participating manufacturers and wholesalers who dispense lawfully prescribed dialysis devices and approved legend drugs, including commercially available dialysate, to homes of patients undergoing kidney dialysis treatment at home. The proposed rule protects and promotes public health and safety by implementing safeguards and quality assurance measures for patients receiving dialysis devices and approved legend drugs from manufacturers and wholesalers.

The proposed rule began with the passage of SHB 1675 during the 2022 legislative session. Effective June 9, 2022, SHB 1675 amended RCW 18.64.257 and 69.41.032 to ensure manufacturers and wholesalers may distribute dialysis devices and approved legend drugs directly to home dialysis patients. The proposed rule is needed because SHB 1675 also directed the commission to adopt rules to implement RCW 18.64.257 and 69.41.032 in state regulation. That is why the commission filed a CR-101 as WSR 23-21-010 on October 5, 2023. On March 7, 2024, the commission voted to approve the filing of the CR-102.

For manufacturers and wholesalers that elect to distribute prescriptions to home dialysis patients, the proposed rule is needed to establish important safeguards and quality assurance measures. The purpose of the safety measures is to hold participating manufacturers and wholesalers to similar quality assurance, shipment and delivery, and risk management standards as facilities that regularly interact with patients (e.g. pharmacy). Participating manufacturers and wholesalers will need to establish an agreement with a pharmacist for consultation on an as needed basis, attach a record of shipment to each practitioner's order, develop quality assurance programs for shipment and delivery, and maintain a record of shipment and delivery errors.

Manufacturers and wholesalers that choose to distribute prescriptions to home dialysis patients must secure and utilize a pharmacist consultant. Distributing manufacturers and wholesalers must also develop and implement protocol for shipments, deliveries, and error documentation. Finally, these manufacturers and wholesalers must also provide quality assurance measures to protect medications from diversion or tampering in line with their own security policies and procedures.

SBEIS Table 1 identifies and summarizes of which businesses are required to comply with the proposed rule using the North American Industry Classification System (NAICS).

SBEIS Table 1. Summary of Businesses Required to comply to the Proposed Rule

NAICS Code (4, 5, or 6 digit)	NAICS Business Description	Number of Businesses in Washington State	Minor Cost Threshold
424210	Drugs and Druggists' Sundries Merchant Wholesalers	121	\$10,305.83

The following is an analysis of probable costs of businesses in the industry to comply to the proposed rule and includes the cost of equipment, supplies, labor, professional services, and administrative costs. The analysis considers if compliance with the proposed rule will cause businesses in the industry to lose sales or revenue.

WAC 246-945-090 Home dialysis programs, manufacturers, and wholesalers—Legend drugs.

Description: The commission is proposing to amend WAC 246-945-090 to allow manufacturers and wholesalers to sell, deliver, possess, or dispense materials used in home dialysis programs directly to patients, provided that the treatment was prescribed by a practitioner acting within the scope of their practice.

Manufacturers and wholesalers will need to apprise staff of the rule adoption and train pertinent staff on the rule adoption's implementation protocol. The content may be supplemental to an existing training session.

Cost(s): \$187 Total probable cost per participating manufacturer or wholesaler for 90 minutes of staff time to prepare and deliver training to employees. This probable cost assumes an average health service manufacturer or wholesaler employing 200 employees has a shipping and receiving team of 10 production workers and one manager.^{1,2,3} Commission staff estimate that the training will require 60 minutes of the manager's time (\$62/hour) to prepare and deliver the training on patient home deliveries and 30 minutes of each production worker's time (\$25/hour) to receive the training.^{4,5}

WAC 246-945-091 Home dialysis programs, manufacturers, and wholesalers—Pharmacist consultant.

Description: Manufacturers and wholesalers will need to establish an agreement with a pharmacist for consultation on an as needed basis. Pharmacist consultations are needed to deliver and dispense dialysis devices and approved legend drugs safely to patients. The shipment and delivery content of the agreement may be in addition or stand alone to an existing pharmacist consultant agreement.

Cost(s): \$426 ongoing probable cost for six hours of a pharmacist's time (\$71/hour) for consultation.⁶ The commission estimates manufacturers and wholesalers will consult with a contracted pharmacist one hour every other month.

WAC 246-945-092 Home dialysis programs, manufacturers, and wholesalers—Records.

Description: Manufacturers and wholesalers will need to attach a record of shipment to each practitioner's order. The record of shipment needs to include the name of the patient, strengths and quantities of drugs, manufacturers' names, date of shipment, names of people who selected, assembled and packaged the shipment, and the name of the pharmacist or designated person responsible for the shipment.

Cost(s): \$300 One-time probable cost for a printer and \$304 ongoing probable cost for toner and paper for printing records of shipment.⁷ These probable costs are based on commission staff's estimate of 10,000 shipments per manufacturer or wholesaler requiring printed records annually.⁸

WAC 246-945-093 Home dialysis programs, manufacturers, and wholesalers—Quality assurance.

Description: Manufacturers and wholesalers will need to develop quality assurance programs for shipment and delivery and maintain a record of shipment and delivery errors. The shipment and delivery quality assurance plan and error record may be supplemental to an existing quality assurance program.⁹

Cost(s): \$328 One-time probable cost for three hours of a production manager's time (\$62/hour) and two hours of a pharmacist consultant's time (\$71/hour) to fulfill the quality assurance program requirements.^{10,11} \$124 One-time probable cost for two hours of a production manager's time (\$62/hour) will be needed annually to maintain a record of shipment and delivery errors.

Summary of all Cost(s):

SBEIS Table 2. Summary of probable cost(s)

WAC Section and Title	Probable Cost(s)
WAC 246-945-090 Home dialysis programs, manufacturers, and wholesalers—Legend drugs	\$187 one-time for employee training
WAC 246-945-091 Home dialysis programs, manufacturers, and wholesalers—Pharmacist consultant	\$426 ongoing for pharmacist consultations
WAC 246-945-092 Home dialysis programs, manufacturers, and wholesalers—Records	\$300 one-time for a printer for records of shipment \$304 ongoing for toner and paper for records of shipment
WAC 246-945-093 Home dialysis programs, manufacturers, and wholesalers—Quality assurance	\$328 one-time for quality assurance program development \$124 ongoing for quality assurance program improvement
Total	\$1,669.00

Analysis on if the proposed rule may impose more-than-minor costs for businesses in the industry. Includes a summary of how the costs were calculated.

The costs of the proposed rule (\$1,669) are **less than** the minor cost threshold (\$10,305.83).

Summary of how the costs were calculated: The probable costs were calculated for participating manufacturers and wholesalers to comply with the proposed rule. Probable costs affiliated with compliance primarily pertain to staff time. Average staff wages in Washington state were sourced from data produced by the United States Bureau of Labor and Statistics. Additional resources were used to estimate employee quantities. Commission staff, including a pharmacist consultant, determined the estimated time requirements.

- 1 What is compliance training, and why is it important? What is compliance training, and why is it important? (powerdms.com). (Accessed March 26, 2024)
- 2 43.5 percent of manufacturing workers in establishments with 250 or more workers in March 2018. 43.5 percent of manufacturing workers in establishments with 250 or more workers in March 2018 : The Economics Daily: U.S. Bureau of Labor Statistics (bls.gov). (Accessed March 25, 2024)
- 3 The Ideal Manager to Employee Ratio: How Many Managers Do You Need? The Ideal Manager to Employee Ratio: How Many Managers Do You Need? - Don Romans (Accessed March 25, 2024)
- 4 Occupational Employment and Wages, May 2023. Transportation, Storage, and Distribution Managers (bls.gov) (Accessed March 25, 2024)
- 5 Occupational Employment and Wages, May 2023. Production Workers, All Other (bls.gov) (Accessed March 25, 2024)
- 6 Occupational Employment and Wages, May 2023 - 29-1051 Pharmacists. Pharmacists (bls.gov) (Accessed March 25, 2024)
- 7 Staples® Official Online Store (Accessed April 22, 2024)
- 8 National ESRD Census Data. National ESRD Census Data (esrdnetworks.org) (Accessed April 9, 2024)
- 9 Manufacturing and Quality Assurance: A Comprehensive Guide. Manufacturing [Manufacturing] Quality Assurance: A Comprehensive Guide (cashflowinventory.com) (Accessed March 25, 2024)
- 10 See footnote 4
- 11 See footnote 8

A copy of the detailed cost calculations may be obtained by contacting Julia Katz, P.O. Box 47852, Olympia, WA 98504-7852, phone 360-502-5058, fax 360-236-2901, email PharmacyRules@doh.wa.gov.

July 2, 2024
Hawkins DeFrance, PharmD, Chair
Pharmacy Quality Assurance Commission

OTS-5459.1

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. 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 who sells, delivers, ~~((possess))~~ possesses, or dispenses directly to its home dialysis patients, in case ~~((s))~~ or full shelf ~~((package))~~ lots, if prescribed by a ~~((physician))~~ practitioner, the following legend drugs:

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

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 ~~((7))~~ shall have an agreement with a pharmacist which provides for consultation as necessary. This agreement shall include advice on the drug ~~((distribution))~~ shipment and delivery process to home dialysis patients and on the location used for storage and ~~((distribution))~~ shipment of the authorized drugs, 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;
- (c) The manufacturers' names;
- (d) Date of shipment;
- (e) Names of persons who selected, assembled and packaged for shipment; and
- (f) The name of the pharmacist or designated individual responsible for the ~~((distribution))~~ shipment.

(2) Prescription and drug ~~((distribution))~~ 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 ~~((7))~~ shall develop a quality assurance program for drug ~~((distribution))~~ shipment and delivery, and shall maintain records of drug ~~((distribution))~~ shipment and delivery errors and other problems, including loss due to damage or theft.