Washington State Department of HEALTH
Pharmacy Quality Assurance Commission
PO Box 47852 Olympia, WA 98504
www.doh.wa.gov · TDD Relay: 711

Pharmacy Quality Assurance Commission
December 12, 2024 - Minutes

Convene: Hawkins DeFrance, Chair, called the meeting to order December 12, 2024, 9:07 a.m.

Commission Members:	***Commission Members Absent:***	***Staff:***
Hawkins DeFrance, Chair	Jerrie Allard	Marlee O'Neill, Executive Director
Ann Wolken, Vice Chair	Bonnie Bush	Lindsay Trant-Sinclair, Deputy Director
Stephanie Bardin	Teri Ferreira	Si Bui, Inspector Supervisor
Patrick Gallaher	Matthew Ray	Christopher Gerard, AAG
Judy Guenther	Uyen Thorstensen	Rachel Sahi
William Hayes		Taifa "Nomi" Peaks
Kenneth Kenyon		Joshua Munroe
Craig Ritchie		Haleigh Mauldin
Huey Yu		Julia Katz
		Irina Tiginyanu
		Madison Washington
		Amy Robertson
		Crystal Phipps
		Scott Craig
		Justin Sisney
		Mariam Boulos

1. Call to Order Hawkins DeFrance, Chair

1.1. Meeting Agenda Approval – December 12, 2024

MOTION: Ann Wolken moved to amend the agenda to remove 2.3.2. Doctors Pharmacy LLC and add 7.8. PQAC Bill Report. Ken Kenyon, seconded. Motion carried, 9:0.

MOTION: Craig Ritchie moved to approve the amended business meeting agenda for December 12, 2024. Stephanie Bardin, seconded. Motion carried, 9:0.

1.2. Meeting Minutes Approval – October 10, 2024

MOTION: Craig Ritchie moved to approve the business meeting minutes for October 10, 2024. Ken Kenyon, seconded. Motion carried, 9:0.

1.3. Meeting Minutes Approval – October 11, 2024

MOTION: Craig Ritchie moved to approve the business meeting minutes for October 11, 2024. Ken Kenyon, seconded. Motion carried, 9:0.

2. Consent Agenda

2.1. Correspondence
- **2.1.1.** National Precursor Log Exchange Monthly Dashboard – October and November
- **2.1.2.** Pharmaceutical Firms Application Report

2.2. Ancillary Utilization Plans Approval
- **2.2.1.** Chinook Pharmacy
- **2.2.2.** Evergreen Professional Center Pharmacy
- **2.2.3.** Family Pharmacy
- **2.2.4.** Prosser Memorial Hospital Pharmacy
- **2.2.5.** Whidbey Health Community Pharmacy

2.3. Pharmacy Technician Training Program Approval
- **2.3.1.** CityScript Pharmacy, LLC
- **2.3.3.** Peninsula Community Health Services
- **2.3.4.** QuickRX LLC (Brewster Pharmacy)
- **2.3.5.** Skyline Hospital Pharmacy
- **2.3.6.** Sumas Drug

MOTION: Craig Ritchie moved to remove item 2.3.3., Peninsula Community Health Services. Ann Wolken, seconded. Motion carried, 9:0.

2.4. Regular Agenda Items Pulled from 2.1, 2.2, or 2.3.

2.3.3. Peninsula Community Health Services

MOTION: Ken Kenyon moved to approve item 2.3.3. Peninsula Community Health Services, contingent on striking 12.a.i. and rewording 12.b.i. to say "restock prefilled pharmacist verified crash kit" on the pharmacy assistant AUPUP attached to the technician training program. Craig Ritchie, seconded. Motion carried, 9:0.

3. Rulemaking for Medication Assistance

3.1. **PUBLIC HEARING** The commission and the Department of Health (DOH) held a public rules hearing on the rulemaking to propose adding WACs 246-945-710, 246-945-712, 246-945-714, 246-945-716, and 246-945-718 in chapter 246-945 WAC to establish standards for the practice of medication assistance.

The public rule hearing began at 9:30am and was closed at 9:35am. The commission received one written comment during the public comment period and two oral comments during the public hearing.

3.2. Approval of Comment Responses and Authorization to file CR-103P (Medication Assistance).

The commission discussed the comments received both in writing and orally and approved responses to those comments.

MOTION: Ken Kenyon moved to approve the responses to the comments received, adopt the language for WAC 246-945-710, WAC 246-945-712, WAC 246-945-714, WAC 246-945-716, and WAC 246-945-718 without edits, and authorized staff to file a CR-103P. Huey Yu, seconded. Motion carried, 9:0.

4. Presentations

4.1. Health Systems Quality Assurance (HSQA) Legislative Team

Cori Tarzwell, Legislative Affairs Manager, Sherry Thomas, Legislative Coordinator, and Jacob O'Connor, Legislative Coordinator, provided a presentation on the upcoming legislative session.

4.2. Presentation and Demonstration on Health Care Enforcement and Licensing Management System (HELMS)

Elizabeth Geisler, HELMS Business Deputy Project Director, provided an update and demonstration of HELMS.

4.3. Presentation from the Office of Investigative and Legal Services (OILS)

Rayne Pearson, Executive Director of Legal Services, and Maggie Pagel, Supervising Staff Attorney, provided an annual update.

4.4. Presentation on Washington Recovery Assistance Program for Pharmacy (WRAPP)

Will Rhodes, WRAPP Program Manager, and Heather Ferguson, WRAPP Advisory Board Member, provided an annual update.

5. New Business

5.1. Guidance Document on Inspection Requirements for Modifications or Remodels and WAC-246-945-230

Staff asked the commission to consider authorizing rulemaking on WAC-945-230 to clarify when a facility needs to submit a modification or remodel application and consider issuing a guidance document while the rulemaking is ongoing.

MOTION: Ann Wolken moved to authorize staff to file a CR-101 to consider rulemaking on WAC 246-945-230 to clarify when a facility needs to submit a modification or remodel application, rescind the current guidance document (G002), and approve the draft guidance document with one edit that adds "Not all equipment changes will be considered structural or functional changes" to the end of the second paragraph. Ken Kenyon, seconded. Motion carried, 9:0.

5.2. Policy Statement on Commission Approved Examinations and WAC 236-945-165 and WAC 246-945-205

MOTION: Stephanie Bardin moved to approve draft policy statement on commission-approved exams for WAC 236-945-165 and WAC 246-945-205 without edits. Huey Yu, seconded. Motion carried, 9:0.

5.3. Update Signature Authority Delegation

MOTION: Ken Kenyon moved to approve the signature delegation form without edits. Judy Guenther, seconded. Motion carried, 9:0.

6. Strategic Plan

6.1. Annual Review of Commission Bylaws

MOTION: Ken Kenyon moved to approve the commission bylaws without edits. Judy Guenther, seconded. Motion carried, 9:0.

6.2. Strategic Plan Implementation Update

Marlee O'Neill updated the commission on the strategic plan implementation.

7. Rules Update

7.1. Refresher on the Rules Process and Rules Tracker Spreadsheet

Joshua Munroe presented the rulemaking process and provided an overview of the rules tracker and number of rules projects completed this year.

7.2. Emergency Rule Refile Request for Medical Assistance

MOTION: Ann Wolken moved to authorize the refiling of the CR-103E on medication assistance because there is an emergent need for this rule to be extended for the health and safety of the public. Patrick Gallaher, seconded. Motion carried, 9:0.

7.3. Overview of State Regulation of Kratom

Christopher Gerard, AAG, provided an update on the requirements for scheduling a controlled substance and Joshua Munroe provided an overview of research into state regulations on kratom. The Commission took public comments on this agenda item.

7.4. Update on Permanent Facility Closure Requirements

Julia Katz provided updates to the CR-102 proposed rule language for the Permanent Facility Closure Requirements rulemaking.

7.5. Rules Workshop: Utilization of Ancillary Personnel

Haleigh Mauldin presented draft rule language and will take the feedback received and continue to refine the draft rule language for another rules workshop at a future business meeting.

7.6. Rules Workshop: Uniform Facilities Enforcement Framework

This item was moved to the February 2025 business meeting.

7.7. Rules Workshop: Alternate Distribution Models

Joshua Munroe presented draft rule language and will take the feedback received and continue to refine the draft rule language for another rules workshop at a future business meeting.

7.8. PQAC Bill Report

Joshua Munroe reviewed pre-filed bills pertinent to the commission.

8. Open Forum

No public comments.

9. Commission Member Reports

9.1. Legislative Task Force Report Out

Craig Ritchie shared that the Task Force met on November 20, 2024; to discuss topics the commission may consider as future legislative proposals. The task force will bring the recommended topics to the February 2025 business meeting for further discussion.

9.2. Open Discussion Related to Items or Issues Relevant to Commission Business/Pharmacy Practice

Hawkins DeFrance presented Ken Kenyon with a certificate of appreciation as he will complete his two full commission terms in January 2025.

10. Staff Reports

10.1. Executive Director – Marlee O'Neill

- Marlee suggested hosting a biennial team-building event during the May or June 2025 business meeting. However, this is contingent on any restrictions imposed because of the state's budget situation.
- Marlee was joined by staff to present at the WSPA Annual Meeting.
- Marlee and Ann attended the National Association of Boards of Pharmacy (NABP) District 6, 7, & 8 meeting in New Mexico in October 2024.
- Marlee shared that Harold is actively working with HSQA Secretary Sasha De Leon to review the commission's edits to the JOA.
- Marlee advised the NABP Annual Meeting is in May 2025 in Ft. Lauderdale, FL. Hawkins will attend, and Ann will attend if able.

10.2. Deputy Director – Lindsay Trant-Sinclair

- Provided a staffing update for the inspector positions – staff is close to putting an offer out to a candidate and is confident we will fill the position soon.
- Reminded the commission and staff about the credentialing freeze on Friday, February 14, 2025, through Wednesday, February 19, 2025, to transition ILRS to HELMS.
- Kevin Robbins, Credentialing Supervisor, and Amy Vann-Peterson, Credentialing Lead, have been participating in a training program led by HELMS that will allow them to train the rest of the team.
- OHP will not host its weekly legislative calls for the upcoming session and instead will be sending out an e-mail distribution.

10.3. Assistant Attorney General – Christopher Gerard

- Advised the Attorney General's office will be having their first change in Attorney General in 12 years, starting next year, with Nick Brown.

11. Summary of Meeting Action Items

- **1.2 Meeting Minutes** – Staff will finalize the minutes and post them on the commission's website.
- **1.3 Meeting Minutes** – Staff will finalize the minutes and post them on the commission's website.
- **2. Consent Agenda** – Staff will follow up on approvals and contingent approvals as voted on.
- **3.2 Approval of Comment Responses and Authorization to file CR-103P (Medication Assistance).** – Staff will file a CR-103P with the ruling to adopt the language for WAC 246-945-710, WAC 246-945-712, WAC 246-945-714, WAC 246-945-716, and WAC 246-945-718 without edits.

- **4.3 Presentation for OILS** – OILS staff will provide Staff with follow up information and Staff will redistribute that to the commission.
- **5.1 Guidance Document on Inspection Requirements for Modifications or Remodels and WAC-246-945-230** – Replace the guidance document on remodels on the commission's website with the version presented and edited at the meeting and initiate rulemaking on WAC 246-945-230 by filing a CR-101.
- **5.2 Policy Statement on Commission Approved Examinations and WAC 236-945-165 and WAC 246-945-205** – Staff will start the department's review process for policy statements and publish that on the commission's website after its filed with the code revisor.
- **7.2 Emergency Rule Refile Request for Medical Assistance** – Staff will re-file the emergency rule on medication assistance.
- **7.3 Overview of State Regulation on Kratom –** Staff will notify interested parties of public comment opportunities and put that on a future meeting agenda.
- **7.5 Rules Workshop: Utilization of Ancillary Personnel** – Staff will make edits to the rules, based on the discussion with the commission and bring that back at a future meeting for another rules workshop.
- **7.6 Rules Workshop: Uniform Facilities Enforcement Framework** – The commission tabled this discussion until the February 2025 Business Meeting. It will be discussed further with the commission at that time.
- **7.7 Rules Workshop: Alternate Distribution Models** – Staff will make the edits discussed with the commission and hold another workshop at a future date.

5:03pm Business Meeting Adjourned

2.1.1. National Precursor Log Exchange Monthly Dashboard - December 2024

MONTHLY PROGRAM ADMINISTRATOR'S DASHBOARD – December

0 Logins - 0 Searches - 0 Report Queries - 20 Active Watches - 0 Active Watch Hits

NEW USERS THIS MONTH	TOP USAGE AGENCIES	TOP AGENCIES BY ACTIVE WATCHES
New Users = 0	TOP USERS BY USAGE	1. ICE - King County (42)
Total Accounts = 146		
Active Users = 0		

TRANSACTION SUMMARY STATISTICS (2024)

	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC	TOTAL
PURCHASES	74,453	72,185	85,834	81,952	81,528	82,903	71,038	62,291	66,277	71,815	70,381	92,776	**913,433**
BLOCKS	2,948	3,115	3,711	4,013	3,603	4,000	3,265	2,746	2,682	2,647	2,819	3,890	**39,439**
GRAMS SOLD	151,435	147,264	183,713	181,483	180,269	186,862	161,168	135,210	141,746	152,389	136,825	167,037	**1,925,401**
BOXES SOLD	83,333	81,217	96,496	92,140	91,713	92,705	79,971	69,588	76,017	82,770	75,601	94,209	**1,015,760**
GRAMS BLOCKED	7,693	8,306	10,096	11,242	10,271	11,114	9,234	7,615	7,565	7,751	7,345	9,179	**107,411**
BOXES BLOCKED	3,408	3,669	4,458	4,732	4,257	4,578	3,777	3,236	3,358	3,303	3,321	4,126	**46,223**
AVG GRAMS PER BOX BLOCK	2.26	2.26	2.26	2.38	2.41	2.43	2.44	2.35	2.25	2.35	2.21	2.22	**2.32**

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PHARMACY PARTICIPATION STATISTICS (Dec 2024)

Enabled Pharmacies	961
Pharmacies Submitting a Transaction	861
Pharmacies Logging in Without a Transaction	9
Inactive Pharmacies	91
Pharmacy Participation for Dec	90.53%

DISCLAIMER: This is an automated report meant to give you a quick snapshot of the NPLEx system in your state. The statistics listed in this report are only meant to be a general overview and not necessarily the exact final numbers. Prior to releasing any statistics mentioned in this report, we highly recommend that you verify the numbers with your NPLEx customer relationship manager. For questions or issues, please contact krista.mccormick@equifax.com.

PROPOSED RULE MAKING

CR-102 (June 2024)
(Implements RCW 34.05.320)
Do **NOT** use for expedited rule making

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: November 22, 2024
TIME: 4:55 PM

WSR 24-24-028

Agency: Department of Health – Pharmacy Quality Assurance Commission

☐ **Original Notice**
☒ **Supplemental Notice to WSR** 24-14-140
☐ **Continuance of WSR**

☒ **Preproposal Statement of Inquiry was filed as** WSR 23-21-010**; or**
☐ **Expedited Rule Making--Proposed notice was filed as WSR _____; or**
☐ **Proposal is exempt under RCW 34.05.310(4) or 34.05.330(1); or**
☐ **Proposal is exempt under RCW _____.**

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 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 WACs 246-945-091, 246-945-092, and 246-945-093 to conform to the list of dialysis devices.

Hearing location(s):

Date:	**Time:**	**Location:** (be specific)	**Comment:**
02/06/2025	9:30 am	**Physical Location:** Department of Labor & Industries 7273 Linderson Way SW Tumwater, WA 98501 **Virtual Location:** Virtual: To access the meeting on February 6, 2025 at 9:30 am, go to 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: Dial (for higher quality, dial a number based on your current location): +1 253 215 8782 US (Tacoma) +1 253 205 0468 US	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: 2/06/2025 (Note: This is **NOT** the **effective** date)

Submit written comments to:	**Assistance for persons with disabilities:**

Name Julia Katz	Contact Julia Katz
Address PO Box 47852, Olympia, WA 98504-7852	Phone 360-236-4946
Email	Fax 360-236-2260
Fax 360-236-2260	TTY 711
Other https://fortress.wa.gov/doh/policyreview/	Email PharmacyRules@doh.wa.gov
Beginning (date and time) The date and time of this filing	Other None
By (date and time) January 23, 2025 at 11:59pm	By (date) 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 WACs 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 WACs 246-945-090, 246-945-091, 246-945-092, and 246-945-091. 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

Is rule necessary because of a:

Federal Law?	☐ Yes	☒ No
Federal Court Decision?	☐ Yes	☒ No
State Court Decision?	☐ Yes	☒ No

If yes, CITATION:

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters: None

Name of proponent: (person or organization) Pharmacy Quality Assurance Commission
Type of proponent: ☐ Private. ☐ Public. ☒ Governmental.

Name of agency personnel responsible for:

	Name	Office Location	Phone
Drafting	Julia Katz	111 Israel Rd SE, Tumwater, WA 98501	360-236-4946
Implementation	Julia Katz	111 Israel Rd SE, Tumwater, WA 98501	360-236-4946
Enforcement	Marlee B. O'Neill	111 Israel Rd SE, Tumwater, WA 98501	360-480-9108

Is a school district fiscal impact statement required under RCW 28A.305.135? ☐ Yes ☒ No

If yes, insert statement here:

The public may obtain a copy of the school district fiscal impact statement by contacting:
Name
Address
Phone
Fax

TTY
Email
Other

Is a cost-benefit analysis required under RCW 34.05.328?

☒ Yes: A preliminary cost-benefit analysis may be obtained by contacting:

Name Julia Katz
Address PO Box 47852, Olympia, WA 98504-7852
Phone 360-236-4946
Fax 360-236-2260
TTY
Email PharmacyRules@doh.wa.gov
Other None

☐ No: Please explain:

Regulatory Fairness Act and Small Business Economic Impact Statement
Note: The Governor's Office for Regulatory Innovation and Assistance (ORIA) provides support in completing this part.

(1) Identification of exemptions:
This rule proposal, or portions of the proposal, **may be exempt** from requirements of the Regulatory Fairness Act (see chapter 19.85 RCW). For additional information on exemptions, consult the exemption guide published by ORIA. Please check the box for any applicable exemption(s):

☐ This rule proposal, or portions of the proposal, is exempt under RCW 19.85.061 because this rule making is being adopted solely to conform and/or comply with federal statute or regulations. Please cite the specific federal statute or regulation this rule is being adopted to conform or comply with and describe the consequences to the state if the rule is not adopted.
Citation and description:

☐ This rule proposal, or portions of the proposal, is exempt because the agency has completed the pilot rule process defined by RCW 34.05.313 before filing the notice of this proposed rule.

☐ This rule proposal, or portions of the proposal, is exempt under the provisions of RCW 15.65.570(2) because it was adopted by a referendum.

☐ This rule proposal, or portions of the proposal, is exempt under RCW 19.85.025(3). Check all that apply:

- ☐ RCW 34.05.310 (4)(b) (Internal government operations)
- ☐ RCW 34.05.310 (4)(c) (Incorporation by reference)
- ☐ RCW 34.05.310 (4)(d) (Correct or clarify language)
- ☐ RCW 34.05.310 (4)(e) (Dictated by statute)
- ☐ RCW 34.05.310 (4)(f) (Set or adjust fees)
- ☐ RCW 34.05.310 (4)(g) ((i) Relating to agency hearings; or (ii) process requirements for applying to an agency for a license or permit)

☐ This rule proposal, or portions of the proposal, is exempt under RCW 19.85.025(4). (Does not affect small businesses).

☐ This rule proposal, or portions of the proposal, is exempt under RCW _____.
Explanation of how the above exemption(s) applies to the proposed rule:

(2) Scope of exemptions: *Check one.*

☐ The rule proposal: Is fully exempt. *(Skip section 3.)* Exemptions identified above apply to all portions of the rule proposal.

☐ The rule proposal: Is partially exempt. *(Complete section 3.)* The exemptions identified above apply to portions of the rule proposal, but less than the entire rule proposal. Provide details here (consider using this template from ORIA):

☒ The rule proposal: Is not exempt. *(Complete section 3.)* No exemptions were identified above.

(3) Small business economic impact statement: *Complete this section if any portion is not exempt.*

If any portion of the proposed rule is **not exempt**, does it impose more-than-minor costs (as defined by RCW 19.85.020(2)) on businesses?

☒ No Briefly summarize the agency's minor cost analysis and how the agency determined the proposed rule did not impose more-than-minor costs.

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 Druggists' Sundries Merchant Wholesalers, the minor cost threshold is not met per RCW 19.85.020. A full 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 Pharmacy Quality Assurance Commission (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 Substitute House Bill (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 rulemaking 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 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 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 clarifies that 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 ninety 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 1 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 is 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 program involved in the distribution of legend drugs to have an agreement with a pharmacist with 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 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 $426 ongoing probable cost to manufacturers and wholesalers for 6 hours of a pharmacist's time ($71/hour) for consultation annually.[6] Commission staff estimate that approximately 6 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 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.

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[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)

Cost(s): It is estimated that a manufacturer or wholesaler will incur $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 an assumption of 10,000 shipments annually requiring printed records.[8] The clarification provided as part of the supplemental 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 $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 cost 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 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 U.S. Bureau of Labor and Statistics. Additional resources were used to estimate employee quantities. Commission staff, including a Pharmacist Consultant, determined the estimated time requirements.

☐ Yes Calculations show the rule proposal likely imposes more-than-minor cost to businesses and a small business economic impact statement is required. Insert the required small business economic impact statement here:

[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)

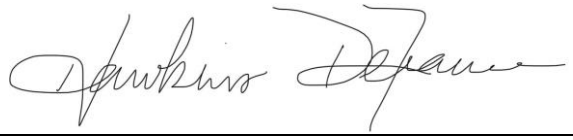
[9] Manufacturing and Quality Assurance: A Comprehensive Guide. Manufaturing Quality Assurance: A Comprehensive Guide (cashflowinventory.com) (Accessed March 25, 2024)

[10] See footnote 4

[11] See footnote 8

The public may obtain a copy of the small business economic impact statement or the detailed cost calculations by contacting:

Name Julia Katz
Address PO Box 47852, Olympia, WA 98504-7852
Phone 360-236-4946
Fax 360-236-2260
TTY 711
Email PharmacyRules@doh.wa.gov
Other None

Date: November 22, 2024 **Name:** Hawkins DeFrance, PharmD **Title:** Pharmacy Quality Assurance Commission Chair	**Signature:** 

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.

PROPOSED RULE MAKING

CR-102 (June 2024)
(Implements RCW 34.05.320)
Do **NOT** use for expedited rule making

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: December 11, 2024
TIME: 4:53 PM

WSR 25-01-067

Agency: Department of Health – Pharmacy Quality Assurance Commission

☒ **Original Notice**
☐ **Supplemental Notice to WSR**
☐ **Continuance of WSR**

☒ **Preproposal Statement of Inquiry was filed as** WSR 24-13-061**; or**
☐ **Expedited Rule Making--Proposed notice was filed as WSR _____; or**
☐ **Proposal is exempt under RCW 34.05.310(4) or 34.05.330(1); or**
☐ **Proposal is exempt under RCW _____.**

Title of rule and other identifying information: Permanent Closure Reporting Requirements for pharmacies, health care entities, hospital pharmacy associated clinics, wholesalers, and manufacturers. The Pharmacy Quality Assurance Commission (commission) is proposing to amend WAC 246-945-480 to require additional reporting requirements provided to customers and the commission in advance of permanent closures. The commission is proposing to add WAC 246-945-231 to consolidate the reporting requirement for pharmaceutical firms to report disciplinary action to the commission and add WAC 246-945-592 to establish reporting requirements for permanently closing manufacturers and wholesalers.

Hearing location(s):

Date:	**Time:**	**Location:** (be specific)	**Comment:**
02/06/2024	10:30 am	**Physical Location:** Department of Labor & Industries 7273 Linderson Way SW Tumwater, WA 98501 **Virtual Location:** Virtual: To access the meeting on February 6, 2025 at 9:30 am, go to 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: Dial (for higher quality, dial a number based on your current location): +1 253 215 8782 US (Tacoma) +1 253 205 0468 US	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: 02/06/2024 (Note: This is **NOT** the **effective** date)

Submit written comments to:	**Assistance for persons with disabilities:**
Name: Julia Katz	Contact: Julia Katz
Address: PO Box 47852, Olympia, WA 98504-7852	Phone: 360-236-4946

Email: None	Fax: 360-236-2260
Fax: 360-236-2260	TTY: 711
Other: https://fortress.wa.gov/doh/policyreview/	Email: PharmacyRules@doh.wa.gov
Beginning (date and time): The date and time of this filing	Other: None
By (date and time): January 23, 2025 at 11:59 pm	By (date): January 23, 2025

Purpose of the proposal and its anticipated effects, including any changes in existing rules:
The commission is proposing rule amendments to provide customers earlier and more detailed notification of permanent facility closures. “Facility” includes pharmacies, health care entities, and hospital pharmacy associated clinics. The anticipated effect of the proposal is to provide customers additional time to transfer prescriptions and plan accordingly prior to a facility permanently closing.

The proposed rules also revise reporting requirements for pharmaceutical firms and require additional reporting requirements, within specified time frames, prior to permanent facility, manufacturer, and wholesaler closures.

Reasons supporting proposal: This rulemaking is in response to a rules petition filed by an interested party and approved by the commission during the December 2023 business meeting. The objective of the additional notification and reporting requirements for facilities, manufacturers, and wholesalers prior to permanently closing is to increase communication with the public and commission to benefit continuity of care. Providing timelines for notification of closures will allow customers timely notice to transfer prescriptions. Increased regulation on the accounting for and inventory of legend drugs and controlled substances helps to ensure accountability and prevent diversion. Enhancing facility, manufacturer, and wholesaler permanent closure requirements will allow the commission better oversight in the event of permanent facility, manufacturer, and wholesaler closures.

Statutory authority for adoption: RCW 18.64.005, 69.41.075, and 69.50.301

Statute being implemented: RCW 18.64.005

Is rule necessary because of a:

Federal Law?	☐ Yes	☒ No
Federal Court Decision?	☐ Yes	☒ No
State Court Decision?	☐ Yes	☒ No

If yes, CITATION:

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters: None

Name of proponent: Pharmacy Quality Assurance Commission
Type of proponent: ☐ Private. ☐ Public. ☒ Governmental.

Name of agency personnel responsible for:

Name		Office Location	Phone
Drafting	Julia Katz	111 Israel Rd SE, Tumwater, WA 98501	360-236-4946
Implementation	Julia Katz	111 Israel Rd SE, Tumwater, WA 98501	360-236-4946
Enforcement	Marlee B. O’Neill	111 Israel Rd SE, Tumwater, WA 98501	360-480-9108

Is a school district fiscal impact statement required under RCW 28A.305.135? ☐ Yes ☒ No
If yes, insert statement here:

The public may obtain a copy of the school district fiscal impact statement by contacting:
Name
Address
Phone
Fax
TTY
Email
Other

Is a cost-benefit analysis required under RCW 34.05.328?
☒ Yes: A preliminary cost-benefit analysis may be obtained by contacting:
Name Julia Katz
Address PO Box 47852, Olympia, WA 98504-7852

Phone 360-236-4946
Fax 360-236-2260
TTY 711
Email PharmacyRules@doh.wa.gov
Other None

☐ No: Please explain:

Regulatory Fairness Act and Small Business Economic Impact Statement
Note: The Governor's Office for Regulatory Innovation and Assistance (ORIA) provides support in completing this part.

(1) Identification of exemptions:
This rule proposal, or portions of the proposal, **may be exempt** from requirements of the Regulatory Fairness Act (see chapter 19.85 RCW). For additional information on exemptions, consult the exemption guide published by ORIA. Please check the box for any applicable exemption(s):

☐ This rule proposal, or portions of the proposal, is exempt under RCW 19.85.061 because this rule making is being adopted solely to conform and/or comply with federal statute or regulations. Please cite the specific federal statute or regulation this rule is being adopted to conform or comply with, and describe the consequences to the state if the rule is not adopted.
Citation and description:

☐ This rule proposal, or portions of the proposal, is exempt because the agency has completed the pilot rule process defined by RCW 34.05.313 before filing the notice of this proposed rule.

☐ This rule proposal, or portions of the proposal, is exempt under the provisions of RCW 15.65.570(2) because it was adopted by a referendum.

☐ This rule proposal, or portions of the proposal, is exempt under RCW 19.85.025(3). Check all that apply:

- ☐ RCW 34.05.310 (4)(b) (Internal government operations)
- ☐ RCW 34.05.310 (4)(c) (Incorporation by reference)
- ☐ RCW 34.05.310 (4)(d) (Correct or clarify language)
- ☐ RCW 34.05.310 (4)(e) (Dictated by statute)
- ☐ RCW 34.05.310 (4)(f) (Set or adjust fees)
- ☐ RCW 34.05.310 (4)(g) ((i) Relating to agency hearings; or (ii) process requirements for applying to an agency for a license or permit)

☐ This rule proposal, or portions of the proposal, is exempt under RCW 19.85.025(4). (Does not affect small businesses).

☐ This rule proposal, or portions of the proposal, is exempt under RCW _____.

Explanation of how the above exemption(s) applies to the proposed rule:

(2) Scope of exemptions: *Check one.*

☐ The rule proposal: Is fully exempt. *(Skip section 3.)* Exemptions identified above apply to all portions of the rule proposal.

☐ The rule proposal: Is partially exempt. *(Complete section 3.)* The exemptions identified above apply to portions of the rule proposal, but less than the entire rule proposal. Provide details here (consider using this template from ORIA):

☒ The rule proposal: Is not exempt. *(Complete section 3.)* No exemptions were identified above.

(3) Small business economic impact statement: *Complete this section if any portion is not exempt.*

If any portion of the proposed rule is **not exempt**, does it impose more-than-minor costs (as defined by RCW 19.85.020(2)) on businesses?

☒ No Briefly summarize the agency's minor cost analysis and how the agency determined the proposed rule did not impose more-than-minor costs.

The costs of the proposed rule ($117 per facility, $12 per pharmaceutical firm, and $98 to $122 per manufacturer or wholesaler) are all less than the minor cost threshold ($19,161.74 for pharmacies and drug stores and $10,305.83 for drugs and druggists' sundries merchant wholesalers).

The minor cost analysis demonstrated that the estimated cost to pharmacies, health care entities, and hospital pharmacy associated clinics is $117 per facility, $12 per pharmaceutical firm, and $98 to $122 per manufacturer and wholesaler. Using the Governor's Office for Regulatory Innovation and Assistance's Minor Cost Threshold Calculator with NAICS Code Titles 446110 Pharmacies and Drug Stores and 424210 Drugs and Druggists' Sundries Merchant Wholesalers, the minor cost threshold is not met per RCW 19.85.020. A full SBEIS may not be required since the minor cost threshold is not met.

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 Washington State Pharmacy Quality Assurance Commission (commission) is proposing rule amendments to provide customers earlier and more detailed notification of permanent facility closures. “Facility” includes pharmacies, health care entities, and hospital pharmacy associated clinics.

The proposed rules also require additional and revised reporting requirements, within specified time frames prior to permanent facility, manufacturer, and wholesaler closures.

This proposed rule package is in response to a rule petition filed by an interested individual requesting pharmacies provide clear communication and a timeline for prescription transfers to patients ahead of a facility closure in December 2023. On December 14, 2023, the commission voted to approve the request and consider rulemaking.

Small facilities, manufacturers, and wholesalers that permanently close must fulfill reporting and notification requirements to the commission and customers. Commission reporting requirements for closing facilities, manufacturers, and wholesalers consist of communicating in writing planned and actualized logistics pertaining to closure plans. Customer notification requirements for closing facilities include informing customers verbally of the closure, informing employees of the rule adoptions, creating a notice to include with dispensed prescriptions, and advertising in a print and digital version of the newspaper, if available. Manufacturers and wholesalers must notify customers in writing of the closure date and the last day to place orders for fulfillment. Compliance with the proposed reporting requirements will involve time of the manager in charge.

SBEIS Table 1 identifies and summarizes 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 with the Proposed Rule

NAICS Code (4, 5 or 6 digit)	NAICS Business Description	Number of businesses in Washington State	Minor Cost Threshold
446110	Pharmacies and Drug Stores	267	$19,161.74
424210	Drugs and Druggists' Sundries Merchant Wholesalers	388	$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 246-945-231(1) Reporting Disciplinary Action.

Description: Only three license types the commission regulates are currently required by state rule to report to the commission disciplinary action taken by another state, federal, or foreign authority. The commission is proposing to amend the term “facility” to “pharmaceutical firm” in WAC 246-945-480(5) and replace WAC 246-945-480(5) with WAC 246-945-231(1) thereby requiring all 15 licensee types the commission regulates to report disciplinary action taken by authorized entities to the commission. “Facility” includes pharmacies, health care entities, and hospital pharmacy associated clinics per WAC 246-945-405. “Pharmaceutical firm” refers to any business engaged in the dispensing, delivering, distributing, manufacturing, or wholesaling of prescription drugs or devices within or into Washington state per WAC 246-945-001. All pharmaceutical firms are also listed in WAC 246-945-990. This proposed reporting requirement applies to pharmaceutical firms at any time.

Cost(s): Pharmaceutical firms will need to report to the commission when a disciplinary action occurs.

The estimated probable total cost is $12 per incident for a pharmaceutical firm to report to the commission of a disciplinary action by another state, federal, or foreign authority. The department is unable to estimate how many times this will happen per year.

Cost assumptions for estimate:

- Commission reporting cost assumptions:
  - Each pharmaceutical pharmaceutical firm is required to designate a responsible person whose responsibilities include accountability for transferred drugs and substances per the FDA Drug Quality and Security Act.[1]
  - For the purpose of this estimate, the commission assumes that the closest probable job title is a general operations manager.
  - Commission staff estimate based on experience that reporting an applicable disciplinary action will require 10 minutes of a general operations manager's time ($69.43/hour).[2]

Calculations for estimate:

- Calculations for commission reporting costs:
  - $11.57 for 10 minutes of the general operations manager's time to report an applicable disciplinary action.

WAC 246-945-480(1) Facility Reporting Requirements.
Description: The proposed WAC 246-945-480(1) amendment is to replace the "ten" with "10." Per RCW 34.05.310(4)(d), this amendment is exempt from analysis as it exclusively corrects a typographical error.

WAC 246-945-480(2) Facility Reporting Requirements.
Description: Currently, when a facility (i.e., pharmacy, health care entity, or hospital pharmacy associated clinic) is closing permanently, 30 days prior they must notify the commission of the name and address of the person(s) who will acquire legend drugs from the facility to be closed. The commission is proposing to amend WAC 246-945-480(2)(a) to require permanently closing facilities to additionally report to the commission during this time frame the credential number of the people who are anticipated to acquire the facility's legend drugs and the name, address, and credential number of the people anticipated to acquire the facility's controlled substances. Pharmacy managers will need to apprise the commission of the credential number of the people who shall acquire the legend drugs and the name, address, and credential number of the people who shall acquire the controlled substances, if known at the time. The information may be included with an existing communication.

Facilities currently should notify customers of imminent permanent closures via direct mail, public notice in a newspaper, and signage in a conspicuous area of the pharmacy without a time parameter. Proposed WAC 246-945-480(2)(b) amends the patient notification requirements to mandate informing customers of the closure during prescription pick-up or delivery, include a notice with dispensed prescriptions informing them of their right to request a prescription transfer, and public notice in a legal newspaper of general circulation in both print and digital versions, if applicable, in addition to the signage in a conspicuous area of the pharmacy. These notifications must begin no later than 30 calendar days prior to closing. Pharmacy managers will need to apprise pertinent staff of the rule adoption, develop and print notices to be included in dispensed prescriptions to inform customers of their right to request a prescription transfer, and determine if the newspaper in which they are circulating the announcement has a digital version.

After a facility closes, they have 15 days to report several items to the commission, including the name and address of the person(s) to whom the legend drugs and controlled substances were transferred. The proposed WAC 246-945-480(2)(c) amends the post-closure requirements to require the facility closing to additionally report the credential numbers of the people who acquired both the legend drugs and controlled substances. The information may be included with an existing communication.

Cost(s): The probable costs only impact facilities that permanently close. Permanently closing facilities will need to report to the commission the credential numbers for the people anticipated to acquire the legend drugs, the name, address, and credential number of the people anticipated to acquire the controlled substances, if known at the time, and credential numbers of the people who ultimately acquired legend drugs and controlled substances. To communicate to the public, they will also need to apprise pertinent staff to inform customers upon prescription pick-up or delivery, include notices of prescription transfer rights in dispensed prescriptions, and, if available, publicize a notice of permanent closure in a digital version of the selected newspaper.

[1] H.R. 3204 – Drug Quality and Security Act, 113th Congress (2013-2014), https://www.congress.gov/bill/113th-congress/house-bill/3204/text?s=10&r=1&q=%7B%22search%22%3A%22hr3204%22%7D (visited September 23, 2024).

[2] Bureau of Labor Statistics, General and Operations Manager, $69.43 Hourly mean wage in WA https://www.bls.gov/oes/current/oes119111.htm (visited September 23, 2024).

The commission assumes that all facilities dispensing prescriptions have a working computer and printer, but should they have to purchase one the cost could be $300 to $2,000 for a computer and $100 to $300 for a printer.[3,4]

The estimated probable total cost is $117 per permanently closing facility to communicate additional reporting and notification requirements to the commission and public.

Cost assumptions for estimate:

- Commission reporting cost assumptions:
  - Assumes each facility has 1 pharmacy manager per WAC 246-945-410(5).[5]
  - Commission staff estimate based on experience that requesting a credential number for the people anticipated to acquire the legend drugs and communicating it in writing will take 5 minutes of a pharmacy manager's time ($73.50/hour).[6]
  - Commission staff estimate based on experience that reporting the name, address, and credential number of the people anticipated to acquire the controlled substances will take 10 minutes of a pharmacy manager's time ($73.50/hour).[7]
  - Communicating the name, address, and credential number of the people who ultimately acquired legend drugs and controlled substances will take 20 minutes of a pharmacy manager's time ($73.50/hour) according to commission staff's estimate based on pharmacist consultation.[8]
- Customer notification cost assumptions:
  - Assumes each facility has 1 pharmacy manager per WAC 246-945-410(5).[9]
  - Commission staff estimate based on consultation with a pharmacist that apprising pertinent staff of the rule adoption and the need to inform customers of the permanent closure upon prescription pick-up or delivery will require 30 minutes of the pharmacy manager's time ($73.50/hour) to prepare and deliver the communication.[10]
  - Commission staff estimate based on consultation with a pharmacist that creating a paper notice to include with dispensed prescriptions that informs the customer of their right to request a prescription transfer will require 30 minutes of the pharmacy manager's time ($73.50/hour) to prepare and insert the notice.[11]
  - Informing customers of the permanent closure will occur verbally and refer customers to the noticed inserted with the dispensed prescription. The time required to convey the information to the customer will vary greatly, depending on the number of questions received from the customer, but is anticipated to generally be a negligible amount of time.
  - The cost of notices inserted with dispensed prescriptions is minimal, about one to two reams of paper, depending on the facility's dispensing capacity. The commission considers this cost negligible for the purposes of this analysis.
  - The cost of an advertisement in a digital version of a newspaper does not impose an additional cost as print newspaper advertisements include digital publication.[12] Facilities currently have to advertise in a print newspaper when permanently closing.

[3] Lenovo, new laptops range from $300 to $2,000, https://www.lenovo.com/us/en/d/deals/business/?orgRef=https%253A%252F%252Fwww.bing.com%252F&sortBy=bestSelling&cid=us%3Asem%7Cse%7Cmsn%7Cnonbrand_pc%7C%7Coffice%20laptop%7Cp%7C506005685%7C1268838063590376%7Ckwd-79302875432137%3Aloc-190%7Csearch%7Cnonbrand%7Cconsumer&msclkid=cb523a8cb13f12b648eb5c602cb4e2f7&visibleDatas=1014%3ALaptops (visited September 19, 2024).

[4] Lenovo, new printers range from $100 to $300, https://www.lenovo.com/us/en/search?fq=&text=printer&rows=20&sort=relevance (visited September 19, 2024).

[5] WAC 246-945-410(5) "The facility shall designate a pharmacy manager," https://app.leg.wa.gov/WAC/default.aspx?cite=246-945-410 (visited September 19, 2024).

[6] Bureau of Labor Statistics, U.S. Department of Labor, Occupational Employment and Wage Statistics, Health Service Managers in WA in May 2023, https://www.bls.gov/oes/current/oes119111.htm (visited September 20, 2024).

[7] Bureau of Labor Statistics, U.S. Department of Labor, Occupational Employment and Wage Statistics, Health Service Managers in WA in May 2023, https://www.bls.gov/oes/current/oes119111.htm (visited September 20, 2024).

[8] Bureau of Labor Statistics, U.S. Department of Labor, Occupational Employment and Wage Statistics, Health Service Managers in WA in May 2023, https://www.bls.gov/oes/current/oes119111.htm (visited September 20, 2024).

[9] WAC 246-945-410(5) "The facility shall designate a pharmacy manager," https://app.leg.wa.gov/WAC/default.aspx?cite=246-945-410 (visited September 19, 2024).

[10] Bureau of Labor Statistics, U.S. Department of Labor, Occupational Employment and Wage Statistics, Health Service Managers in WA in May 2023, https://www.bls.gov/oes/current/oes119111.htm (visited September 20, 2024).

[11] Bureau of Labor Statistics, U.S. Department of Labor, Occupational Employment and Wage Statistics, Health Service Managers in WA in May 2023, https://www.bls.gov/oes/current/oes119111.htm (visited September 20, 2024).

[12] Phil Kearney, National Marketing Strategist at The Seattle Times, (phone call on September 20, 2024).

Calculations for estimate:

- Calculations for commission reporting costs:
  - $6.13 for 5 minutes of a pharmacy manager's time to report a credential number for people anticipated to acquire legend drugs and communicate it in writing to the commission.
  - $12.25 for 10 minutes of a pharmacy manager's time to report the name, address, and credential number for people anticipated to acquire controlled substances and communicate them in writing to the commission.
  - $24.50 for 20 minutes of a pharmacy manager's time to report the name, address, and credential number for people who ultimately acquired legend drugs and controlled substances.
- Calculations for customer notification costs:
  - $36.75 for 30 minutes of a pharmacy manager's time to prepare and deliver a communication apprising pertinent staff of the rule adoption and the need to inform customers of the closure.
  - $36.75 for 30 minutes of a pharmacy manager's time to create and include a paper notice with dispensed prescriptions that informs customers of their right to request a prescription transfer.

WAC 246-945-480(3) Facility Reporting Requirements.
Description: There are no proposed amendments to WAC 246-945-480(3) making it exempt from analysis.

WAC 246-945-480(4) Facility Reporting Requirements.
Description: The proposed WAC 246-945-480(4) amendment is to replace the first "The" with "A." Per RCW 34.05.310(4)(d), this amendment is exempt from analysis as it exclusively corrects a typographical error.

WAC 246-945-592(1) Wholesaler and Manufacturer Reporting Requirements.
Description: Manufacturers and wholesalers that are permanently closing are not explicitly required in rule to inform the commission nor their customers. The commission is proposing to add WAC 246-945-592 to require manufacturers and wholesalers to notify the commission and their customers in the event of a permanent closure.
Proposed WAC 246-945-592(1)(a) includes a customer notification requirement in the form of a written communication which includes the last day the manufacturer or wholesaler will be open and the last day the customer may place an order to be fulfilled.

Reporting requirements to the commission are included in proposed WAC 246-945-592(1)(b) and WAC 246-945-592(1)(c). At least 30 calendar days prior to permanently closing, a manufacturer or wholesaler shall report to the commission in writing the date of the closure and the names, credential numbers, and addresses of the people who will receive any legend drugs or controlled substances, if known at the time. Within 15 calendar days from the closure date, the manufacturer or wholesaler will return their license, confirm the name, credential number, and address of the people who received any legend drugs and controlled substances, confirm U.S. Drug Enforcement Agency (DEA) registration and unused DEA 222 forms were returned to the DEA, and confirm all signs and symbols indicating the presence of the wholesaler and manufacturer have been removed, if applicable, to the commission.

Cost(s): The probable costs only impact manufacturers and wholesalers that permanently close. Permanently closing manufacturers and wholesalers will need to report to the commission the date of the closure and the names, credential numbers, and addresses of the people anticipated to receive any legend drugs or controlled substances, if known at the time. After the manufacturer or wholesaler location has closed, they will need to report to the commission the return of their license, the name, credential number, and address of the people who received any legend drugs and controlled substances, confirmation of returned U.S. Food and Drug Administration's (FDA) Drug Enforcement Agency (DEA) registration and unused DEA 222 forms, and, if applicable, confirmation of removal of all signs and symbols indicating the presence of the wholesaler and manufacturer.

The estimated probable total cost ranges from $98 to $110 per permanently closing manufacturer or wholesaler to fulfill reporting requirements to the commission and notify customers.

Cost assumptions for estimate:

- Commission reporting cost assumptions:
  - Each pharmaceutical wholesaler or manufacturer is required to designate a responsible person whose responsibilities include accountability for transferred drugs and substances per the FDA Drug Quality and Security Act.[13]
  - For the purpose of this estimate, the commission assumes that the closest probable job title is a general operations manager.

[13] H.R. 3204 – Drug Quality and Security Act, 113th Congress (2013-2014), https://www.congress.gov/bill/113th-congress/house-bill/3204/text?s=10&r=1&q=%7B%22search%22%3A%22hr3204%22%7D (visited September 23, 2024).

- Commission staff estimate based on experience that reporting the date of the closure will require 5 minutes of a general operations manager's time ($69.43/hour).[14]
- Communicating the name, address, and credential number of people anticipated to acquire the legend drugs and controlled substances will take 20 minutes of a general operations manager's time ($69.43/hour).[15]
- Communicating the name, address, and credential number of the people who ultimately acquired legend drugs and controlled substances will take 20 minutes of a general operations manager's time ($69.43/hour) according to commission staff's estimate based on pharmacist consultation.[16]
- Commission staff estimate based on consultation with a pharmacist that reporting the return of their license will require 5 minutes of a general operation manager's time ($69.43/hour).[17]
- Confirming that DEA registration and unused DEA 222 forms were returned to the DEA is estimated to require 5 minutes of a general operation manager's time ($69.43/hour) per commission staff estimate based on consultation with a pharmacist consultant.[18]
- If there are signs and symbols indicating the presence of the manufacturer or wholesaler, commission staff estimate based on consultation with a pharmacist that confirming their removal will require 10 minutes of a general operation manager's time ($69.43/hour).[19] If the manufacturer or wholesaler does not have signs or symbols, there will be no confirmation and the cost would be $0.

- Customer notification cost assumptions:
  - Commission staff estimate based on consultation with a pharmacist that notifying customers of the manufacturer or wholesaler's closure in writing and the last day to place an order to be fulfilled will require 30 minutes of the general operation manager's time ($69.43/hour) to prepare and distribute the written notice.[20]

Calculations for estimate:

- Calculations for commission reporting costs:
  - $5.79 for 5 minutes of the general operations manager's time to report the date of closure.
  - $23.14 for 20 minutes of the general operations manager's time to communicate the name, address, and credential number of people anticipated to acquire the legend drugs and controlled substances.
  - $23.14 for 20 minutes of the general operations manager's time to communicate the name, address, and credential number of people who ultimately acquired the legend drugs and controlled substances.
  - $5.79 for 5 minutes of the general operations manager's time to report the return of the license.
  - $5.79 for 5 minutes of the general operations manager's time to confirm DEA registration and unused DEA 222 forms were returned to the DEA.
  - $0 to $11.57 range for 0 to 10 minutes of the general operations manager's time to confirm removal of identifying signs and symbols. This cost is only applicable to permanently closing manufacturers and wholesalers with signs and symbols indicating their presence.
- Calculations for customer notification costs:
  - $34.72 for 30 minutes of the general operations manager's time to inform customers of the manufacturer or wholesaler's closure and the last day to place an order to be fulfilled.

WAC 246-945-592(2) Wholesaler and Manufacturer Reporting Requirements.

Description: Manufacturers and wholesalers are not currently required by state rule to report to the commission any disasters, accidents, or emergencies. The commission is proposing to require wholesalers and manufacturers to report to the commission any disasters, accidents, or emergencies which may affect the strength, purity, or labeling of drugs, medications, devices, or other materials used in the diagnosis or the treatment of injury, illness, or disease in new WAC 246-945-592. This proposed reporting requirement applies to manufacturers and wholesalers at any time.

[14] Bureau of Labor Statistics, General and Operations Manager, $69.43 Hourly mean wage in WA in May 2023 https://www.bls.gov/oes/current/oes119111.htm (visited September 23, 2024).

[15] Bureau of Labor Statistics, General and Operations Manager, $69.43 Hourly mean wage in WA in May 2023 https://www.bls.gov/oes/current/oes119111.htm (visited September 23, 2024).

[16] Bureau of Labor Statistics, General and Operations Manager, $69.43 Hourly mean wage in WA in May 2023 https://www.bls.gov/oes/current/oes119111.htm (visited September 23, 2024).

[17] Bureau of Labor Statistics, General and Operations Manager, $69.43 Hourly mean wage in WA in May 2023 https://www.bls.gov/oes/current/oes119111.htm (visited September 23, 2024).

[18] Bureau of Labor Statistics, General and Operations Manager, $69.43 Hourly mean wage in WA in May 2023 https://www.bls.gov/oes/current/oes119111.htm (visited September 23, 2024).

[19] Bureau of Labor Statistics, General and Operations Manager, $69.43 Hourly mean wage in WA https://www.bls.gov/oes/current/oes119111.htm (visited September 23, 2024).

[20] Bureau of Labor Statistics, General and Operations Manager, $69.43 Hourly mean wage in WA https://www.bls.gov/oes/current/oes119111.htm (visited September 23, 2024).

Cost(s): Manufacturers and wholesalers will need to report to the commission when a disaster, accident, or emergency which affects the strength, purity, or labeling of drugs, medications, devices, or other materials used in the diagnosis or the treatment of injury, illness, or disease occurs.

The estimated probable total cost is $12 per incident for a manufacturer or wholesaler to report to the commission of a disaster, accident, or emergency which affects the strength, purity, or labeling of drugs, medications, devices, or other materials used in the diagnosis or the treatment of injury, illness, or disease. The department is unable to estimate how many times this will happen per year.

Cost assumptions for estimate:

- Commission reporting cost assumptions:
  - Each pharmaceutical wholesaler or manufacturer is required to designate a responsible person whose responsibilities include accountability for transferred drugs and substances per the FDA Drug Quality and Security Act.[21]
  - For the purpose of this estimate, the commission assumes that the closest probable job title is a general operations manager.
  - Commission staff estimate based on experience that reporting an applicable disaster, accident, or emergency will require 10 minutes of a general operations manager's time ($69.43/hour).[22]

Calculations for estimate:

- Calculations for commission reporting costs:
  - $11.57 for 10 minutes of the general operations manager's time to report an applicable disaster, accident, or emergency.

Summary of all Cost(s)

SBEIS Table 2. Summary of Section 3 probable cost(s)

WAC Section and Title	Probable Cost(s)
WAC 246-945-231(1) Reporting Disciplinary Action	$12 per pharmaceutical firm occurrence
WAC 246-945-480(2) Facility Reporting Requirements	$117 per facility permanent closure
WAC 246-945-592(1) Wholesaler and Manufacturer Reporting Requirements	$98 to $110 per manufacturer or wholesaler permanent closure
WAC 246-945-592(2) Facility Reporting Requirements	$12 per manufacturer or wholesaler occurrence
TOTAL	**$12 per pharmaceutical firm occurrence** **$117 per facility permanent closure** **$98 to $122 per manufacturer or wholesaler permanent closure and occurrence**

The following is an analysis on if the proposed rule may impose more than minor costs for businesses in the industry and a summary of how the costs were calculated.

The costs of the proposed rule ($12 per pharmaceutical firm, $117 per facility, and $98 to $122 per manufacturer or wholesaler) are less than the minor cost threshold ($19,161.74 for pharmacies and drug stores or $10,305.83 for drugs and druggists' sundries merchant wholesalers).

The probable costs were calculated for pharmaceutical firms, pertinent facilities, 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 U.S. Bureau of Labor and Statistics. Commission staff, including staff licensed as pharmacists, estimated time requirements.

☐ Yes Calculations show the rule proposal likely imposes more-than-minor cost to businesses and a small business economic impact statement is required. Insert the required small business economic impact statement here:

[21] H.R. 3204 – Drug Quality and Security Act, 113th Congress (2013-2014), https://www.congress.gov/bill/113th-congress/house-bill/3204/text?s=10&r=1&q=%7B%22search%22%3A%22hr3204%22%7D (visited September 23, 2024).

[22] Bureau of Labor Statistics, General and Operations Manager, $69.43 Hourly mean wage in WA https://www.bls.gov/oes/current/oes119111.htm (visited September 23, 2024).

The public may obtain a copy of the small business economic impact statement or the detailed cost calculations by contacting:

Name	Julia Katz
Address	PO Box 47852, Olympia, WA 98504-7852
Phone	360-236-4946
Fax	360-236-2260
TTY	711
Email	PharmacyRules@doh.wa.gov
Other	None

Date: December 4, 2024 **Name:** Hawkins DeFrance, PharmD **Title:** Pharmacy Quality Assurance Commission Chair	**Signature:** 

NEW SECTION

WAC 246-945-231 Reporting disciplinary action. Any pharmaceutical firm credentialed by the commission must report to the commission any disciplinary action, including denial, revocation, suspension, or restriction to practice by another state, federal, or foreign authority.

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

WAC 246-945-480 Facility reporting requirements. (1) The outgoing and incoming responsible pharmacy manager must report in writing to the commission a change in a responsible manager designation within ((~~ten~~)) 10 business days of the change.

(2) Unless otherwise specified, when permanently closing a facility, the facility must:

(a) Report to the commission in writing, no later than ((~~thirty~~)) 30 calendar days prior to closing:

(i) The date the facility will close;

(ii) The names and addresses of the ((~~persons~~)) person(s) who shall have custody of the prescription files, bulk compounding records, repackaging records, invoices and controlled substances inventory records of the ((~~pharmacy~~)) facility to be closed; ((~~and~~))

(iii) The names, credential numbers, and addresses of ((~~any~~)) the person(s) who ((~~will~~)) shall acquire any legend drugs from the facility to be closed, if known at the time the notification is filed; and

(iv) The names, credential numbers, and addresses of persons who shall acquire any controlled substances from the facility to be closed, if known at the time the notification is filed.

(b) Provide notification to customers ((~~noting~~)) beginning no later than 30 calendar days prior to closing which includes the last day the pharmacy will be open((~~, name and address of the pharmacy to which prescription records will be transferred and instructions on how patients can arrange for transfer of their prescription records to a pharmacy of their choice~~)) and the last day a transfer may be initiated. Notification ((~~should~~)) shall include:

(i) ((~~Distribution by direct mail; or~~)) Posting a closing notice in a conspicuous place in the public area of the pharmacy;

(ii) ((~~Public notice in a newspaper of general circulation in the area served by the pharmacy~~)) Informing patients of the closure during prescription pick-up or delivery including a notice with dispensed prescriptions informing patients of their right to request a prescription transfer, if applicable; and

(iii) ((~~Posting a closing notice sign in a conspicuous place in the public area of the pharmacy.~~)) Public notice in at least one legal newspaper of general circulation in the area served by the pharmacy that meets the qualifications of RCW 65.16.020. The public notice must appear in both the print and digital versions of the legal newspaper, if available.

(c) No later than ((~~fifteen~~)) 15 calendar days after closing:

(i) Return the facility license to the commission;

(ii) Confirm to the commission that all legend drugs were transferred ((~~or destroyed. If the legend drugs were transferred,~~)) appropriately and provide the names, credential numbers, and addresses of the person(s) to whom ((~~they~~)) the legend drugs were transferred;

(iii) Confirm ((~~if~~)) to the commission that all controlled substances were transferred((~~, including the date of transfer, names, addresses, and a detailed inventory of the drugs~~)) appropriately and provide a detailed inventory of the drugs transferred and the names, credential numbers, and addresses of the person(s) to whom the controlled substances were transferred;

(iv) Confirm ((~~return of~~)) that the DEA registration and all unused DEA 222 forms were returned to the DEA;

(v) Confirm all pharmacy labels and blank prescriptions were destroyed; and

(vi) Confirm all signs and symbols indicating the presence of the pharmacy have been removed.

(3) The commission may conduct an inspection to verify all requirements in subsection (2) of this section have been completed.

(4) ((~~The~~)) A facility shall immediately report to the commission any disasters, accidents and emergencies which may affect the strength, purity, or labeling of drugs, medications, devices or other materials used in the diagnosis or the treatment of injury, illness, and disease.

((~~(5) Any facility credentialed by the commission must report to the commission any disciplinary action, including denial, revocation, suspension, or restriction to practice by another state, federal, or foreign authority.~~))

NEW SECTION

WAC 246-945-592 Wholesaler and manufacturer reporting requirements. (1) Unless otherwise specified, when permanently closing a wholesaler or manufacturer, the wholesaler or manufacturer must:

(a) Provide notification to customers in writing, no later than 30 calendar days prior to closing, which includes the last day the wholesaler or manufacturer will be open and the last day the customer may place an order to be fulfilled.

(b) Report to the commission in writing, no later than 30 calendar days prior to closing:

(i) The date the wholesaler or manufacturer will close; and

(ii) The names, credential numbers, and addresses of the person(s) who shall receive any legend drugs or controlled substances from the wholesaler or manufacturer to be closed, if known at the time the notification is filed.

(c) No later than 15 calendar days after closing:

(i) Return the wholesaler or manufacturer license to the commission;

(ii) Confirm to the commission that all legend drugs were transferred appropriately and provide the names, credential numbers, and addresses of the person(s) to whom the legend drugs were transferred;

(iii) Confirm to the commission that all controlled substances were transferred appropriately and provide a detailed inventory of the drugs transferred and the names, credential numbers, and addresses of each person(s) to whom the controlled substances were transferred;

(iv) Confirm that the DEA registration and all unused DEA 222 forms were returned to the DEA; and

(v) Confirm all signs and symbols indicating the presence of the wholesaler or manufacturer have been removed, if applicable.

(2) A wholesaler or manufacturer shall immediately report to the commission any disasters, accidents, and emergencies which may affect the strength, purity, or labeling of drugs, medications, devices or other materials used in the diagnosis or the treatment of injury, illness, and disease.

Assessing Compliance to the Drug Supply Chain Security Act (DSCSA)

Scope and Disclaimer:

This document is intended to provide a starting point to assess compliance to the federal requirements of the Drug Supply Chain Security Act (DSCSA). This document is **not** intended to provide a comprehensive or exhaustive list of all applicable requirements under DSCSA. It is the ultimate responsibility of licensees of the commission, and where necessary with the guidance of their own legal counsel, to ensure continued compliance to the applicable DSCSA requirements.

Introduction:

Q: What is DSCSA?

A: The Drug Supply Chain Security Act (DSCSA) is federal legislation granting the FDA authority to establish regulations aimed at securing the U.S. drug supply chain to protect patients from receiving drug products that are counterfeit, diverted, stolen, obtained from fraudulent transactions, intentionally adulterated, which may lead to patient harm. DSCSA is a new section of law added under Title II of the Federal Food Drug and Cosmetics Act (FD&C Act).

The primary goals of DSCSA are to:

1. Implement an interoperable system to allow for the electronic tracing of drug products at the package level across trading partners, and when necessary, allow for verification of products in the drug supply chain.
2. Establish national standards for licensure for all entities involved in the drug supply chain.

Q: Who does DSCSA apply to?

A: DSCSA applies to all "trading partners" involved with the drug supply chain. Trading partners include manufacturers, repackagers, wholesale distributors, and dispensers (pharmacies and HCEs) where there is a transfer of ownership of drug product. See Sec. 581. Definitions of the FD&C Act.

Q: Do all drug products fall under the requirements of DSCSA?

A: DSCSA applies to prescription drug "products" in finished dosage form for administration to a patient without further manufacturing (such as capsules, tablets, and lyophilized products before reconstitution).

Certain products **not subject** to the requirements of DSCSA are:

- blood or blood components intended for transfusion;
- radioactive drugs or radioactive biological products;
- imaging drugs;
- certain intravenous products;
- any medical gas
- homeopathic drugs marketed in accordance with applicable guidance under the FD&C Act
- drugs compounded in compliance with sections 503A or 503B of the FD&C Act (21 U.S.C. 353a or 353b)

Please see Section 581(13) of the FD&C Act for additional information regarding excluded products.

Q: Do licensees of the Pharmacy Quality Assurance Commission need to comply with the provisions of DSCSA?

A: **Yes**, RCW 18.64.026(1) requires all facilities licensed by the pharmacy commission to comply with all applicable state and federal laws.

Section 1: Authorized Trading Partners

All transactions of drug products covered under DSCSA, where a change of ownership occurs, **must** be made between authorized trading partners. Depending on type of business entity, to become an "authorized trading partner", a pharmaceutical facility must obtain registration from the FDA and/or obtain a state license from the pharmacy commission. The following table outlines the current requirements to be an "authorized trading partner".

Authorized Trading Partners					
Trading Partner	**Manufacturers & Repackagers**	**Wholesale Distributors & 3PLs**	**Dispensers**		
			All Pharmacies	**Health Care Entities (HCE)**	**Drug Other Controlled Substances Registrants***
Steps to become "authorized"	Obtains a registration with the FDA in accordance with section 510 of the FD&C. Obtains a state manufacturer license if located in WA**	Obtains a state wholesaler license (for WA wholesalers) or a non-resident wholesaler license.	Obtains a WA state pharmacy license (for WA resident pharmacies) or a non-resident pharmacy license.	Obtains a PQAC health care entity license.	Obtains PQAC license or registration.
Links to verify a trading partner is authorized	Drug Establishments Current Registration Site (FDA DECRS)	Check Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers | FDA	WA DOH Facility Search	WA DOH Facility Search	WA DOH Facility Search

*Provisions of DSCSA apply when there is dispensing of drug products to patients (i.e., opioid treatment programs).
**WA state law requires those who engage in the manufacturer of drugs to also obtain a state manufacturers license.

Please refer to the FDA's Guidance Document titled "Identifying Trading Partners under the Drug Supply Chain Security Act" for further information pertaining to authorized trading partners.

Section 2: Labeling Requirements of Drug Products Distributed Under DSCSA

Authorized trading partners may conduct transactions of drug products that meet the following labeling requirements of DSCSA.

- Manufacturers and repackagers must affix or imprint a product identifier on each package and homogenous case of product intended to be introduced in a transaction in commerce.

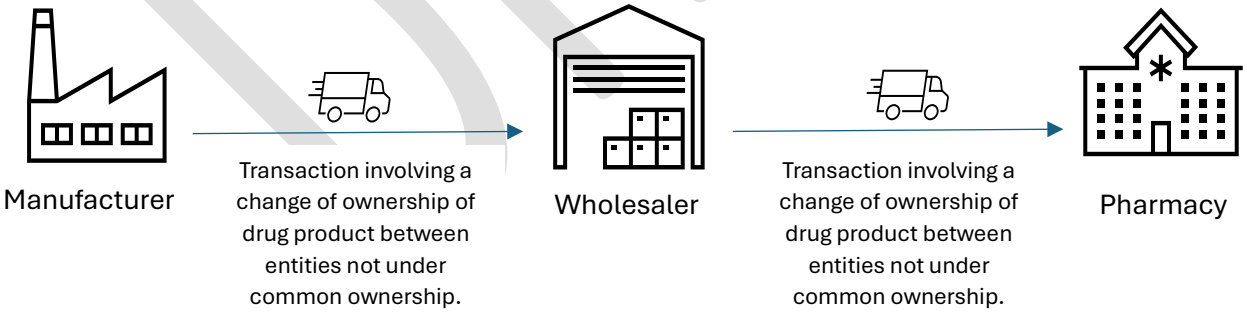
- The human-readable portion of the product identifier must include:
  - National Drug Code (NDC)
  - The standardized numerical identifier (serial number)
  - The lot number
  - The expiration date of the product

- The product identifier must be in both human-readable form and on a machine-readable data carrier that conforms to the standards outlined in the FDA guidance document titled "Product Identifiers Under the Drug Supply Chain Security Act – Questions and Answers".

Section 3: Covered Transactions and Product Tracing Information

DSCSA defines transactions as a "transfer of product between persons in which a change of ownership occurs" Sec. 581 (24). Some examples of transactions covered under DSCSA are illustrated below.

Transactions Subject to DSCSA Requirements:



Transactions Not Subject to DSCSA Requirements:

Intracompany transactions between division, subsidiary, parent or affiliated, or related company under the common ownership and control of a corporate entity would not be subject to the requirements of DSCSA.

Some exemptions include:

- The distribution of a product among hospitals or other health care entities that are under common ownership.
- Dispensing of drug products pursuant to a valid prescription.
- For a full list of exempt transactions, please see Sec 581 (24)(B) Transaction Exemptions.

Required Transaction Information

For each covered transaction, drug product tracing information must be provided that includes the following elements:

- Transaction Information [1]
- Transaction Statement [1]

Product tracing information must be stored in a secure electronic manner that permits the interoperable exchange of product tracing information to facilitate product tracing and verification. Product tracing information must be stored for at least **6 years**.

Please refer to the FDA's Guidance "DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs" for specific guidance on standards to achieve interoperable product tracing requirements.

Exemptions to Product Tracing Requirements:

FDA has the authority to grant waivers, exceptions and exemptions from **certain requirements** in DSCSA. More information on the process to obtain an exemption can be found here: The Drug Supply Chain Security Act (DSCSA) Waivers, Exceptions, and Exemptions | FDA

More recently, the FDA granted exemptions to "connected trading partners" and "small dispensers". Information related to these exemptions can be found here: Waivers and Exemptions Beyond the Stabilization Period | FDA. Please note, that these exemptions apply to specific requirements of DSCSA granted, the entity has made documented efforts to complete data connections with their immediate trading partners, but still face challenges exchanging data.

Section 4: Suspect and Illegitimate Products

The term "suspect product" means a drug product for which there is reason to believe may be counterfeit, diverted, stolen, obtain from fraudulent transactions, intentionally adulterated, and may lead to patient harm (Section 581(21) of the FD&C Act). In contrast, an "illegitimate product" means a product for which credible evidence shows that the product may be counterfeit, diverted, stolen, obtain from fraudulent transactions, intentionally adulterated, and may lead to patient harm (Section 581(8) of the FD&C Act).

[1] Transaction information and transaction statement are defined in sections 581(26) and (27) of the FD&C Act, respectively.

Please refer to the FDA's guidance document "Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act" for additional guidance on identifying suspect and illegitimate products in the U.S. pharmaceutical distribution supply chain.

Authorized trading partners must take the following key steps when a product is believed to be suspect.

Key Steps	**Authorized Trading Partner**		
	Manufacturer	**Wholesaler**	**Dispenser**
Step 1: Quarantine	Immediately quarantine **suspect** drug product		
Step 2: Investigate	Promptly investigate, in coordination with trading partners as applicable, to determine whether the product is an illegitimate product. See FDA Guidance document: "Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act."		
Step 3: Determination	If the manufacturer makes the determination that a suspect product is not an illegitimate product, the manufacturer shall promptly notify the FDA, if applicable, of such determination and such product may be further distributed. If upon determining that a product in the possession or control of a manufacturer is an illegitimate product, the manufacturer shall, take the additional steps below (Steps 4 through 5)	If the wholesale distributor determines that a suspect product is not an illegitimate product, the wholesale distributor shall promptly notify the FDA, if applicable, of such determination and such product may be further distributed. If upon determining, in coordination with the manufacturer, that a product in the possession or control of a wholesale distributor is an illegitimate product, the wholesale distributor shall, take the additional steps below. (Steps 4 through 5)	If the dispenser makes the determination that a suspect product is not an illegitimate product, the dispenser shall promptly notify the FDA, if applicable, of such determination and such product may be further distributed or dispensed. If upon determining, in coordination with the manufacturer, that a product in the possession or control of a dispenser is an illegitimate product, the dispenser shall take the additional steps below. (Steps 4 through 5)
Step 4: Sampling and Disposition	Continue quarantining such product until its disposition. Retain a sample of the product for further physical examination or laboratory analysis by the manufacturer or by Federal or State officials.		
Step 5: Notification	The manufacturer shall notify the FDA and all immediate trading partners that the manufacturer has reason to believe may have received an illegitimate product of such	The wholesaler shall notify the FDA and all immediate trading partners that the wholesaler has reason to believe may have received an illegitimate	The dispenser shall notify the FDA and all immediate trading partners that the dispenser has reason to believe may have received such illegitimate product of such determination

	determination not later than **24 hours** after making such determination. Take reasonable and appropriate steps to assist a trading partner to disposition an illegitimate product not in the possession or control of the manufacturer.	product of such determination not later than **24 hours** after making such determination. Take reasonable and appropriate steps to assist a trading partner to disposition an illegitimate product not in the possession or control of the wholesale distributor.	not later than **24 hours** after making such determination.
Records Retention	A manufacturer shall keep records of the investigation of suspect and illegitimate products for not less than **6 years** after the conclusion of the investigation.	A wholesale distributor shall keep records of the investigation of suspect and illegitimate products for not less than **6 years** after the conclusion of the investigation.	A dispenser shall keep records of the disposition of an illegitimate product for not less than **6 years** after the conclusion of the disposition.

Section 5: Record Retention Requirements

In contrast to the pharmacy commission record retention requirements (WAC 246-945-020), DSCSA requires certain records to be retained for not less than **6 years**. These records include:

- Records related to transactions of drug products. This includes transaction information (including lot level information), transaction history, and transaction statement for each transaction and maintain such information, history, and statement for not less than 6 years after the date of the transaction.
- Records of the investigation of a suspect product for not less than 6 years after the conclusion of the investigation.
- Records related to the disposition of an illegitimate product for not less than 6 years after the conclusion of the disposition.
- Manufacturers shall maintain the product identifier information for such product for not less than 6 years after the date of the transaction.

Read this page carefully

WA Pharmacy Quality Assurance Commission

Pharmacy Self-Inspection Worksheet

2025 Drug Supply Chain Security Act (DSCSA) – Optional Addendum

Attention: Responsible Pharmacy Manager or Equivalent Manager

Washington law holds the responsible manager (or equivalent manager) responsible for ensuring compliance with all state and federal laws governing the practice of pharmacy. It is recommended that this DSCSA addendum be completed along with other required self-inspection worksheets as applicable, within the month of March and within 30 days of becoming responsible manager (as required by WAC 246-945-005). **Although completing the DSCSA addendum is optional for 2025**, compliance with the provisions of DSCSA is **still required** for entities licensed by the commission (RCW 18.64.026(1)). The following addendum once completed should be kept on file**. Do not send to the commission office.**

The primary objective of this self-inspection worksheet is to provide an opportunity to assess compliance with the federal requirements of the Drug Supply Chain Security Act (DSCSA). This worksheet serves as a starting point for compliance with the federal provisions of the DSCSA. (**Note**: Neither the self-inspection nor a commission inspection evaluates your complete compliance with all laws and rules of the practice of pharmacy.) The ultimate responsibility of compliance to DSCSA rests on each pharmaceutical firm and pharmacy personnel.

Date self- inspection was completed: Click or tap to enter a date.

Name of responsible pharmacy manager or equivalent manager: Click or tap here to enter text.

Signature of responsible pharmacy manager or equivalent manager: _____

Type of pharmaceutical firm: ☐ Drug Manufacturer ☐ Drug Wholesalers ☐ Dispensers (Pharmacies, Heath Care Entities)

Name of pharmaceutical firm: Click or tap here to enter text.

Address: Click or tap here to enter text.

Applicable federal or state issued pharmaceutical license(s): Click or tap here to enter text.

To request this document in another format, call 1-800-525-0127. Deaf or hard of hearing customers, please call 711 (Washington Relay) or email doh.information@doh.wa.gov.

General Rule Reference - Applies to all questions through worksheet.

RCW 18.64.026(1): "The commission is authorized to take any of the actions identified in this section against licenses, registrations, permits, or other credentials or approvals issued by the commission under this chapter and chapters 18.64A, 69.38, 69.41, 69.43, 69.45, and 69.50 RCW in any case in which it finds the licensee has failed or refused to comply **with any state or federal statute or administrative rule regulating the license in question** including, but not limited to, Title 69 RCW, this chapter, chapter 18.64A RCW, and administrative rules adopted by the commission, except as otherwise limited in this section.

Purpose of DSCSA:

The Drug Supply Chain Security Act (DSCSA) outlines steps to achieve a secure, interoperable, and electronic way to identify and trace certain prescription drugs at the package level as they move through the supply chain. This helps prevent harmful drugs from entering the U.S. drug supply chain, detect harmful drugs if they do enter the supply chain, and enable rapid response to remove harmful drugs from the supply chain to protect patients.[1, 2]

Applicability:

Each manufacturer, wholesale distributor, and dispenser (i.e., pharmacies and Heath Care Entities (HCEs) shall comply with the requirements set forth in this section with respect to the role of such manufacturer, wholesale distributor, or dispenser in a transaction involving drug products. If an entity meets the definition of more than one of the entities listed in the preceding sentence, such entity shall comply with all applicable requirements in this section but shall not be required to duplicate requirements. See Sec. 582 (1) of FD&C Act.

Exemptions to DSCSA:

The Food & Drug Administration has the authority to grant waivers, exceptions and exemptions from **certain requirements** in section 582 of the Food, Drug and Cosmetic Act (FD&C Act). Please see the FDA website for additional information: https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/drug-supply-chain-security-act-dscsa-waivers-exceptions-and-exemptions

Additional Note on Exemptions:

Meeting an exemption does not exempt a pharmaceutical firm from other obligations under DSCSA. For example, pharmacies meeting the "small dispensers" exemption are still required to obtain drugs through authorized trading partners, have the duty to identify suspect products, appropriately quarantine, investigate, and alert the FDA and relevant trading partners as required in Section 582(g)(1) and 582(d)(4) of the FD&C Act.

1 - https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa
2 - https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/pharmacists-utilize-dscsa-requirements-protect-your-patients

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
Section 1: Authorized Trading Partners						
☐	☐	☐	1.	Does the pharmaceutical firm possess a valid federal registration and/or state issued license to purchase or distribute drug products as an authorized trading partner?	**Title II Food Drug and Cosmetics Act – DSCSA** **Section 581 (2) – Definitions – Authorized** (2) The term 'authorized' means – (A) in the case of a manufacturer or repackager, having a valid registration in accordance with section 510; (B) in the case of a wholesale distributor, having a valid license under State law or section 583, in accordance with section 582(a)(6), and complying with the licensure reporting requirements under section 503(e), as amended by the Drug Supply Chain Security Act; (D) in the case of a dispenser, having a valid license under State law.	Click or tap here to enter text.
☐	☐	☐	2.	Does the pharmaceutical firm **only** purchase or distribute drugs from authorized training partners?	**Title II Food Drug and Cosmetics Act – DSCSA** **Section 582(b)(3), (c)(3), (d)(3), and (e)(3)** **582(b)(3)** Beginning not later than January 1, 2015, the trading partners of a manufacturer may be only authorized trading partners. **582(c)(3)** Beginning not later than January 1, 2015, the trading partners of a wholesale distributor may be only authorized trading partners. **582(b)(3)** - Beginning not later than January 1, 2015, the trading partners of a dispenser may be only authorized trading partners. **WAC 246-945-595** "It is unlawful for a wholesaler or manufacturer to perform, cause the performance of, or aid and abet any of the following acts in Washington state: (5) The purchase or receipt of a drug from a person that is not authorized to distribute drugs…" (6) The sale or transfer of a drug to a person who is not legally authorized to receive a drug…"	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
			3.	Does the pharmaceutical firm have a process in place to routinely verify that trading partners it does business with are authorized trading partners?	**WAC 246-945-410(6)** "The facility shall create and implement policies and procedures related to: (a) Purchasing, ordering…[of] legend drugs, including controlled substances."	
Section 2: Labeling Requirements of Drug Products Distributed Under DSCSA						
☐	☐	☐	4.	Do drug products purchased or distributed under DSCSA meet labeling requirements as it pertains to product identifiers? Please see Section 581(13) of the FD&C Act for exempt drug products.	**Title II Food Drug and Cosmetics Act – DSCSA Section 581(13)(14)** **(13)** Product -- The term `product' means a prescription drug in a finished dosage form for administration to a patient without substantial further manufacturing (such as capsules, tablets, and lyophilized products before reconstitution), but for purposes of section 582, does not include blood or blood components intended for transfusion, radioactive drugs or radioactive biological products (as defined in section 600.3(ee) of title 21, Code of Federal Regulations) that are regulated by the Nuclear Regulatory Commission or by a State pursuant to an agreement with such Commission under section 274 of the Atomic Energy Act of 1954 (42 U.S.C. 2021), imaging drugs, an intravenous product described in clause (xiv), (xv), or (xvi) of paragraph (24)(B), any medical gas (as defined in section 575), homeopathic drugs marketed in accordance with applicable guidance under this Act, or a drug compounded in compliance with section 503A or 503B. **(14)** Product Identifier -- The term `product identifier' means a standardized graphic that includes, in both human readable form and on a machine-readable data carrier that conforms to the standards developed by a widely recognized international standards development organization, the standardized numerical identifier, lot number, and expiration date of the product. See also FDA Guidance Documented Titled: "Product Identifiers Under the Drug Supply Chain Security Act Questions and Answers" https://www.fda.gov/media/116304/download	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
Section 3: Covered Transactions and Product Tracing Information						
☐	☐	☐	5.	Is product tracing information provided with each transaction where a change in ownership of drug product occurs?	**Title II Food Drug and Cosmetics Act – DSCSA** **Section 581(24)** Transaction "(A) In general.--The term `transaction' means the transfer of product between persons in which a change of ownership occurs. (B) Exemptions.--The term `transaction' does not include-- (i) intracompany distribution of any product between members of an affiliate or within a manufacturer; (ii) the distribution of a product among hospitals or other health care entities that are under common control…" Please see Section 581(24) for a **complete list** of exemptions. **Sec 582(b)(1)** Manufacturer Requirements - Product Tracing (C)(i) "…a manufacturer shall provide the transaction information, transaction history, and transaction statement required under subparagraph (A)(i) in electronic format…" **Sec 582(c)(1)** Wholesaler Requirements – Product Tracing (A)(i) "…A wholesale distributor shall not accept ownership of a product unless the previous owner prior to, or at the time of, the transaction provides the transaction history, transaction information, and a transaction statement for the product, as applicable under this subparagraph. (ii)(I)(aa) If the wholesale distributor purchased a product directly from the manufacturer, the exclusive distributor of the manufacturer, or a repackager that purchased directly from the manufacturer, then prior to, or at the time of, each transaction in which the wholesale distributor transfers ownership of a product, the wholesale distributor shall provide to the subsequent purchaser—" **Sec 582(d)(1)** Dispenser Requirements – Product Tracing (A)(i) "…a dispenser -- shall not accept ownership of a product, unless the previous owner prior to, or at the time of, the transaction, provides transaction history, transaction information, and a transaction statement…"	Click or tap here to enter text.

☐	☐	☐	6.	Is product tracing information provided in a secure and electronic manner that permits the interoperable exchange of product tracing information? **Important Note**: Please see additional FDA information on waivers and exemptions from Section 582(g)(1) of DSCSA.	**Title II Food Drug and Cosmetics Act – DSCSA** **Section 582(g)(1) Enhanced Drug Distribution Security** "(A) The transaction information and the transaction statements as required under this section shall be exchanged in a secure, interoperable, electronic manner in accordance with the standards established under the guidance issued pursuant to paragraphs (3) and (4) of subsection (h), including any revision of such guidance issued in accordance with paragraph (5) of such subsection…" (B) The transaction information required under this section shall include the product identifier at the package level for each package included in the transaction. (C) Systems and processes for verification of product at the package level, including the standardized numerical identifier, shall be required in accordance with the standards established under the guidance issued pursuant to subsection (a)(2) and the guidances issued pursuant to paragraphs (2), (3), and (4) of subsection (h), including any revision of such guidances issued in accordance with paragraph (5) of such subsection, which may include the use of aggregation and inference as necessary. (D) The systems and processes necessary to promptly respond with the transaction information and transaction statement for a product upon a request by the Secretary (or other appropriate Federal or State official) in the event of a recall or for the purposes of investigating a suspect product or an illegitimate product shall be required. (E) The systems and processes necessary to promptly facilitate gathering the information necessary to produce the transaction information for each transaction going back to the manufacturer, as applicable, shall be required--…" FDA Guidance Documents titled: "DSCSA Exemptions from Section 582(g)(1) and Other Requirements of the FD&C Act for Certain Trading Partners" https://www.fda.gov/media/182584/download?attachment "DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs Guidance for Industry" https://www.fda.gov/media/171796/download	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
Section 4: Suspect and Illegitimate Products						
☐	☐	☐	7.	The facility has a process in place to identify, quarantine, and appropriately investigate suspect drug products?	**Title II Food Drug and Cosmetics Act – DSCSA** **Sec 582(b)4, (c)(4), (d)(4)** (A)(i) "…Upon making a determination that a product in the possession or control of the [manufacturer, wholesale distributor, or dispenser] is a suspect product, or upon receiving a request for verification from the Secretary that has made a determination that a product within the possession or control of a [manufacturer, wholesale distributor, or dispenser] is a suspect product…" "(I) quarantine such product within the possession or control of the [manufacturer, wholesale distributor, or dispenser] from product intended for distribution until such product is cleared or dispositioned; and (II) promptly conduct an investigation in coordination with trading partners, as applicable, to determine whether the product is an illegitimate product."	Click or tap here to enter text.
☐	☐	☐	8.	If a suspect product is deemed to be illegitimate, does the facility have a process to: 1) notify the FDA within 24 hours 2) quarantine such product until its disposition 3) retain a sample for further analysis by the manufacturer or regulators.	**Title II Food Drug and Cosmetics Act – DSCSA** **Sec 582(b)4, (c)(4), (d)(4)** (B) Illegitimate product.-- (i) In general.--Upon determining, in coordination with the manufacturer, that a product in the possession or control … is an illegitimate product, the [manufacturer, wholesale distributor, or dispenser] shall-- (I) disposition the illegitimate product within [their] possession or control... (II) take reasonable and appropriate steps to assist a trading partner to disposition an illegitimate product not in [their] possession or control… (III) retain a sample of the product for further physical examination or laboratory analysis of the product by the manufacturer or Secretary… as necessary and appropriate. (ii) Making a notification.—"…notify the Secretary and all immediate trading partners that the [manufacturer, wholesale distributor, or dispenser] has reason to believe may have received such illegitimate product of such determination not later than 24 hours after making such determination.	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
Section 5: Recordkeeping Requirements						
☐	☐	☐	9.	Are all records related to DSCSA requirements retained for not less than six (6) years?	**Title II Food Drug and Cosmetics Act – DSCSA** **Sec 582(b)(1), (c)(1), (d)(1)** (ii) "capture the transaction information (including lot level information), transaction history, and transaction statement for each transaction and maintain such information, history, and statement for not less than 6 years after the date of the transaction" **Sec 582(b)(4)(A), (c)(4)(A), (d)(4)(A)** "(iii) Records.--A manufacturer shall keep records of the investigation of a suspect product for not less than 6 years after the conclusion of the investigation "(iii) Records.--A wholesale distributor shall keep records of the investigation of a suspect product for not less than 6 years after the conclusion of the investigation." "(iv) Records.--A dispenser shall keep records of the investigation of a suspect product for not less than 6 years after the conclusion of the investigation." **Sec 582(b)(4)(B), (c)(4)(B), (d)(4)(B)** "(v) Records.--A manufacturer shall keep records of the disposition of an illegitimate product for not less than 6 years after the conclusion of the disposition." "(v) Records.--A wholesale distributor shall keep records of the disposition of an illegitimate product for not less than 6 years after the conclusion of the disposition." "(v) Records.--A dispenser shall keep records of the disposition of an illegitimate product for not less than 6 years after the conclusion of the disposition." **Sec 582(b)(2)** – Manufacturers (Product identifiers) "Such manufacturer shall maintain the product identifier information for such product for not less than 6 years after the date of the transaction."	Click or tap here to enter text.

PQAC RULES TRACKING - FOR COMMISSION BUSINESS MEETING

Ongoing Rulemaking

Title	Short Description	Priority	Current Filing Type	Staff Lead	Recent Actions / Next Steps
Accessible labeling standards (petition)	Adjust standards for prescription drug labels/information to accommodate Limited English Proficient patients and patients who are blind, visually impaired, print disabled, etc.	High	CR-103P (Standard) WSR 25-24-003, filed January 22, 2025	Josh	Recent actions: CR-103p filed Next steps: Effective date set for January 22, 2027
Medication assistance in home care settings (will file jointly with DOH)	Medication assistance rules in accordance with chapter 69.41 RCW	High	CR-102 (Standard) WSR 24-21-154 (Filed October 22, 2024)	Josh	Recent actions: Public hearing on December 12, 2024 Next steps: File CR-103p rules adoption package
Alternate Distribution Models (White and Brown Bagging)	Determine the regulatory approach to practices such as white bagging, brown bagging, or any other transfer of a prescription or drug for the purpose of re-dispensing or subsequent administration to a patient	High	CR-101 (Standard) WSR 23-20-115, filed October 3, 2023	Josh	Recent actions: Rules workshop on December 12, 2024 Next steps: Rules workshop on February 6, 2025

Placing kratom in the list of Schedule I controlled substances	Consider placing kratom and its active alkaloid compounds in the list of Schedule I controlled substances in WAC 246-945-051	High	WSR 24-18-005 (Filed August 22, 2024)	Josh	Recent actions: Commission discussion of state-level research at December 2024 business meeting Next steps: Listening session at February 2025 business meeting
DSCSA Enforcement	Incorporate by reference federal language and standards pertaining to the Drug Supply Chain Security Act.	High	Not yet filed	Josh	Next steps: Build and file CR-102
Mobile OTP Unit licenses	Open WAC 246-945-060 to exempt mobile units from acquiring separate licenses if associated physical location is already licensed	Medium	CR-101 (Standard) WSR 23-18-046, filed August 30, 2023	Haleigh	Recent actions: Commission approved rule language draft Next steps: File CR-102
Zero Order Reports and Suspicious Orders	Amending WAC 246-945-001 and WAC 246-945-585 to adjust suspicious order and zero reporting requirement	Medium	CR-101 (Standard) WSR 23-10-012, filed April 24, 2023	Haleigh	Recent actions: Commission approved rule language draft Next steps: File CR-102
Utilization of Pharmacist Ancillary Personnel	Rulemaking to amend WACs 246-945-001, 246-945-315, 246-945-317, 246-945-320, and new sections to chapter 246-945 WAC related to pharmacy technician final product, pharmacy assistants scope-of-practice, and the use of technology	Medium	CR-101 (Standard) WSR 24-18-032, filed August 26, 2024)	Haleigh	Recent actions: CR-101 filed Next steps: Rules Workshop at December 2024 business meeting

Medication assistance (filed jointly with DOH)	Reinstating chapter 246-888 WAC (with edits) per DSHS request	High	CR-103E (Emergency) WSR 24-22-013, filed October 25, 2024	Haleigh	Recent actions: Cr-103E filed Next steps: Refile request at December 2024 business meeting
Manufacturers/Wholesalers of Dialysate and Dialysis Devices (SHB 1675)	Amend WACs 246-945-090 through 246-945-093 to allow manufacturers and wholesalers to deliver to patients' homes.	Medium	Supplemental CR-102 (Standard) WSR 24-24-028, filed November 22, 2024	Julia	Recent actions: Supplemental CR-102 filed Next steps: Rule hearing at February 2025 business meeting
Facility Closure Requirements (petition)	Amend WAC 246-945-480 to enhance patient awareness of pharmacy closures and instructions to transfer prescriptions.	Medium	CR-101 (Standard) WSR 24-13-061, filed June 13, 2024	Julia	Recent actions: CR-102 under review Next steps: Rule hearing at February 2025 business meeting
Uniform Facilities Enforcement Framework (ESSB 5271)	Promulgate rules for facility license violations constituting grounds for application denial, civil fine, limited stop service, etc. and establish specific fine amounts.	High	CR-101 (Standard) WSR 24-15-057, filed July 16, 2024	Julia	Recent actions: CR-101 filed Next steps: Rule workshop at February 2025 business meeting
Inspection Requirements for Modifications or Remodels	Rulemaking to amend WAC 246-945-230 pertaining to inspection requirements for facility modifications or remodels.	Medium	Not yet filed	Julia	Next steps: Build and file CR-101

Implementing FDA MOU	Rulemaking needed to implement the FDA MOU should the commission choose to sign the MOU. This rulemaking would add a new section related to the regulation of the distribution of human compounded products.	On Hold	Not yet filed	Josh	On hold
Out-of-state OTC-only Wholesaler requirements	Reviewing WAC 246-945-246 to review requirements for out-of-state OTC-only wholesalers	On Hold	Not yet filed	Josh	On hold

9.2. DOH Sunrise Review: Pharmacist Scope of Practice

Notice of Sunrise Review - Department of Health

The Washington State Senate Health and Long Term Care Committee has requested the Department of Health (department) review a proposal to increase the pharmacist scope of practice to assess whether it meets the sunrise criteria in RCW 18.120.010.

The request would grant the Pharmacy Quality Assurance Commission the authority to regulate pharmacist prescribing outside of a collaborative drug therapy agreement (CDTA). The applicant group for the proposal is the Washington State Pharmacy Association (WSPA). The proposal documents and other information about this review are available on the sunrise webpage.

- The department is now inviting public comments on the proposal. Please submit your comments to sunrise@doh.wa.gov by April 1, 2025.
- There will also be an opportunity to provide oral comments. If you are interested, please hold the date for a public comment meeting May 14 beginning at 1:00 p.m. Watch for details to come out in the spring, including instructions for signing up to speak.
- To receive further communication about this review, including updates and details on the May 14 public comment meeting, please sign up for our GovDelivery list here - Washington State Department of Health. (Scroll down to "Rule Making," hit the "+" to expand it and then select "Pharmacist Sunrise")

Please email sunrise@doh.wa.gov if you have any questions. Thank you.

El Comité de Salud y Atención de Largo Plazo del Senado del Estado de Washington (The Washington State Senate Health and Long Term Care Committee) ha solicitado al Departamento de Salud (Departamento) que revise una propuesta para aumentar el ámbito de práctica de los farmacéuticos para evaluar si la propuesta cumple con los

criterios de “Sunrise” de RCW 18.120.010.

La solicitud otorgaría a la Comisión de Garantía de Calidad de Farmacia (Pharmacy Quality Assurance Commission) la autoridad para regular la prescripción de medicamentos por parte de farmacéuticos fuera de un acuerdo colaborativo de terapia farmacologica (CDTA por sus siglas en ingles, collaborative drug therapy agreement). El grupo solicitante de la propuesta es la Asociación de Farmacia del Estado de Washington (WSPA por sus siglas en ingles, Washington State Pharmacy Association). Los documentos de la propuesta y mayor información sobre esta revisión están disponibles en la página web de Sunrise, sunrise webpage.

- El Departamento está invitando al público a realizar comentarios sobre la propuesta. Por favor, envíe sus comentarios a sunrise@doh.wa.gov hasta el 1 de abril de 2025.
- También habrá una oportunidad para proporcionar comentarios orales. Si está interesado(a), reserve la fecha para una reunión de comentarios públicos el 14 de mayo de 2025 a partir de la 1:00 p.m. Espere los detalles que se darán a conocer durante la primavera, incluyendo instrucciones para inscribirse para participar.
- Para recibir más información sobre esta revisión, incluyendo actualizaciones y detalles sobre la reunión de comentarios públicos del 14 de mayo, suscribase aquí - Washington State Department of Health. (Desplácese hacia abajo hasta la sección "Rule Making", haga clic en el “+” para expandirlo y luego seleccione "Pharmacist Sunrise").

Por favor, envíe un correo electrónico a sunrise@doh.wa.gov si tiene preguntas. Gracias.

WAC 246-945-007 Civil fines.

(1) This section does not govern actions taken under chapter 18.130 RCW.

(2) The commission may assess civil fines on licensees pursuant to RCW 18.64.024 and RCW 18.64.026, and these rules.

(a) The commission may assess a civil fine of up to $10,000 per violation, not to exceed a total fine of $1,000,000, on a licensee when:

(i) The licensee has previously been subject to an enforcement action for the same or similar type of violation of the same or similar statute or rule; or

(ii) The licensee has been given any previous statement of deficiency that included the same or similar type of violation of the same or similar statute or rule; or

(iii) The licensee has failed to correct noncompliance with a statute or rule by a date established or agreed to by the commission.

(b) The commission may assess a civil fine that is higher than the maximum fine amounts in Table 1, Table 2 or Table 3, not to exceed $10,000 per violation, if it determines that the maximum fine amounts would not be sufficient to deter future noncompliance.

(c) The commission shall determine the amount of a civil fine in accordance with Table 1, Table 2, Table 3, or subsection (d)(i) of this section:

Table 1

Fine Amounts in Relation to the Severity of the Violation for Remote OUD Dispensing Sites and Pharmacies (including HPACs, Nuclear Pharmacies, and Nonresident Pharmacies)			
Operation Size - Small	<30,000 prescriptions dispensed annually		
	Impact of Potential or Actual Harm		
Scope	Low	Moderate	High
Limited	$100-$500	$1,750-$2,750	$3,000-$6,000
Pattern	$500-$1,500	$2,750-$3,750	$4,000-$7,000
Widespread	$1,500-$2,500	$3,750-$4,750	$5,000-$8,000
Operation Size - Medium	30,000-69,999 prescriptions dispensed annually		
	Impact of Potential or Actual Harm		
Scope	Low	Moderate	High
Limited	$250-$750	$1,125-$3,125	$4,000-$7,000
Pattern	$750-$1,750	$2,125-$4,125	$5,000-$8,000

Widespread	$1,750-$2,750	$3,125-$5,125	$6,000-$9,000
Operation Size - Large	70,000+ prescriptions dispensed annually		
	Impact of Potential or Actual Harm		
Scope	Low	Moderate	High
Limited	$500-$1,000	$1,500-$3,500	$5,000-$8,000
Pattern	$1,000-$2,000	$2,400-$4,500	$6,000-$9,000
Widespread	$2,000-$3,000	$3,500-$5,500	$7,000-$10,000

Table 2

Fine Amounts in Relation to the Severity of the Violation for Drug Other Controlled Substances Registrant (OTPs and Precursor Chemical Registrants), Drug Sample Distributor Registrant, Pharmaceutical Manufacturers, Pharmaceutical Wholesaler, Shopkeeper Registrants and Poison Distributors			
Operation Size - Small	<9 FTEs		
	Impact of Potential or Actual Harm		
Scope	Low	Moderate	High
Limited	$100-$500	$1,750-$2,750	$3,000-$6,000
Pattern	$500-$1,500	$2,750-$3,750	$4,000-$7,000
Widespread	$1,500-$2,500	$3,750-$4,750	$5,000-$8,000
Operation Size – Medium	10-24 FTEs		
	Impact of Potential or Actual Harm		
Scope	Low	Moderate	High
Limited	$250-$750	$1,125-$3,125	$4,000-$7,000
Pattern	$750-$1,750	$2,125-$4,125	$5,000-$8,000
Widespread	$1,750-$2,750	$3,125-$5,125	$6,000-$9,000
Operation Size - Large	25+ FTEs		

	Impact of Potential or Actual Harm		
Scope	Low	Moderate	High
Limited	$500-$1,000	$1,500-$3,500	$5,000-$8,000
Pattern	$1,000-$2,000	$2,400-$4,500	$6,000-$9,000
Widespread	$2,000-$3,000	$3,500-$5,500	$7,000-$10,000

Table 3

Fine Amounts in Relation to the Severity of the Violation for Health Care Entities (HCEs)			
Operation Size - Small	<5,000 drug orders administered and dispensed annually		
	Impact of Potential or Actual Harm		
Scope	Low	Moderate	High
Limited	$100-$500	$1,750-$2,750	$3,000-$6,000
Pattern	$500-$1,500	$2,750-$3,750	$4,000-$7,000
Widespread	$1,500-$2,500	$3,750-$4,750	$5,000-$8,000
Operation Size - Medium	5,001-19,999 drug orders administered and dispensed annually		
	Impact of Potential or Actual Harm		
Scope	Low	Moderate	High
Limited	$250-$750	$1,125-$3,125	$4,000-$7,000
Pattern	$750-$1,750	$2,125-$4,125	$5,000-$8,000
Widespread	$1,750-$2,750	$3,125-$5,125	$6,000-$9,000
Operation Size - Large	20,000+ drug orders administered and dispensed annually		
	Impact of Potential or Actual Harm		
Scope	Low	Moderate	High
Limited	$500-$1,000	$1,500-$3,500	$5,000-$8,000
Pattern	$1,000-$2,000	$2,400-$4,500	$6,000-$9,000
Widespread	$2,000-$3,000	$3,500-$5,500	$7,000-$10,000

(d) The "operation size" of a licensee will be considered when calculating fine amounts. Licensee operation sizes are categorized as small, medium, and large.

(i) The following additional licensees shall be categorized as "small": Animal Control/Humane Society Registrants, Drug Other Controlled Substance Registrants (Drug Dog Handlers K9 Registrants, Drug Controlled Substance Researcher Registrants, Analytical Laboratories), Drug Itinerant Vendor Registrants, Wildlife Chemical Capture Drug Registrants, Ancillary Utilization Pharmacies, and Technician Training Programs.

(ii) "Prescriptions" in Table 1 and "drug orders" in Table 3 includes prescriptions and drug orders for legend drugs as defined in RCW 69.41.010 and controlled substances as defined in RCW 69.50.101. (e) The licensee shall assist the commission with determining their operation size, including

providing information necessary to determine a licensee's operation size. A licensee who fails to assist the commission will be deemed a large operation size.

(f) The "severity of the violation" will be considered when determining fines. Levels of severity are categorized as low, moderate, or high, and defined as:

(i) "Low" means harm could happen but would be rare. The violation undermines safety or quality or contributes to an unsafe environment but is very unlikely to directly contribute to harm;

(ii) "Moderate" means harm could happen occasionally. The violation could cause harm directly, but is more likely to cause harm as a continuing factor in the presence of special circumstances or additional failures. If the deficient practice continues, it would be possible that harm could occur but only in certain situations or patients;

(iii) "High" means harm could happen at any time or did happen. The violation could directly lead to harm without the need for other significant circumstances or failures. If the deficient practice continues, it would be likely that harm could happen at any time to any patient.

(g) Factors the commission will consider when determining the severity of the violation include, but are not limited to:

(i) Whether harm to the patient has occurred, or could occur including, but not limited to, a violation of patient's rights;

(ii) The impact of the actual or potential harm on the patient;

(iii) The degree to which the licensee failed to meet the patient’s highest practicable physical, mental, and psychosocial well-being;

(iv) Whether a fine at a lower severity has been levied and the condition or deficiency related

to the violation has not been adequately resolved; and

(v) Whether the licensee has been offered, or requested, and received and implemented technical assistance from the commission.

(j) The scope of the violation is the frequency, incidence or extent of the occurrence of the violation(s). The levels of scope are defined as follows:

(i) "Limited" means a unique occurrence of the deficient practice that is not representative of routine or regular practice and has the potential to impact only one or a very limited number of patient or staff. It is an outlier. The scope of the violation is limited when one or a very limited number of patients are affected or one or a very limited number of staff are involved, or the deficient practice occurs in a very limited number of locations.

(ii) "Pattern" means multiple occurrences of the deficient practice, or a single occurrence that has the potential to impact more than a limited number of patients or staff. It is a process variation. The scope of the violation becomes a pattern when more than a very limited number of patients are affected, or more than a very limited number of staff are involved, or the situation has occurred in several locations, or the same patient(s) have been affected by repeated occurrences of the same deficient practice.

(iii) "Widespread" means the deficient practice is pervasive in the facility or represents a systemic failure or has the potential to impact most or all patients, visitors, or staff. It is a process failure. Widespread scope refers to the entire organization, not just a subset of patients or one unit.

(h) When determining the scope of the violation, the commission will also consider the duration of time that has passed between violations that relate to the same or similar circumstances.

(i) A licensee may appeal the commission's action of assessing civil fines under RCW 18.64.024.

[Statutory Authority: RCW 18.64.005, RCW 18.64.026]

Utilization of Pharmacy Ancillary Personnel Draft Rule Language
February 2025 PQAC Business Meeting

WAC 246-945-001 Definitions.

The definitions in chapters 18.64 and 18.64A RCW and those in this section apply throughout this chapter unless otherwise stated.

(1) "ACPE" means accreditation council for pharmacy education.

(2) "Active ingredient" means any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of humans or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in that drug product in a modified form intended to furnish the specified activity or effect.

(3) "Adulterated" refers to a drug that was produced and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with WAC 246-945-550 as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.

(4) "Animal control agency" means any agency authorized by law to euthanize or destroy animals; to sedate animals prior to euthanasia or to engage in chemical capture of animals.

(5) "Approved legend drugs" means any legend drug approved by the commission for use by registered humane societies or animal control agencies for the sole purpose of sedating animals prior to euthanasia, when necessary, and for use in chemical capture programs.

(6) "Audit trail" means all materials and documents required for the entire process of filling a prescription, which shall be sufficient to document or reconstruct the origin of the prescription, and authorization of subsequent modifications of that prescription.

(7) "Blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

(8) "Blood component" means that part of the blood separated by physical or mechanical means.

(9) "Central fill pharmacy" means a pharmacy contracting with an originating pharmacy, or having the same owner as an originating pharmacy, that provides centralized prescription filling on behalf of the originating pharmacy pursuant to these rules.

(10) "Chemical capture program" means wildlife management programs registered under RCW 69.41.080 and 69.50.320 to use approved legend drugs and controlled substance for chemical capture. Chemical capture includes immobilization of individual animals in order for the animals to be moved, treated, examined, or for other legitimate purposes.

(11) "Collaborative drug therapy agreement" or "CDTA" means a written guideline or protocol previously established and approved by a practitioner authorized to prescribe drugs that enables a pharmacist to exercise prescriptive authority.

(12) "Controlled substances" has the same meaning as RCW 69.50.101.

(13) "Controlled substance wholesaler" means a wholesaler licensed under RCW 18.64.046 to possess and sell controlled substances to a licensed pharmacy or other legally licensed or authorized person.

(14) "Commission" means the pharmacy quality assurance commission.

(15) "Counterfeit" means a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor.

(16) "CPE" means continuing pharmacy education accredited by the ACPE.

(17) "Consultation" means:

(a) A communication or deliberation between a pharmacist and a patient, a patient's agent, or a patient's health care provider in which the pharmacist uses professional judgment to provide advice about drug therapy.

(b) A method by which the pharmacist meets patient information requirements as set forth in WAC 246-945-325.

(18) "Credential" means a license, certification, or registration under the chapters specified in RCW 18.130.040 issued to a person to practice a regulated health care profession. Whether the credential is a license, certification, or registration is determined by the law regulating the profession.

(19) "DEA" means the United States Drug Enforcement Administration.

(20) "Delegated tasks" means tasks that are performed pursuant to a pharmacist's direction, without the exercise of the pharmacy ancillary personnel's own judgment and discretion, and which do not require the pharmacy ancillary personnel's to exercise the independent professional judgment that is the foundation of the practice of the profession of pharmacy.

(21) "Department" means the Washington state department of health.

(22) "Dose" means the amount of drug to be administered at one time.

(23) "Drug(s) of concern" are those drugs identified by the commission as demonstrating a potential for abuse by all professionals licensed to prescribe, dispense, or administer such substances in this state.

(24) "Drug price advertising" means the dissemination of nonpromotional information pertaining to the prices of legend or prescription drugs.

(25) "Drug product" means a finished dosage form (e.g., tablet, capsule, solution) that contains an active drug ingredient generally, but not necessarily, in association with inactive ingredients. The term also includes a finished dosage form that does not contain an active ingredient but is intended to be used as a placebo.

(26) "Drug sample" means a unit of prescription drug that is not intended to be sold and is intended to promote the sale of the drug.

(27) "Drug standard and information sources" means industry recognized reference and resources.

(28) "Drug storage area" means an area where legend drugs, controlled substances, or other restricted items are stored, compounded, or dispensed.

(29) "Drug utilization review" includes, but is not limited to, the following activities:

(a) Evaluation of prescriptions and patient records for known allergies, rational therapy-contraindications, appropriate dose, and route of administration and appropriate directions for use;

(b) Evaluation of prescriptions and patient records for duplication of therapy;

(c) Evaluation of prescriptions and patient records for interactions between drug-drug, drug-food, drug-disease, and adverse drug reactions; and

(d) Evaluation of prescriptions and patient records for proper utilization, including over- or under-utilization, and optimum therapeutic outcomes.

(30) "Electronic means" means an electronic device used to send, receive, or store prescription information, including computers, facsimile machines, etc.

(31) "Electronic signature" means an electronic sound, symbol, or process attached to or logically associated with a contract or other record and executed or adopted by a person with the intent to sign the record.

(32) "Enrolled student" means a student who has accepted an offer of admission in writing and the student has made the appropriate deposit securing admission to an accredited school or college of pharmacy.

(33) "Equivalent manager" means an individual authorized to act on behalf of a pharmaceutical firm not licensed as a pharmacy to serve as the primary contact for the department and is responsible for managing the facility operations which includes, but is not limited to, actively involved in and aware of the daily operations of the facility.

(34) "Export wholesaler" means any wholesaler authorized by the commission to export legend drugs and nonprescription (OTC) drugs to foreign countries.

(35) "FDA" - United States Food and Drug Administration.

(36) “Final accuracy verification” means a pharmacist has reviewed a patient prescription initiated by an authorized prescriber, has examined the patient's drug profile, and has approved the prescription.

(37) “Final product verification” means a final verification in the prescription dispensing process that the filled product is the correct drug, strength, formulation, and expiration date consistent with the prescribed order or medication prescription label where a licensed pharmacist completed final accuracy verification.

~~(36) "Full-line wholesaler" means a drug wholesale distributor that is licensed under RCW **18.64.046** to possess and sell legend drugs, controlled substance and nonprescription drugs to a licensed pharmacy or other legally licensed or authorized person.~~

(3~~7~~8) "FPGEC" means foreign pharmacy graduate examination committee.

(3~~8~~9) "FPGEE" means foreign pharmacy graduate equivalency examination.

(~~36~~40) "Full-line wholesaler" means a drug wholesale distributor that is licensed under RCW **18.64.046** to possess and sell legend drugs, controlled substance and nonprescription drugs to a licensed pharmacy or other legally licensed or authorized person.

(~~39~~41) "Generic substitution" means the act of switching between a branded drug and its therapeutically equivalent generic version.

(4~~0~~2) "HIPAA" means Health Insurance Portability and Accountability Act.

(4~~1~~3) "Hospital" means any institution licensed under chapter **70.41** or **71.12** RCW or designated under RCW **72.23.020**.

(4~~2~~4) "Hospital pharmacy" means that portion of a hospital licensed under RCW **18.64.043** which is engaged in the manufacture, production, preparation, dispensing, sale, or distribution of drugs, components, biologicals, chemicals, devices and other materials used in the diagnosis and treatment of injury, illness and diseases.

(4~~3~~5) "Hospital pharmacy associated clinic" or "HPAC" means an individual practitioner's office or multipractitioner clinic owned, operated, or under common control of a parent hospital or health system, where the physical address of the office or clinic is identified on a hospital pharmacy license.

(4~~4~~6) "Immediate supervision" means supervision by a pharmacist who is immediately available at all times the delegated tasks are being performed; who is aware of delegated tasks being performed; and who provides personal assistance, direction and approval throughout the time the delegated tasks are being performed.

(a) "Immediately available" means the pharmacist and pharmacy ancillary personnel or interns are on the same physical premises, or if not, technology is used to enable real time, two-way communications between the pharmacist and pharmacy ancillary personnel and interns.

(b) Use of technology: A pharmacist, as an adjunct to assist in the immediate supervision of the pharmacy ancillary personnel or intern, may employ technological means to communicate with or observe the pharmacy ancillary personnel or intern. A pharmacist shall make certain all applicable state and federal laws including, but not limited to, confidentiality, are fully observed when employing technological means of communication and observation. If technology is being used to provide immediate supervision of pharmacy ancillary personnel or intern such technology shall be sufficient to provide the personal assistance, direction and approval required to meet the standard of practice for the delegated tasks.

(4~~5~~7) "Inoperable" means a credential status indicating that an individual cannot practice because he or she is not actively participating or enrolled in a required training program when this condition is a requirement of the credential. Inoperable status is not the result of enforcement action. The health care professional can resume practice when appropriately enrolled in a required training program and the credential is reactivated.

(4~~6~~8) "Internal test assessment" means, but is not limited to, conducting those tests of quality assurance necessary to ensure the integrity of the test.

(4~~7~~9) "Investigational drug" means any article drug that has an investigational drug application (INDA) that has been approved by the FDA.

(~~48~~50) "Key party" means immediate family members and others who would be reasonably expected to play a significant role in the health care decisions of the patient or client and includes, but is not limited to, the spouse, domestic partner, sibling, parent, child, guardian and person authorized to make health care decisions of the patient or client.

(~~49~~51) "Law enforcement" means any general or limited authority Washington peace officer or federal law enforcement officer or tribal officer.

(5~~0~~2) "License transfer" means the process used by licensed pharmacists to transfer their existing pharmacist license to Washington using NABP's Electronic Licensure Transfer Program® (e-LTPTM).

(5~~1~~3) "Lot" means a batch or a specific identified portion of a batch having uniform character and quality within specified limits, or in the case of a drug product produced by continuous process, it is a specific identified amount produced in a unit of time or quantity in a manner that assures it is having uniform character and quality within specified limits.

(5~~2~~4) "Manual signature" means a printed or wet signature.

(5~~3~~5) "Misbranded" applies to all drugs the package or label of which bears any statement, design or device regarding such article or the ingredients or substances contained therein which is false or misleading in any particular way, and drug product which is falsely branded as to the state, territory or country in which it is manufactured or produced.

(5~~4~~6) "NABP" means the National Association of Boards of Pharmacy.

(5~~5~~7) "NDC" means National Drug Code.

(5~~6~~8) "Nuclear pharmacy" means a pharmacy providing radiopharmaceutical services.

(5~~7~~9) "Nuclear pharmacist" means a pharmacist licensed under RCW 18.64.080 who holds an endorsement that meets the requirements of WAC 246-945-180.

(~~58~~60) "Originating pharmacy" means a pharmacy that receives a prescription from a patient, the patient's agent, or a prescriber, outsources prescription filling or processing functions to another pharmacy, and ultimately dispenses the prescription drug or device to the patient or the patient's agent. This does not include pharmacies engaged in shared pharmacy services in accordance with RCW 18.64.570.

(~~59~~61) "Over-the-counter drugs" or "OTC" means "nonlegend" or "nonprescription" drugs, and any drugs which may be lawfully sold without a prescription.

(6~~0~~2) "Over-the-counter only wholesaler" means any wholesaler licensed under RCW 18.64.046 to possess and sell OTC drugs to any outlets credentialed for resale.

(6~~1~~3) "Pharmaceutical firm" means a business engaged in the dispensing, delivering, distributing, manufacturing, or wholesaling of prescription drugs or devices within or into Washington state.

(6~~2~~4) "Pharmacy intern" means a person who is registered with the commission under RCW 18.64.080(3) as a pharmacy intern.

(6~~3~~5) "Pharmacy services" means any services provided that meet the definition of the practice of pharmacy, RCW 18.64.011.

(6~~4~~6) "Plan of correction" is a proposal devised by the applicant or credential holder that includes specific corrective actions that must be taken to correct identified unresolved deficiencies with time frames to complete them.

(6~~5~~7) "Precursor drugs" as defined in chapter 69.43 RCW.

(6~~6~~8) "Prescription drug" means any drug, including any biological product required by federal statute or regulation to be dispensed only by a prescription, including finished dosage forms and bulk drug substances subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act.

(6~~7~~9) "Protocol" means a written set of procedures, steps or guidance.

(~~68~~70) "Radiopharmaceutical service" means, but is not limited to:

(a) The preparing, compounding, dispensing, labeling, and delivery of radiopharmaceuticals;

(b) The participation in radiopharmaceutical selection and radiopharmaceutical utilization reviews;

(c) The proper and safe storage and distribution of radiopharmaceuticals;

(d) The maintenance of radiopharmaceutical quality assurance;

(e) The responsibility for advising, where necessary or where regulated, of therapeutic values, hazards and use of radiopharmaceuticals; or

(f) The offering or performing of those acts, services, operations or transactions necessary in the conduct, operation management and control of a nuclear pharmacy.

(~~69~~71) "Radiopharmaceutical" means any substance defined as a drug in section 201 (g)(1) of the Federal Food, Drug, and Cosmetic Act which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any nonradioactive reagent kit or nuclide generator which is intended to be used in the preparation of any such substance but does not include drugs such as carbon-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides. The term "radioactive drug" includes a "radioactive biological product."

(7~~0~~2) "Radiopharmaceutical quality assurance" means, but is not limited to, the performance of appropriate chemical, biological and physical tests on radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals, including internal test assessment authentication of product history and the keeping of proper records.

(7~~1~~3) "Readily retrievable" means a record that is kept by automatic data processing systems or other electronic, mechanized, or written recordkeeping systems in such a manner that it can be separated out from all other records in a reasonable time.

(7~~2~~4) "Reverse distributor" means a pharmaceutical wholesaler that receives drugs for destruction, return credit, or otherwise disposes of drugs received from a registrant that holds a credential to dispense or possess drugs.

(7~~3~~5) "Secretary" means the secretary of the Washington state department of health.

(7~~4~~6) "Strength" means:

(a) The concentration of the drug product; or

(b) The potency, that is, the therapeutic activity of the drug product as indicated by appropriate laboratory tests or by adequately developed and controlled clinical data.

(7~~5~~7) "U.S. jurisdiction" means a state of the United States, the District of Columbia, the Commonwealth of Puerto Rico, or a territory or insular possession subject to the jurisdiction of the United States.

(7~~6~~8) "USP" means the United States Pharmacopeia.

(7~~7~~9) "Therapeutic substitution" means the act of dispensing an alternative drug that is believed to be therapeutically similar but may be chemically different, in a different category, or with different pharmacokinetic properties. This substitution is based on the premise that the substituted drug will provide similar clinical efficacy, desired outcome, and safety profile.

(~~78~~80) "TOEFL iBT" means an internet based test which measures the ability to use and understand English. It evaluates the combined use of reading, listening, speaking and writing skills.

(~~79~~81) "Virtual manufacturer" means an individual or facility that sells his or her own prescription drugs, but never physically possesses the drugs.

(8~~0~~2) "Virtual wholesaler" means an individual or facility that sells a prescription drug or device, but never physically possesses the product.

(8~~1~~3) "Wholesale distribution" means distribution of prescription drugs to persons other than a consumer or patient, but does not include:

(a) The sale, purchase, or trade of a drug, an offer to sell, purchase or trade a drug, or the dispensing of a drug pursuant to a prescription;

(b) The lawful distribution of drug samples by manufacturers' representatives or distributors' representatives;

(c) The sale, purchase, or trade of blood and blood components intended for transfusion;

(d) Intracompany sales, being defined as any transaction or transfer between any division, subsidiary, parent or affiliated, or related company under the common ownership and control of a corporate entity, unless such transfer occurs between a wholesale distributor and a health care entity or practitioner; or

(e) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons, for purposes of this section, "emergency medical reasons" includes transfers of prescription drugs by retail pharmacy to another retail pharmacy or practitioner to alleviate a temporary shortage, except that the gross dollar value of such transfers shall not exceed five percent of the total prescription drug sale revenue of either the transferor or transferee pharmacy during any 12 consecutive month period.

WAC 246-945-315 Delegation of pharmacy functions to pharmacy ancillary personnel.

(1) All delegated pharmacy functions shall be performed under a pharmacist's immediate supervision. A pharmacist, as an adjunct to assist in the immediate supervision of the pharmacy ancillary personnel or intern, may employ technological means to communicate with or observe the pharmacy ancillary personnel or intern. A pharmacist shall make certain all applicable state and federal laws including, but not limited to, confidentiality, are fully observed when employing technological means of communication and observation. If technology is being used to provide immediate supervision of pharmacy ancillary personnel or intern such technology shall be sufficient to provide the personal assistance, direction and approval required to meet the standard of practice for the delegated tasks.

(2) When delegating a pharmacy function to a pharmacy technician:

(a) A pharmacist shall consider the pharmacy technician's scope of practice, education, skill, and experience and take them into account; and

(b) A pharmacist will not delegate a pharmacy function that is listed in WAC 246-945-320.

(3) A pharmacist may delegate to a pharmacy assistant those functions defined in RCW 18.64A.030 and the following:

(a) Prepackage and label drugs for subsequent use in prescription dispensing operations; and

(b) Count, pour, and label for individual prescriptions.

(4) For the purposes of this section and RCW 18.64A.030,

(a) "Stocking" means placing drugs or devices that are in their FDA approved packaging without further manipulation within a pharmacy.

(b) "Typing of prescription labels" means:

(i) Producing a prescription label that was generated by a pharmacist, pharmacy intern, or pharmacy technician; or

(ii) Generating a refill prescription label where no changes were made to the prescription.

WAC 246-945-316 Pharmacy Technician Final Product Verification

(1) Pharmacists may delegate final product verification to a licensed pharmacy technician if a pharmacy technician has demonstrated proficiency in final product verification and meets the following criteria:

(a) Completed at least 2,000 hours of pharmacy technician work experience in the same pharmacy practice setting in which the final product verification will be performed; and

(b) Obtained certification for technician product verification from a certification program recognized by the commission.

(2) When utilizing pharmacy technician final product verification, the pharmacy must:

(a) Possess a commission-approved ancillary utilization plan (AUP) documenting that a pharmacy technician will perform final product verification;

(b) Implement policies and procedures that include the following:

(i) Utilization of a technology assisted verification system that uses barcode scanning or similar technology to electronically verify the prescription and electronically verify the device, drug product, or medication has been properly dispensed. The technology must be quality tested daily through random quality testing. If an error is detected, use of the technology must be immediately terminated until a licensed pharmacist can inspect and revalidate the machine.

(iii) A process that monitors and ensures the accuracy and safety of the product dispensed;

(v) The monitoring and evaluation procedures to be used to ensure competency of the pharmacy technician;

(viii) Protocol for technology malfunction or error that prohibits a pharmacy technician from completing visual verification of the product or manually entering the drug product into the pharmacy processing system; and

(ix) A continuous quality assurance program that audits and evaluates dispensing accuracy.

(3) If delegating final product verification to a pharmacy technician, the following restrictions apply:

(a) A pharmacist must perform the final accuracy verification of the completed prescription label. The final accuracy verification process must generate an audit trail that identifies the pharmacist.

(b) The pharmacy technician only performs final product verification during the dispensing process of a product filled by another pharmacy technician. The pharmacy technician may not conduct pharmacy technician final product verification as part of the final check of their own product preparation;

(c) The product dispensed is not a controlled substance or compounded medication;

(d) The pharmacy technician may have no other assigned tasks when performing final product verification; and

(e) A pharmacy technician may not perform overrides for technology error or exception.

(4) A pharmacy technician-in-training may not perform final product verification.

WAC 246-945-317 ~~Tech check tech.~~Tech check tech in facilities licensed under chapter 70.41, 71.12, 71A.20, and 74.42 RCW.

(1) "Verification" as used in this section means the pharmacist has reviewed a patient prescription initiated by an authorized prescriber, has examined the patient's drug profile, and has approved the prescription after taking into account pertinent drug and disease information to ensure the correctness of the prescription for a specific patient. The verification process must generate an audit trail that identifies the pharmacist. The pharmacist who performs the verification of a prescription is responsible for all reports generated by the approval of that prescription. The unit-dose medication fill and check reports are an example.

(2) A pharmacist may allow for unit-dose medication checking. Following verification of a prescription by the pharmacist, a technician may check unit-dose medication cassettes filled by another pharmacy technician or pharmacy intern in pharmacies serving facilities licensed under chapter 70.41, 71.12, 71A.20, or 74.42 RCW. No more than a forty-eight hour supply of drugs may be included in the patient medication cassettes and a licensed health professional must check the drug before administering it to the patient.

WAC 246-945-318 Pharmacy Technician Administration of Drugs and Devices

(1) Pharmacists may delegate the administration of drugs and devices to a pharmacy technician or pharmacy technician-in-training if the pharmacy has a commission-approved AUP that meets all the following criteria:

(a) The pharmacist or pharmacy intern must retain the discretionary function to determine the patient's needs and all clinical assessments, including patient counseling regarding potential risks and side effects.

(b) The pharmacy technician or pharmacy technician-in-training must have completed adequate and appropriate training on what medications and devices they may administer.

(c) Training for pharmacy technicians or pharmacy technicians-in-training who will administer drugs and devices must include the following:

(i) Describe proper techniques when preparing and administering medications and devices;
(ii) Recognize commonly used medications and devices and their corresponding routes of administration;
(iii) Distinguish proper needle specifications based on medications and patient age, size, and anatomical features;
(iv) Identify proper documentation procedures;
(v) Recall medications storage requirements;
(vi) Describe safety measures to avoid accidental needle stick injuries;
(vii) Recognize appropriate actions to take in emergency situations;
(viii) Demonstrate a successful technique when administering an intramuscular and subcutaneous injections;
(ix) Demonstrate appropriate distraction techniques during medication and device administration;
(x) Demonstrate the use of universal precautions as they pertain to bloodborne pathogens; and
(xi) Explain the procedures for managing a medication reaction emergency.

DRAFT Legislative Ideas – February 2025 Business Meeting

MODERNIZING PHARMACEUTICAL FIRMS

Multiple amendments in chapter 18.64 RCW

Definitions

- Amend definition of manufacturer for the purposes of DSCSA
- Add virtual entities to definitions of manufacturer and wholesaler
- Amending the definition of wholesaler to include minimal use exemption

Licensure Types

- Add licensure type for 3PLs
- Add licensure type for repackager (separate from manufacturer)
- Add licensure type for out-of-state manufacturers

REMOVING LICENSURE BARRIERS FOR PHARMACY PERSONNEL AND INCREASING REPRESENTATIVE MEMBERSHIP ON THE COMMISSION

Multiple amendments in chapters 18.64 and 18.64A RCW

Commission Membership

- Add additional pharmacy technician member(s)

Examinations

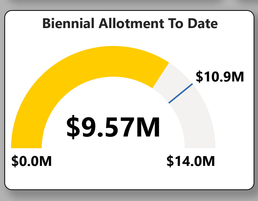
- Move exam requirements in RCW 18.64.080 to rule to allow for more flexibility
- Remove the study plan approval by the commission in the event of three failures

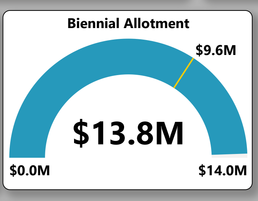
Ancillary Personnel and Facilities

- Remove requirement to submit ancillary utilization plans (AUPs) to the commission prior to utilizing ancillary personnel

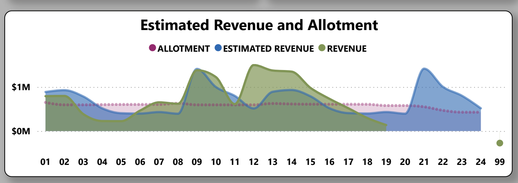
Pharmacy Commission

FY2024 Starting Fund Balance	Current Fund Balance	Helms Allocation	Revenue	Expenses+Total Indirect+HELMS
$5.99M	$8.73M	($272K)	$14.13M	$11.31M

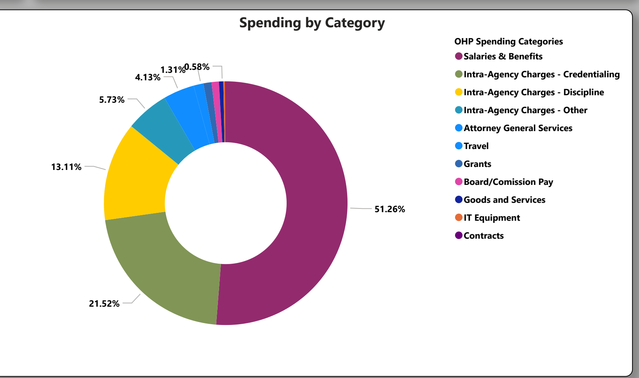




Health Professions	EXPENSES TO DATE	ALLOTMENT TO DATE	VARIANCE TO DATE	ALLOTMENT	ACTUAL TOTAL INDIRECT
Pharmacy Commission	$9,567,355	$10,948,822	$1,381,467	$13,987,147	$1,547,083
Travel	$124,923	$65,862	($59,061)	$87,816	
Salaries & Benefits	$4,903,854	$5,390,838	$486,984	$7,182,282	
IT Equipment	$21,973	$20,936	($1,037)	$20,936	
Intra-Agency Charges - Other	$548,610	$695,958	$147,348	$954,640	
Intra-Agency Charges - Discipline	$1,254,530	$1,405,389	$150,859	$1,588,510	
Intra-Agency Charges - Credentialing	$2,058,801	$2,712,228	$653,427	$3,276,196	
Indirect					$1,547,083
Grants	$103,162	$128,268	$25,106	$171,024	
Goods and Services	$55,205	$47,195	($8,010)	$62,879	
Contracts	$7,950		($7,950)		
Board/Comission Pay	$92,961	$73,350	($19,611)	$97,800	
Attorney General Services	$395,388	$408,798	$13,410	$545,064	
Total	$9,567,355	$10,948,822	$1,381,467	$13,987,147	$1,547,083



Job (POS)	Vacant Permanent Positions
ADMINISTRATIVE ASSISTANT 3	0
EXEC DIRECTOR, PHARMACY COMMISSION - DOH	0
HEALTH SERVICES CONSULTANT 1	0
HEALTH SERVICES CONSULTANT 2	0
HEALTH SERVICES CONSULTANT 4	0
MANAGEMENT ANALYST 4	1
PHARMACIST - INVESTIGATOR	3
PHARMACIST SUPERVISOR	0
WMS BAND 2	0
Total	4



Master Indexes+Title	EXPENSES BY STAFF MONTHS -PAYROLL	ALLOTMENT TO DATE BY STAFF MONTHS
62401600 - PHARMACY COMMISSION	361.59	354.40
62401601 - PHARMACY INVESTIGATIONS	69.49	74.16
62401603 - PHARMACY COMMISSION CREDENTIALING	6.95	
Total	438.03	428.56

Health Professions	REVENUE	ESTIMATED REVENUE	REVENUE VARIANCE
Pharmacy Commission	$13,854,015	$12,409,769.00	$1,444,246
Total	$13,854,015	$12,409,769.00	$1,444,246