WSR 24-24-028
PROPOSED RULES
DEPARTMENT OF HEALTH
(Pharmacy Quality Assurance Commission)
[Filed November 22, 2024, 4:55 p.m.]

Supplemental Notice to WSR 24-14-140.

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. This supplemental [notice] further amends 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.

Hearing Location(s): On February 6, 2025, at 9:30 a.m., at the Department of Labor and Industries, 7273 Linderson Way S.W., Tumwater, WA 98501; or virtual via Zoom https://us02web.zoom.us/j/86309299195 or https://zoom.us/join, and use the Webinar ID 863 0929 9195. The access options include one tap mobile +12532158782,,86309299195# US (Tacoma), +12532050468,,86309299195# US; or telephone +1 253-215-8782 US (Tacoma), +1 253-205-0468 US. Attendees are welcome to attend either in person at the physical location or virtual via Zoom.

Date of Intended Adoption: February 6, 2025.

Submit Written Comments to: Julia Katz, P.O. Box 47852, Olympia, WA 98504-7852, fax 360-236-2260, https://fortress.wa.gov/doh/policyreview/, beginning the date and time of this filing, by January 23, 2025, at 11:59 p.m.

Assistance for Persons with Disabilities: Contact Julia Katz, phone 360-236-4946, fax 360-236-2260, TTY 711, email PharmacyRules@doh.wa.gov, by January 23, 2025.

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. Conforming amendments to WAC 246-945-091, 246-945-092, and 246-945-093 intend to ensure dialysis devices are considered in consultation, record keeping, and quality assurance practices. RCW 18.64.257 and 69.41.032, amended by SHB 1675, direct the commission to adopt rules to implement the statutes.

Following the public rules hearing held on August 22, 2024, the commission determined that the proposed rule language required two amendments to WAC 246-945-090. The first amendment is to reinstate the term "may." The second amendment is to add a list of approved dialysis devices that manufacturers and wholesalers may sell, deliver, possess, and dispense to home dialysis patients. Amendments were needed to WAC 246-945-091, 246-945-092, and 246-945-093 in association with the WAC 246-945-090 amendments.

Reasons Supporting Proposal: The amended rules are needed to implement SHB 1675, which amended RCW 18.64.257 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 manufacturers dispensing approved legend drugs and dialysis devices directly to home dialysis patients.

The commission determined during the August 22, 2024, public rules hearing that "may," the list of approved dialysis devices, and conforming revisions regarding the list of dialysis devices were missing from WAC 246-945-090, 246-945-091, 246-945-092, and 246-945-091 [246-945-093]. It was decided that adding the word "may" corrects a typographical error and clarifies intent, and that SHB 1675 directs the commission to adopt rules to implement the statutes, including a list of approved dialysis devices.

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 and Implementation: Julia Katz, 111 Israel Road S.E., Tumwater, WA 98501, 360-236-4946; Enforcement: Marlee B. 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 Julia Katz, P.O. Box 47852, Olympia, WA 98504-7852, phone 360-236-4946, fax 360-236-2260, 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 North American Industry Classification System (NAICS) Code Title, 424210 Drugs and Druggists' 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.

It was further determined that the proposed amendments to WAC 246-945-090 to add "may" and the list of dialysis devices would not affect existing cost estimates. Excerpts of the 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 rule amendments to increase access to dialysis devices and approved legend drugs, including dialysate,

for patients undergoing kidney dialysis treatment at home by allowing manufacturers and wholesalers to dispense lawfully prescribed dialysis devices and approved legend drugs to patients' homes.

The proposed rule is necessary to implement SHB 1675 (chapter 23, Laws of 2022), as well as establish important quality assurance measures for wholesalers and manufacturers dispensing approved legend drugs, and dialysis devices directly to home dialysis patients. SHB 1675 amended RCW 18.64.257 and 69.41.032 to ensure manufacturers and wholesalers may distribute approved medications and devices directly to dialysis patients.

Prior to the passage of SHB 1675, manufacturers and wholesalers would need either a pharmacy or nonresident pharmacy license to dispense directly to patients. Pharmacy licenses are issued to facilities located in Washington that dispense prescriptions to patients. Nonresident pharmacy licenses are issued to facilities located outside of Washington that dispense prescriptions to patients. Both the pharmacy and nonresident pharmacy licenses require annual renewal applications and an application fee of $575. Current statute does not require pharmacy and nonresident pharmacy licensees dispensing legend drugs to patients to have an agreement with a pharmacist to provide consultation on shipment and delivery of prescriptions, develop a quality assurance program for shipment and delivery of prescriptions, nor maintain a record of shipment and delivery errors. WAC 246-945-016 does require pharmacy and nonresident pharmacy licensees dispensing legend drugs to patients to affix labels to prescription containers. Since the passage of SHB 1675, manufacturers and wholesalers in compliance with quality assurance measures may distribute approved medications and devices directly to patients without a pharmacy or nonresident pharmacy license.

In October 2022, the commission filed a policy statement under WSR 22-21-062 to clarify the commission's position on this subject until rule making can be completed. Per the policy statement, the commission will not take enforcement action against a manufacturer or wholesaler acting in compliance with the minimum requirements of SHB 1675 and WAC 246-945-090 through 246-945-093.

Small 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.

At the August 2024 business meeting, the commission considered feedback from interested parties at a rule hearing on this topic and voted to approve filing a supplemental CR-102. The commission's approved revisions to the proposed rule language are applicable to small-scale manufacturers and wholesalers; however, no additional costs are anticipated as their intent is to provide clarification. The commission determined that the proposed rule needed to be further amended and required two amendments to WAC 246-945-090. The first amendment is to reinstate the term "may." The second amendment is to add a list of approved dialysis devices that manufacturers and wholesalers may sell, deliver, possess, and dispense to home dialysis patients. Amendments are also needed to WAC 246-945-091, 246-945-092, and 246-945-093 in association with the WAC 246-945-090 amendments.

SBEIS Table 1 identifies and summarizes of which businesses are required to comply with the proposed rule using 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 current rule allows a medicare-approved dialysis center or facility operating a medicare-approved home dialysis program to sell, deliver, or dispense directly to its home dialysis patients specified legend drugs. The proposed rule allows manufacturers and wholesalers to sell, deliver, possess, or dispense approved legend drugs 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 that ship and deliver approved legend drugs and dialysis devices directly to patients will not be required to retain a pharmacy or nonresident pharmacy license to do so.

The language proposed as part of the supplemental [notice] clarifies that a medicare-approved dialysis center or facility operating a medicare-approved home dialysis program, a manufacturer or a wholesaler may sell, deliver, or dispense directly to its home dialysis patients specified legend drugs. The proposed rule also list the dialysis devices that may be sold, delivered, or dispensed directly to patients.

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] There are no anticipated costs associated with adding the list of devices that may be sold, delivered, or dispensed. The list provides clarification but does not require the devices to be sold.

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

Description: The current rule requires home dialysis programs involved in the distribution of legend drugs to have an agreement with a pharmacist that provides consultation as necessary. The proposed rule requires manufacturers and wholesalers that ship and deliver approved legend drugs and dialysis devices to patients to also establish an agreement with a pharmacist for consultation on an as needed basis. This is not currently required by statute. The shipment and delivery

content of the agreement may be in addition to or stand alone to an existing pharmacist consultant agreement.

The language proposed as part of the supplemental [notice] clarifies that the agreement shall include advice on both the drug and device shipment and delivery process.

Cost(s): It is estimated that there will be a $426 ongoing probable cost to manufacturers and wholesalers for six hours of a pharmacist's time ($71/hour) for consultation annually.[6] Commission staff estimate that approximately six hours, one hour every other month of a year, will be necessary for a wholesaler or manufacturer to discuss shipment and delivery protocol with a pharmacist in order to deliver and dispense dialysis devices and approved legend drugs safely to patients. The clarification provided as part of the supplemental [notice] is not anticipated to add any additional time or costs.

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

Description: The current rule outlines what is required to be on the record of shipment and attached to the prescriber's order. The proposed rule requires manufacturers and wholesalers that ship and deliver approved legend drugs and dialysis devices directly to home patients to attach a record of shipment to each practitioner's order that includes additional information than currently required of manufacturers and wholesalers with pharmacy or nonresident pharmacy licensees by WAC 246-945-016. 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. The language proposed as part of the supplemental clarifies that the record shall also include information on devices if applicable.

Cost(s): It is estimated that a manufacturer or wholesaler will incur a $300 one-time probable cost for a printer and a $304 ongoing probable cost for toner and paper for printing records of shipment.[7] These probable costs are based on an assumption of 10,000 shipments annually requiring printed records.[8] The clarification provided as part of the supplemental [notice] is not anticipated to add any additional time or costs.

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

Description: The current rule requires home dialysis programs involved in the distribution of legend drugs to develop a quality assurance program for drug distribution and to maintain records of drug distribution errors and other problems, including loss due to damage or theft. The proposed rule will require manufacturers and wholesalers who ship and deliver approved legend drugs and dialysis devices directly to patients, to develop quality assurance programs for shipment and delivery and maintain a record of shipment and delivery errors. The current statute does not require manufacturers and wholesalers to maintain quality assurance programs for shipment and delivery, nor records 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] The language proposed as part of the supplemental clarifies that the quality assurance program requirements apply to devices if applicable.

Cost(s): It is estimated that a manufacturer or wholesaler will incur a $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] In addition, there are $124 of estimated ongoing probable costs for two hours of a production manager's time ($62/hour) to maintain a record of shipment and delivery errors. The clarification provided as part of the supplemental [notice] is not anticipated to add any additional time or costs.

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. 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. Manufaturing 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 360-236-4946, fax 360-236-2260, TTY 711, email PharmacyRules@doh.wa.gov.

November 22, 2024
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((~~,~~)) 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((~~,~~)) 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.