STATE OF WASHINGTON
Pharmacy Quality Assurance Commission
PO Box 47852 – Olympia, Washington 98504-7852
Tel: 360-236-4030 – 711 Washington Relay Service

Pharmacy Quality Assurance Commission Meeting
May 2, 2024 – Minutes

Convene: Kenneth Kenyon, Chair, called the meeting to order May 2, 2024, 9:07 A.M.

Commission Members:
Ken Kenyon, PharmD, BCPS, Chair
Hawkins DeFrance, Nuclear Pharmacist, Vice Chair (arrived at 10:19 a.m.)
Stephanie Bardin, PharmD
Bonnie Bush, Public Member (arrived at 9:15 a.m.)
Teri Ferreira, RPh
Patrick Gallaher, BS, BPharm, MBA, MPH
Judy Guenther, Public Member
William Hayes, PharmD CCHP
Matthew Ray, PharmD
Craig Ritchie, RPh, JD
Uyen Thorstensen, CPhT
Ann Wolken, PharmD, RPh
Huey Yu, PharmD

Staff:
Marlee O'Neill, Executive Director
Lindsay Trant-Sinclair, Deputy Director
Si Bui, Inspector Supervisor
Christopher Gerard, AAG
Julia Katz, Program Consultant
Irina Tiginyanu, Pharmacy Technician Consultant
Joshua Munroe, Legislative and Rules Consultant
Taifa "Nomi" Peaks, Pharmacist Consultant
Haleigh Mauldin, Program Consultant
Amy L Robertson, Communications Coordinator and Program Support
Desire Gudmundson, Administrative Support

Commission Members Absent:
Jerrie Allard, Public Member

1. Call to Order Kenneth Kenyon, Chair

1.1 Meeting Agenda Approval – May 2, 2024

MOTION: Craig Ritchie moved to approve the business meeting agenda for May 2, 2024. Teri Ferreira seconded. Motion carried, 11:0.

1.2 Meeting Minutes Approval – March 7, 2024

MOTION: Craig Ritchie moved to approve the March 7, 2024 business meeting minutes. Teri Ferreria seconded. Motion carried, 11:0.

2. Consent Agenda

2.1 Correspondence

- 2.1.1 National Precursor Log Exchange Monthly Dashboard
- 2.1.2 Pharmaceutical Firms Application Report

2.2 Ancillary Utilization Plans Approval

- 2.2.1 Colton Pharmacy
- 2.2.2 Hart Family Pharmacy
- 2.2.3 Panorama Pharmacy
- 2.2.4 Schweitzer Engineering Laboratories Health Clinic
- 2.2.5 Skyline Hospital Pharmacy
- 2.2.6 Unity Care Northwest
- 2.2.7 Valley Drug Co. – Multiple Locations
- 2.2.8 Virginia Mason Franciscan Health – Multiple Locations
- 2.2.9 CHAS
- 2.2.10 Hoagland Pharmacy

2.3 Pharmacy Technician Training Program Approval

- 2.3.1 BioCompound, LLC
- 2.3.2 Columbia Basin Health Association
- 2.3.3 Horizon Pharmacy
- 2.3.4 Lake Chelan Health
- 2.3.5 Nooksack Valley Drug
- 2.3.6 Pima Medical Institute
- 2.3.7 Astria Sunnyside Hospital Pharmacy
- 2.3.8 Tri-Cities Community Health

MOTION: Craig Ritchie moved to approve the consent agenda with the exception of items 2.2.6 Unity Care Northwest, 2.2.7 Valley Drug Co. – multiple locations, and 2.2.10 Hoagland Pharmacy. Teri Ferreria, seconded. Motion carried, 11:0.

2.4 Regular Agenda Items Pulled from 2.1, 2.2, or 2.3. The commission will discuss items removed from the consent agenda and placed on the regular agenda for separate discussion.

MOTION: Ann Wolken moved to approve the AUP for item 2.2.6 Unity Care Northwest contingent on the entity removing letter P for the technician AUP and letter K for the assistant AUP. William Hayes seconded. Motion carried, 11:0.

MOTION: Matthew Ray moved to approve item 2.2.7 Valley Drug Co – Multiple Locations contingent on the entity changing the language in A2. h to state nonjudgmental or demographic information. Stephanie Bardin seconded. Motion carried, 11:0.

MOTION: William Hayes moved to approve the AUP for item 2.2.10 Hoagland Pharmacy contingent upon the entity removing letter X from the compounding and retail AUP and removing letter V from the long-term care AUP. Ann Wolken seconded. Motion carried, 11:0.

3. Rulemaking for the WDFW Wildlife Capture Antibiotics

3.1 **PUBLIC HEARING** The commission held a public rule hearing on the rulemaking to propose amending WAC 246-945-507 to add certain intramammary antibiotics to the list of approved legend drugs in chapter 246-945 WAC in response to a petition request.

No comments were received in writing or during the public hearing.

3.2 Approval of Comment Responses and Authorization to file CR-103P (WDFW Wildlife Capture Antibiotics)

MOTION: Teri Ferreira moved to adopt WAC 246-945-507 without any edits and authorized staff to file a CR-103P. Stephanie Bardin seconded. Motion carried, 12:0.

4. Welcome Credentialing Staff

Kevin Robbins, pharmacy credentialing supervisor, introduced his team.

5. Rulemaking for Removing Fenfluramine from Schedule IV Substances List

5.1 **PUBLIC HEARING** The commission held a public rule hearing on the rulemaking to propose amending a section of rule, WAC 246-945-055 Schedule IV, to remove fenfluramine from the list of Schedule IV substances, in response to a petition request. No comments were received in writing or during the public hearing.

5.2 Approval of Comment Responses and Authorization to file CR-103P (Removing Fenfluramine from the List of Schedule IV Substances).

MOTION: Teri Ferreira moved to adopt WAC 246-945-055 and WAC 246-945-05001 without any edits and to authorize staff to file a CR-103p. Judy Guenther seconded. Motion carried, 12:0.

6. Rules Update

6.1 Rules Workshop: Pharmacy Interns

MOTION: Matthew Ray moved to have staff file the CR-102 with an edit to the rule language to reflect that pharmacy intern registrations will automatically have a three-renewal limit and there will be a process to request additional renewals for good cause. Ann Wolken seconded. Motion carried, 12:0.

7. Old Business

7.1 Updated Request for Consideration Form

MOTION: Teri Ferriera moved to approve Request for Consideration form a corresponding approval letter as presented. Judy Guenther seconded. Motion carried, 12:0.

7.2 Review Revised Ancillary Utilization Plans and Pharmacy Technician Administration Guidance Document

MOTION: Matthew Ray moved to approve the guidance document with the following edits. Change "pharmacists" to "pharmacy" in the heading "guidance to pharmacists submitting AUPs to allow pharmacy technicians or pharmacy technicians-in-training to administer medications or devices" and strike "or pharmacy intern" from the second sentence of #1 under this heading. Also, add a paragraph that makes it clear ancillary staff must work under the immediate supervision of a pharmacist and outlines the rules around immediate supervision. Ann Wolken seconded. Motion carried, 13:0.

MOTION: Hawkins DeFrance moved to retroactively approve AUP's addressing medication administration by technicians to also include pharmacy technicians in training without having to submit to the Commission for re-approval. William Hayes seconded. Motion carried, 13:0.

8. Rules Updates

8.1 Review Revised Rules Tracker Spreadsheet

MOTION: Stephanie Bardin moved to adopt the tracker as presented with the established priorities. Matthew Ray seconded. Motion carried, 13:0.

8.2 Rules Workshop: Prescription Transfers

MOTION: Craig Ritchie moved to authorize staff to file the CR-102 with the addition of the term "provision of" in WAC 246-945-345(2) and WAC 246-945-346(2) such that both read "… not adversely impact the provision of medication therapy, whichever comes first" and to have staff draft an FAQ related to the electronic transfer of Schedule II-V controlled substance prescriptions. Hawkins DeFrance seconded. Motion carried, 13:0.

8.3 Rules Workshop: Medication Assistance

MOTION: Hawkins DeFrance moved to approve draft rule language as edited and authorize staff to file a CR-102. Teri Ferreira seconded. Motion carried, 13:0.

8.4 Emergency Rule (CR-103E) Refile Request: Medication Assistance

MOTION: Teri Ferriera moved to authorize refiling CR-103E due to an emergent need for the health and safety of the public. Stephanie Bardin seconded. Motion carried, 13:0.

8.5 CR-101 Authorization Request: ESSB 5271 – Uniform Facility Enforcement Framework Fining Authority Severity Matrix

MOTION: Teri Ferriera moved to authorize rulemaking to consider adding new WACs and amending current WACs as needed to establish the UFEF fine severity matrix but that the CR-101 not be filed before June 6, 2024. Hawkins DeFrance seconded. Motion carried, 13:0.

9. Strategic Plan Update

The commission reviewed the 2024-2025 Strategic Plan Implementation.

MOTION: Ann Wolken moved to approve Craig Ritchie, Bonnie Bush, William Hayes, and Patrick Gallaher as members of the Legislative Task Force. Huey Yu seconded. Motion carried, 13:0.

Ken Kenyon, chair of the commission, appointed Craig Ritchie the chair of the task force.

MOTION: William Hayes moved to approve Hawkins DeFrance, Craig Ritchie, and Judy Guenther as members of the orientation program for new commissioners task force. Matthew Ray seconded. Motion carried, 13:0.

Ken Kenyon, chair of the commission, appointed Hawkins DeFrance chair of the task force.

10. Open Forum

Boris Zhang, Washington State Pharmacy Association, asked a question about whether pharmacists can do N95 mask fit testing. Staff will research this question.

11. Summary of Meeting Action Items

1.1 Meeting Minutes Approval March 7, 2024

- Staff will post final minutes on the commission's website.

2. Consent Agenda

- Convey the decisions to the applicants and the Office of Customer Service

3.2 Rulemaking for the WDFW Wildlife Capture Antibiotics - Approval of Comment Responses and Auth to file CR-103P

- Staff will file CR-103P on WAC 246-945-507.

5.2 Rulemaking for Removing Fenfluramine from Schedule IV Substances List – Approval of Comment Responses and Authorization to file CR-103P

- Staff will file CR-103P on WACs 246-945-05001 and 246-945-055.

6.1 Rules Workshop Pharmacy Interns

- Staff will file a CR-102 with a hybrid version of the intern renewal limit rule language allowing for three renewals plus an extension process and also increasing the duration of the temporary practice permit from 90 days to 180 days.

7.1 Updated Request for Consideration Form

- Post updated request for consideration form and corresponding approval letter. Look into making a webform version as well.

7.2 Review Revised Ancillary Personnel Utilization Plans and Pharmacy Technician Administration Guidance Document

- Staff will file the post the updated guidance document to the commission's webpage and send a communication out via GovDelivery. We will include in that GovDelivery the motion captured here today on the retroactive application of previously approved AUPs related to technician medication administration to include technicians in training without having to resubmit their AUPs. Also update Sample AUP to reflect the changes to the administration guidance document.

8.1 Rules Updates - Review Revised Rules Tracker Spreadsheet

- Staff will present the next version of the tracker at the August business meeting.

8.2 Rules Workshop Prescription Transfer

- Staff will make the amendments discussed to the proposed WACs 246-945-345 and 246-945-346 and file the CR-102. Staff will also draft an FAQ to correspond to the implementation of the rule and bring it back to the commission for review at a future business meeting.

8.3 Rules Workshop Medication Assistance

- Staff will file the CR-102 on WACs 246-945-710 through 246-945-718 on medication assistance.

8.4 Emergency Rule (CR-103E) Refile Request: Medication Assistance

- Staff will refile the CR-103E.

8.5 CR-101 Authorization Request: ESSB 5271 – Uniform Facility Enforcement Framework Fining Authority Severity Matrix

- Staff will file CR-101 on establishing a fining severity matrix for the UFEF, not to begin before June 6.

9.2 Select members to serve on the Legislative Task Force

- Staff will schedule meetings for the Legislative Task Force to convene which will include William Hayes, Bonnie Bush, and Patrick Gallaher with Craig Ritchie as Chair.

9.3 Select members to serve on the Orientation Program for New Commissioners Task Force

- Staff will schedule meetings for the Orientation Program for New Commissioners Task Force to convene which will include Craig Ritchie and Judy Guenther with Hawkins DeFrance as Chair.

10. Open Forum

- Staff will research the question asked during open forum.

Business Meeting Adjourned

Kenneth Kenyon, Chair, called the meeting adjourned at 1:29 P.M.

STATE OF WASHINGTON
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Pharmacy Quality Assurance Commission Meeting
May 3, 2024 - Minutes

Convene: Chair, Kenneth Kenyon called the meeting to order May 3, 2024, 9:07 A.M.

Commission Members:
Ken Kenyon, PharmD, BCPS, Chair
Hawkins DeFrance, Nuclear Pharmacist, Vice Chair
Stephanie Bardin, PharmD
Bonnie Bush, Public Member
Teri Ferreira, RPh
Patrick Gallaher, BS, BPharm, MBA, MPH
Judy Guenther, Public Member
William Hayes, PharmD CCHP
Matthew Ray, PharmD
Craig Ritchie, RPh, JD
Uyen Thorstensen, CPhT
Ann Wolken, PharmD, RPh
Huey Yu, PharmD

Staff:
Marlee O'Neill, Executive Director
Lindsay Trant-Sinclair, Deputy Director
Si Bui, Inspector Supervisor
Christopher Gerard, AAG
Julia Katz, Program Consultant
Irina Tiginyanu, Pharmacy Technician Consultant
Joshua Munroe, Legislative and Rules Consultant
Taifa "Nomi" Peaks, Pharmacist Consultant
Haleigh Mauldin, Program Consultant
Amy L Robertson, Communications Coordinator and Program Support
Desire Gudmundson, Administrative Support

Commission Members Absent:
Jerrie Allard, Public Member

1. Call to Order Kenneth Kenyon, Chair

1.1 Meeting Agenda Approval – May 3, 2024

MOTION: Hawkins DeFrance moved to amend the business meeting agenda for May 3, 2024, to add item 1.2 – Hoagland Pharmacy Assistant AUP. Craig Ritchie, seconded. Motion carries, 13:0.

MOTION: Craig Ritchie moved to approve amended business meeting agenda for May 3, 2024. Bonnie Bush, seconded. Motion carried, 13:0.

1.2 Hoagland Pharmacy Assistant AUP

MOTION: William Hayes moved to approve the pharmacy assistant AUP for Hoagland Pharmacy contingent upon striking article (M) and amending article (L) to remove "daily operations and preparation" and to provide licensee with technical assistance regarding its decision. Bonnie Bush, seconded. Motion carried, 13:0.

2. Presentations

2.1 Executive Ethics Board – Ethics in Public Service Act

Kate Reynolds, Executive Director for the Washington State Executive Ethics Board, provided a presentation on the Ethics in Public Service Act.

2.2 DOH Legislative Team – Legislative Session Recap

Christie Spice, Deputy Assistant Secretary of Policy for the Health Systems Quality Assurance (HSQA) Division and Megan Veith, Director of Policy and Legislative Development for HSQA provided a presentation reviewing this past legislative session.

3. Open Forum

The purpose of the open forum is to provide the public an opportunity to address the commission on issues of significance to or affecting the practice of pharmacy. Discussion items may not relate to topics for which a hearing has or will be scheduled, or which are under investigation.

Three individuals, Zandra Brown, Dorene Cornwell, and Judy Brown, spoke to the importance of the accessible labeling rulemaking to patients and encouraged the commission to ensure timely progress on the rules.

4. Commission Member Reports

4.1 Task Force Reports

Hawkins DeFrance reported on the Nonresident Pharmacy Directive Task Force:

The task force held its first of three scheduled public meetings last month on April 11th. This task force is reviewing the Nonresident Pharmacy: List of Approved Inspection Programs directive. The goal is for the task force to provide the full commission with recommendations for any changes to the directive at an upcoming business meeting.

Teri Ferreira reported to the commission on the Pharmacy Assistant Scope of Practice Task Force:

The task force met for the first time on April 23, 2024. The task force had a great discussion regarding how and whether to further define “stocking” as set out in RCW 18.64A.030(2). Staff is using this discussion to draft a plan to move this rules project forward.

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

No items or issues raised or discussed.

5. Staff Reports

5.1 Executive Director – Marlee O'Neill

Marlee informed the commission that she, Ken, Hawkins, and Lindsay will attend the NABP Annual Meeting later in May. Marlee also outlined the proposed amendment to NABP Bylaws to remove the Bahamas from the list of member organizations.

MOTION: Bonnie Bush moved to vote in favor of the proposed amendment to remove the Bahamas from the list of member organizations. Stephane Bardin, seconded. Motion carried, 13:0.

Marlee reminded the commission that leadership elections will be held at the June business meeting.

Marlee shared that on March 15th she, along with other DOH staff, attended the Governor's bill signing of the Uniform Facility Enforcement Framework.

5.2 Deputy Director – Lindsay Trant-Sinclair

Lindsay updated the commission on the current status of the recruitment for the Operations Manager position stating that while a candidate had been selected and offered the position, the individual accepted another position and staff will update with any change of status.

Chris Humberson, who has been with the commission for many years in different capacities retired on April 1, 2024. He most recently served as a pharmacy investigator. OILS will be posting an opening for that position in the near future.

Kseniya Efremova, former policy analyst to the commission, has accepted a new role with the Environmental Public Health Division. Rachel Sahi will be assuming her position with the commission and will be introducing herself at the June business meeting.

5.3 Pharmacist Supervisor – Si Bui

Si announced that Stephanie Martin will be leaving her position.

5.4 Assistant Attorney General – Christopher Gerard

Christopher reported that at the next business meeting he will be presenting on the intersection between the DSCSA and the Commission's regulatory framework.

5.5 Rules and Legislative Consultant – Joshua Munroe

Joshua provided the commission with an update on the Accessible Labeling Rulemaking.

6. Summary of Meeting Action Items

2.1 Correspondence

- Staff will communicate the decision on the AUP, including the technical assistance, to the applicant and to OCS.

3.2 Review Proposed Amendment to NABP Bylaws:

- Ken Kenyon will vote in favor of the proposed amendment to the NABP bylaws.

Business Meeting Adjourned

Kenneth Kenyon, Chair, called the meeting adjourned at 11:09 A.M.

2.1.1. National Precursor Log Exchange Dashboard - April and May

MONTHLY PROGRAM ADMINISTRATOR'S DASHBOARD – April

2 Logins - 0 Searches - 0 Report Queries - 21 Active Watches - 0 Active Watch Hits		
NEW USERS THIS MONTH New Users = 0 Total Accounts = 145 Active Users = 2	TOP USAGE AGENCIES TOP USERS BY USAGE	TOP AGENCIES BY ACTIVE WATCHES 1. ICE - King County (34)

TRANSACTION SUMMARY STATISTICS (2024)

	JAN	FEB	MAR	APR	TOTAL
	74,296	72,050	85,682	81,813	**313,841**
	2,948	3,115	3,709	4,013	**13,785**
	151,093	146,960	183,371	181,150	**662,574**
	83,176	81,082	96,344	92,001	**352,603**
	7,693	8,306	10,088	11,242	**37,329**
	3,408	3,669	4,456	4,732	**16,265**
	2.26	2.26	2.26	2.38	**2.29**

PHARMACY PARTICIPATION STATISTICS (Apr 2024)

Enabled Pharmacies	956
Pharmacies Submitting a Transaction	872
Pharmacies Logging in Without a Transaction	0
Inactive Pharmacies	84
Pharmacy Participation for Apr	91.21%

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.

MONTHLY PROGRAM ADMINISTRATOR'S DASHBOARD - MAY

1 Logins - 0 Searches - 0 Report Queries - 21 Active Watches - 3 Active Watch Hits

NEW USERS THIS MONTH	TOP USAGE AGENCIES	TOP AGENCIES BY ACTIVE WATCHES
New Users = 1		1. ICE - King County (39)
Total Accounts = 146	TOP USERS BY USAGE	
Active Users = 1		

TRANSACTION SUMMARY STATISTICS (2024)

	JAN	FEB	MAR	APR	MAY	TOTAL
PURCHASES	74,296	72,050	85,682	81,813	81,404	**395,245**
BLOCKS	2,948	3,115	3,709	4,013	3,600	**17,385**
GRAMS SOLD	151,093	146,960	183,371	181,150	179,947	**842,521**
BOXES SOLD	83,176	81,082	96,344	92,001	91,589	**444,192**
GRAMS BLOCKED	7,693	8,306	10,088	11,242	10,259	**47,588**
BOXES BLOCKED	3,408	3,669	4,456	4,732	4,254	**20,519**
AVG GRAMS PER BOX BLOCKED	2.26	2.26	2.26	2.38	2.41	**2.31**

PHARMACY PARTICIPATION STATISTICS (May 2024)

Enabled Pharmacies	956
Pharmacies Submitting a Transaction	870
Pharmacies Logging in Without a Transaction	0
Inactive Pharmacies	86
Pharmacy Participation for May	91.0%

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.

2.1.2. Pharmaceutical Firms Application Report

Opened

Credential #	Status	First Issuance Date
PHAR.CF.61553831	ACTIVE	05/01/2024
PHAR.CF.61434834	ACTIVE	05/02/2024
PHNR.FO.61557541	ACTIVE	05/03/2024
PHNR.FO.61555506	ACTIVE	05/06/2024
PHNR.FO.61559083	ACTIVE	05/09/2024
PHAR.CF.61553934	ACTIVE	05/14/2024
PHAR.CF.61547790	ACTIVE	05/16/2024
DRCS.FX.61532417	ACTIVE	05/17/2024
PHNR.FO.61494639	ACTIVE	05/17/2024
PHNR.FO.61556165	ACTIVE	05/17/2024
PHAR.CF.61458201	ACTIVE	05/28/2024
PHNR.FO.61554145	ACTIVE	05/28/2024
PHNR.FO.61501904	ACTIVE	05/29/2024
PHNR.FO.61546470	ACTIVE	05/30/2024
PHNR.FO.61558878	ACTIVE	05/31/2024

Closed

Credential #	Status	Expiration Date
PHNR.FO.00059071	CLOSED	05/01/2024
PHWH.FX.60277195	CLOSED	05/01/2024
PHNR.FO.60741932	CLOSED	05/03/2024
PHAR.CF.60298365	CLOSED	05/06/2024
DRDG.FX.60630990	CLOSED	05/09/2024
PHNR.FO.60748958	CLOSED	05/09/2024
PHNR.FO.60839197	CLOSED	05/09/2024
PHNR.FO.61501185	CLOSED	05/09/2024
PHWH.FX.60078632	CLOSED	05/16/2024
PHNR.FO.60391630	CLOSED	05/17/2024
PHNR.FO.61225431	CLOSED	05/21/2024
PHWH.FX.60482660	CLOSED	05/23/2024
PHHC.FX.61005087	CLOSED	05/24/2024
PHNR.FO.60742416	CLOSED	05/28/2024
PHWH.FX.60117510	CLOSED	05/28/2024
PHWH.FX.60965685	CLOSED	05/28/2024
PHMF.FX.61154188	CLOSED	05/29/2024
PHNR.FO.60921259	CLOSED	05/30/2024
PHAR.CF.00058369	CLOSED	05/31/2024
PHAR.CF.61397993	CLOSED	05/31/2024
PHAR.CF.61398006	CLOSED	05/31/2024
PHAR.CF.61312025	CLOSED	05/31/2024
PHMF.FX.60174272	CLOSED	05/31/2024
PHNR.FO.61006755	CLOSED	05/31/2024
PHNR.FO.61333831	CLOSED	05/31/2024
PHNR.FO.61257167	CLOSED	05/31/2024
PHNR.FO.61303518	CLOSED	05/31/2024
PHNR.FO.60769048	CLOSED	05/31/2024
PHNR.FO.00059171	CLOSED	05/31/2024
PHWH.FX.60260214	CLOSED	05/31/2024
PHWH.FX.60820203	CLOSED	05/31/2024

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

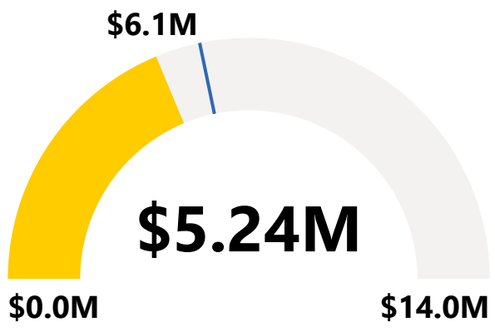
2025 PQAC Business Meetings

Date	Time	Location
February 6, 2025	9:00 am	Zoom and TBD
March 27, 2025	9:00 am	Zoom and TBD
May 22, 2025	9:00 am	Zoom and TBD
June 26, 2025	9:00 am	Zoom and TBD
August 14, 2025	9:00 am	Zoom and TBD
October 16, 2025	9:00 am	Zoom and TBD
December 4, 2025	9:00 am	Zoom and TBD

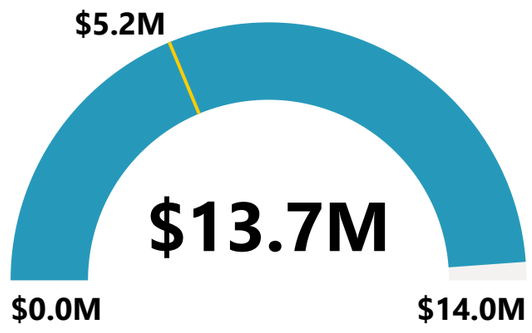
Pharmacy Commission

FY2024 Starting Fund Balance	Current Fund Balance	Helms Allocation	Revenue	Expenses+Total Indirect+HELMS
$5.99M	$6.2M	$195K	$6.77M	$6.76M

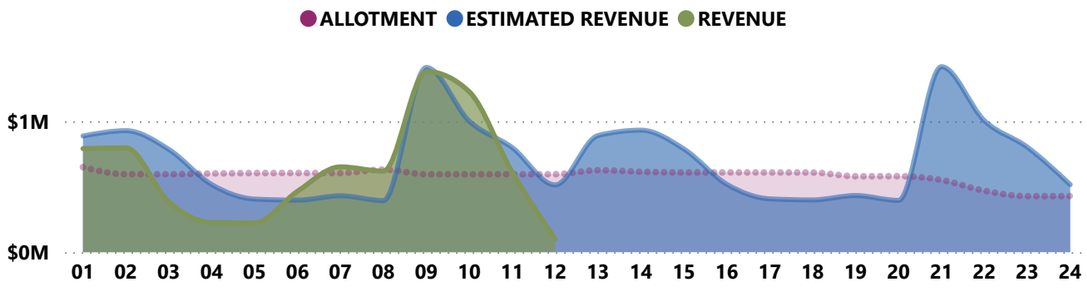
Biennial Allotment To Date



Biennial Allotment



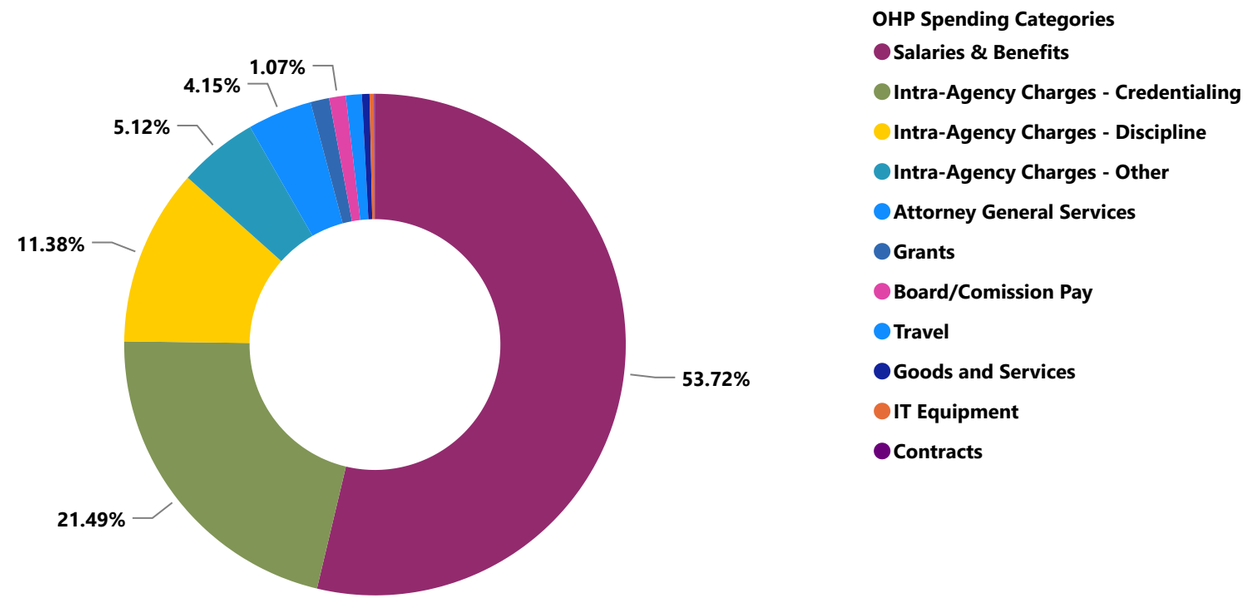
Estimated Revenue and Allotment



Health Professions	EXPENSES TO DATE	ALLOTMENT TO DATE	VARIANCE TO DATE	ALLOTMENT	ACTUAL TOTAL INDIRECT
Pharmacy Commission	$5,235,231	$6,079,699	$844,468	$13,987,147	$1,329,695
Travel	$53,820	$36,590	($17,230)	$87,816	
Salaries & Benefits	$2,812,181	$3,010,816	$198,635	$7,182,282	
IT Equipment	$15,146	$10,468	($4,678)	$20,936	
Intra-Agency Charges - Other	$267,933	$389,007	$121,074	$954,640	
Intra-Agency Charges - Discipline	$595,956	$772,817	$176,861	$1,588,510	
Intra-Agency Charges - Credentialing	$1,124,852	$1,494,741	$369,889	$3,276,196	
Indirect					$1,329,695
Grants	$63,222	$71,260	$8,038	$171,024	
Goods and Services	$25,600	$26,140	$540	$62,879	
Contracts	$2,950		($2,950)		
Board/Comission Pay	$56,106	$40,750	($15,356)	$97,800	
Attorney General Services	$217,466	$227,110	$9,644	$545,064	
Total	$5,235,231	$6,079,699	$844,468	$13,987,147	$1,329,695

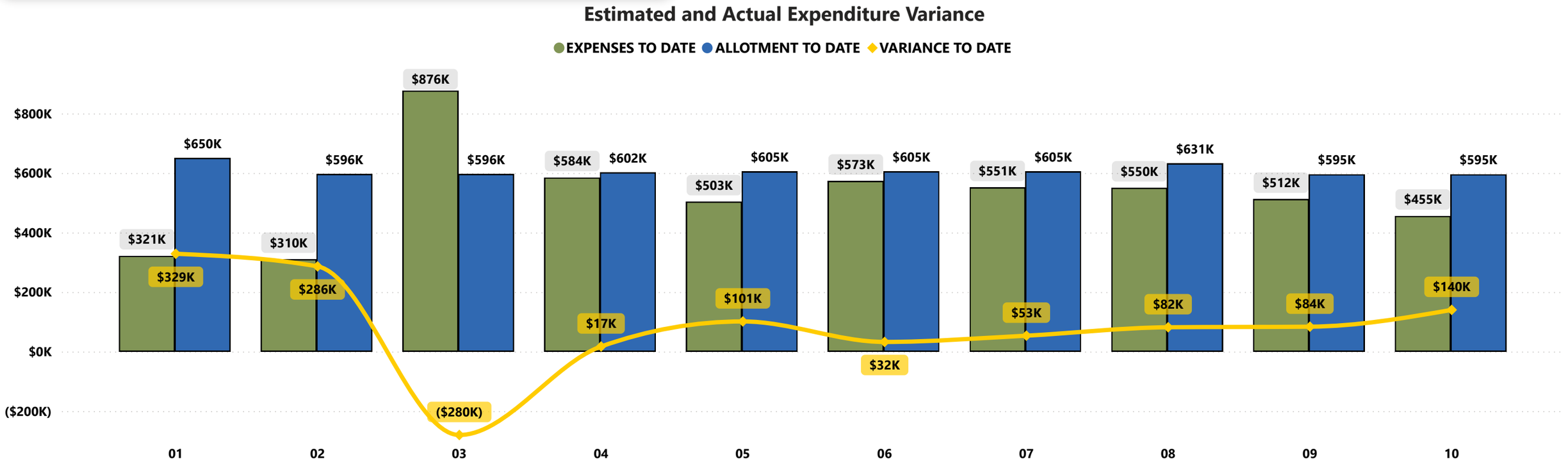
Job (POS)	Vacant Permanent Positions
ADMINISTRATIVE ASSISTANT 3	0
EXEC DIRECTOR, PHARMACY COMMISSION - DOH	0
HEALTH SERVICES CONSULTANT 1	0
HEALTH SERVICES CONSULTANT 2	0
HEALTH SERVICES CONSULTANT 4	0
MANAGEMENT ANALYST 4	1
PHARMACIST - INVESTIGATOR	2
PHARMACIST SUPERVISOR	0
WMS BAND 2	0
Total	3

Spending by Category



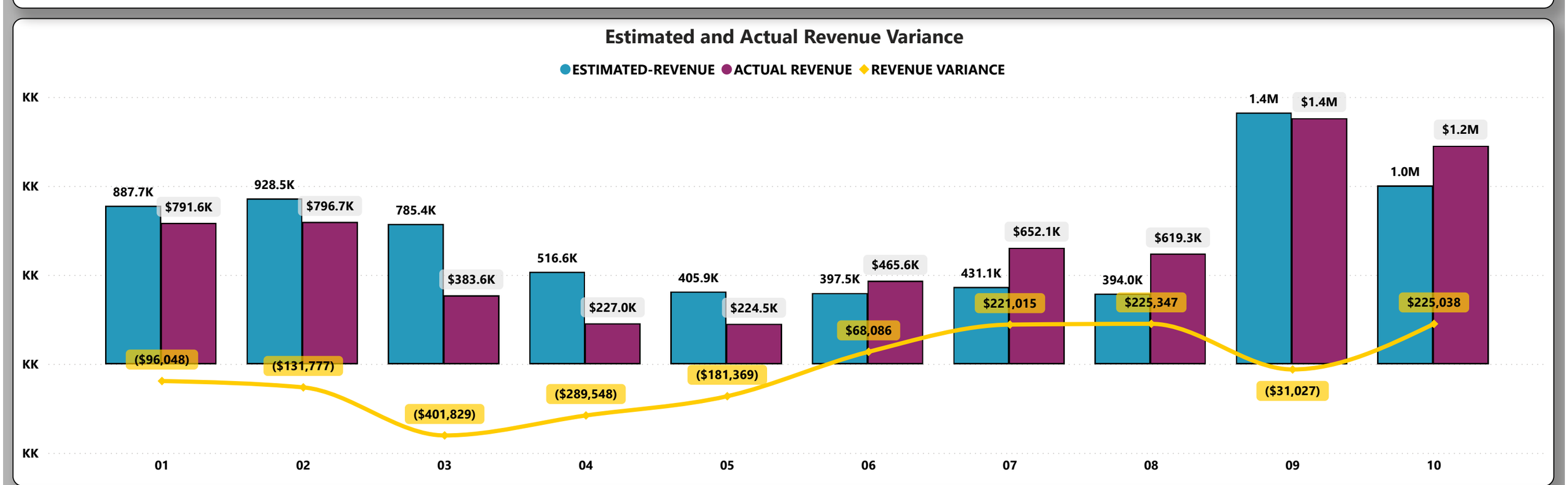
Master Indexes+Title	EXPENSES BY STAFF MONTHS -PAYROLL	ALLOTMENT TO DATE BY STAFF MONTHS
62401600 - PHARMACY COMMISSION	213.03	200.00
62401601 - PHARMACY INVESTIGATIONS	44.03	41.20
Total	257.06	241.20

Estimated and Actual Expenditure Variance



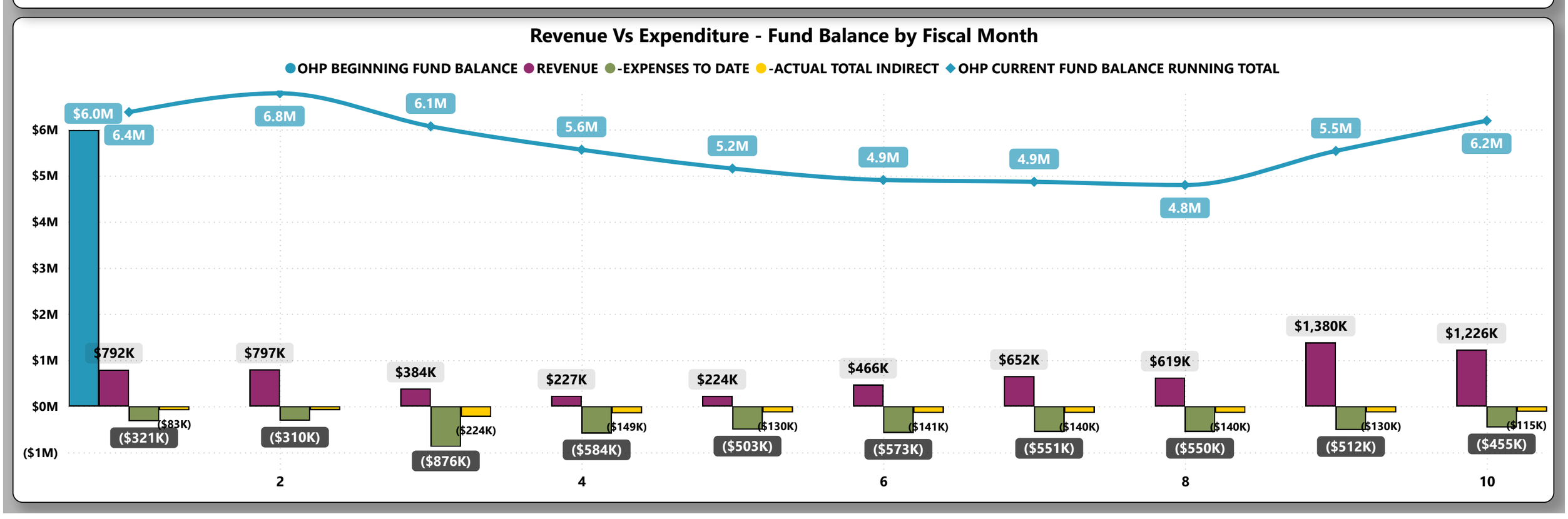
Health Professions	REVENUE	ESTIMATED REVENUE	REVENUE VARIANCE
Pharmacy Commission	$6,766,472	$7,158,583.00	($392,111)
Total	$6,766,472	$7,158,583.00	($392,111)

Estimated and Actual Revenue Variance



Health Professions	REVENUE	Expenses + Total Indirect
Pharmacy Commission	$6,766,472	$6,564,926
Total	$6,766,472	$6,564,926

Revenue Vs Expenditure - Fund Balance by Fiscal Month



SBAR Presented at the December 15, 2024 Business Meeting

Commission SBAR Communication

Agenda Item/Title: Regulations on Telepharmacy and Remote Supervision

Date SBAR Communication Prepared: September 14, 2023

Reviewer: T. Nomi Peaks

Link to Action Plan:

☐ **Action** ☐ **Information** ☐ **Follow-up** ☒ **Discussion**

Situation: At the Pharmacy Quality Assurance Commission (commission) business meeting on August 25, 2023, program staff members were tasked with facilitating a discussion at the October 2023 business meeting of WAC 246-945-315 and other relevant regulations related to telepharmacy and the remote supervision of multiple facilities by one pharmacist.

Background: For background, WAC 246-945-315(1) states, " 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."

WAC 246-945-001(44) defines “immediate supervision.” It 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. Subsection (a) further clarifies that “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 technician(s).”

WAC 246-945-001(44)(b) states, “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."

WAC 246-945-430 discusses pharmacies storing, dispensing, and delivering drugs to patients without a pharmacist on-site. It reads,

(1) The following requirements apply to pharmacies storing, dispensing and delivering drugs to patients without a pharmacist on-site and are in addition to applicable state and federal laws applying to pharmacies.

(2) The pharmacy is required to have adequate visual surveillance of the full pharmacy and retain a high quality recording for a minimum of thirty calendar days.

(3) Access to a pharmacy by individuals must be limited, authorized, and regularly monitored.

(4) A visual and audio communication system used to counsel and interact with each patient or patient's caregiver, must be clear, secure, and HIPAA compliant.

(5) The responsible pharmacy manager, or designee, shall complete and retain, in accordance with WAC **246-945-005** a monthly in-person inspection of the pharmacy.

(6) A pharmacist must be capable of being on-site at the pharmacy within three hours if an emergency arises.

(7) The pharmacy must be closed to the public if any component of the surveillance or visual and audio communication system is malfunctioning, and remain closed until system corrections or repairs are completed or a pharmacist is on-site to oversee pharmacy operations.

Assessment/Recommendation: The commission's rules do not prohibit one pharmacist from remotely supervising multiple pharmacies. However, there are several questions that commission staff members recommend the commissioners consider during their discussion of this topic.

- What impact might one pharmacist's remote supervision of multiple pharmacies have on patient safety and public welfare?
- How might a remote pharmacist manage simultaneous emergencies at multiple pharmacies?
- What impact will a single pharmacist's remote supervision of multiple pharmacies have on each pharmacy's ancillary personnel utilization plan (AUP)?

Follow-up Action: Staff will take note of the commission's evaluation of these and any other pertinent discussion points and follow the commission's guidance regarding the best next steps.

7. Rulemaking Tracker Table

PQAC RULES TRACKING - FOR COMMISSION BUSINESS MEETING					
Standard 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-101 (Standard) WSR 22-13-035, filed June 12, 2023	Josh	**Recent actions**: Commission approved rule language draft at July 2023 special meeting **Next steps:** CR-102 will be filed upon conclusion of department review
Medication assistance in home care settings (will file jointly with DOH)	Medication assistance rules in accordance with chapter 69.41 RCW	High	CR-101 (Standard) WSR 22-02-015, filed December 27, 2021	Josh	**Recent actions:** Rules Workshop held at May 2024 business meeting; commission approved rule language draft and tasked staff with completing the CR-102 **Next steps:** Building of the CR-102 rules package starting with the Significant Analysis (SA) document

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:** Task force held on June 13th **Next steps:** Schedule follow-up alternative distribution model task force meeting
Technical fixes to chapter 246-945 WAC	Typos and small edits to multiple sections in chapter 246-945 WAC	Complete	CR-103P (Expedited) WSR 24-11-060 (Filed May 13, 2024)	Josh	**Recent actions:** CR-103p filed on May 13, 2024; rule went into effect on June 13 and is now complete
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
Incorporations by Reference and Naloxone	Updating incorporations by reference and making fixes for Naloxone	High	Not yet filed	Haleigh	**Recent actions:** Commission approved CR-105 filing with updated language **Next steps:** File CR-105

Incorporation by Reference for USP 795 and 797	Amend WAC 246-945-100 to incorporate by reference changes in USP <795> and <797> with a November 1, 2023 effective date	High	CR-103P (Standard) WSR 24-09-051, filed April 15, 2024	Haleigh	**Recent actions:** CR-103p filed
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:** Draft rule language **Next steps:** Solicit interested party feedback and schedule a rules workshop
Access to drugs stored outside pharmacy	Allowing access to drugs stored outside the pharmacy by unlicensed employees of a health care facility	Medium	CR-101 (Standard) WSR 23-01-111, filed December 19, 2022	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
Pharmacist Assistant Scope-of-Practice	Amend WACs 246-945-001, 246-945-315, and add new sections to chapter 246-945 WAC related to the definition of stocking, assistants scope-of-practice, and the use of technology	Medium	Not yet filed	Haleigh	**Recent actions:** Commission approved staff filing a CR-101 and creating a task force for discussion **Next steps:** File CR-101 and schedule task force meeting dates

Pharmacy Technician Final Product Verification	Amending WAC 246-945-317 and/or -320 and adding new WAC to amend the pharmacy technician scope of practice, codify the pharmacy tech administration guidance document, and consider final technician product verifcation.	Medium	Not yet filed	Haleigh	**Recent actions:** Commission approved staff filing a CR-101 and amending the technician administration guidance document **Next steps:** File CR-101 and prepare guidance document for review at May 2024 meeting
Medication assistance (filed jointly with DOH)	Reinstating chapter 246-888 WAC (with edits) per DSHS request	High	CR-103E (Emergency) WSR 24-06-047, filed March 1, 2024	Haleigh	**Recent actions:** CR-103e filed **Next steps:** Reauthorization request prior to June 29, 2024 expiration
Naloxone	Reclassifying 4mg of Naloxone as an OTC, amend WAC 246-945-030 and create a new section of WAC (-034)	High	CR-103E (Emergency) WSR 24-09-013, filed April 5, 2024	Haleigh	**Recent actions:** CR-103e filed **Next steps:** Reauthorization request prior to August 3, 2024 expiration
Deschedule Fenfluromine (petition)	Amend WAC 246-945-055 to remove Fenfluromine from Schedule IV and create a new section of WAC for exemptions.	High	CR-102 (Standard) WSR 24-06-067, filed March 15, 2024	Julia	**Recent actions:** Authorization to file CR-103 approved at May 2024 business meeting **Next steps:** CR-103 anticipated to be adopted by August 2024 business meeting

WDFW Wildlife Capture Drugs (petition)	Amend WAC 246-945-507 to add four intramammary antibiotics to the list of approved legend drugs.	High	CR-102 (Standard) WSR 24-07-066, filed March 15, 2024	Julia	**Recent actions:** Authorization to file CR-103 approved at May 2024 business meeting **Next steps:** CR-103 anticipated to be adopted by August 2024 business meeting
Pharmacy Interns - military spouse permits and renewal extension	Amend WACs 246-945-155 and 246-945-156 to extend temporary practice permits to 180 days and establish a renewal extension process.	High	CR-101 (Standard) WSR 24-07-105, filed March 20, 2024	Julia	**Recent actions:** Commission approved rule draft language and staff filing a CR-102 at May 2024 business meeting **Next steps:** Hold rule hearing at October 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	CR-101 (Standard) WSR 23-21-010, filed October 5, 2023	Julia	**Recent actions:** Commission approved rule language draft and staff filing CR-102 at March 2024 business meeting **Next steps:** Hold rule hearing at August 2024 business meeting

Prescription Transfers	Amend WAC 246-945-345(2) to change "may transfer" to "shall transfer" and add specifications to prescription transfers.	Medium	CR-101 (Standard) WSR 23-23-051, filed November 7, 2023	Julia	**Recent actions:** Commission approved rule language draft and staff filing CR-102 at May 2024 business meeting **Next steps:** Hold rule hearing at October 2024 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) WAC 24-13-061, filed June 13, 2024	Julia	**Recent actions:** CR-101 filed on June 13, 2024 **Next steps:** Rule workshop at August 2024 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	Not yet filed	Julia	**Recent actions:** Commission authorized rulemaking and staff filing CR-101 at May business meeting **Next steps:** File CR-101

RULE-MAKING ORDER
EMERGENCY RULE ONLY

CR-103E (December 2017)
(Implements RCW 34.05.350 and 34.05.360)

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: April 05, 2024
TIME: 11:21 AM

WSR 24-09-013

Agency: Department of Health – Pharmacy Quality Assurance Commission

Effective date of rule:

Emergency Rules

☒ Immediately upon filing.

☐ Later (specify)

Any other findings required by other provisions of law as precondition to adoption or effectiveness of rule?

☐ Yes ☒ No If Yes, explain:

Purpose: Naloxone nasal spray as over-the-counter status**.** In March 2023, the United States Food and Drug Administration (FDA) approved the first 4 mg naloxone hydrochloride nasal spray as an over-the-counter (OTC) drug and has approved other naloxone nasal sprays since that time. Naloxone is an opioid antagonist used for the emergency treatment of known or suspected opioid overdose. Currently, WAC 246-945-030 incorporates the 39th edition of the Approved Drug Products with Therapeutic Equivalence Evaluations, or "Orange Book," which has naloxone listed as a prescription drug. The Pharmacy Quality Assurance Commission (commission) considers the ongoing opioid epidemic to be a public health emergency in Washington state. In order to combat this epidemic in Washington, the commission is amending WAC 246-945-030 and adding a new section, WAC 246-945-034, classifying the 3mg and 4mg naloxone hydrochoride nasal spray as approved by the FDA for OTC distribution as an OTC drug in Washington state.

The time line for the availability of naloxone nasal spray is set by the manufacturers, although some are already available. This emergency rule prepares Washington state for the moment that the drug becomes available by manufacturers. The proposed new rule WAC 246-945-034, will also allow for expansion of different formularies if the FDA makes further changes. This preparation will allow for a faster release of the drug throughout the state, meaning this life saving drug would be in the hands of Washingtonians faster. Increasing patient access to the drug is critical to reduce opioid overdoses.

This emergency rule filing allows for the 3mg and 4mg dosage versions of naloxone spray to be prescribed as OTC products. This rule is unchanged from the previous emergency rule under WSR 24-01-021 filed on December 8, 2023. This emergency rule will be continued until the permanent rulemaking is effective.

Citation of rules affected by this order:

New: WAC 246-945-034
Repealed: None
Amended: WAC 246-945-030
Suspended: None

Statutory authority for adoption: RCW 18.64.005

Other authority:

EMERGENCY RULE

Under RCW 34.05.350 the agency for good cause finds:

☒ That immediate adoption, amendment, or repeal of a rule is necessary for the preservation of the public health, safety, or general welfare, and that observing the time requirements of notice and opportunity to comment upon adoption of a permanent rule would be contrary to the public interest.

☐ That state or federal law or federal rule or a federal deadline for state receipt of federal funds requires immediate adoption of a rule.

Reasons for this finding: The immediate adoption of this rule is necessary for the preservation of public health, safety, and general welfare. The opioid epidemic is a public health emergency which requires the use of the emergency rulemaking process. Observing the time requirements of notice and opportunity to comment upon adoption of a permanent rule would be contrary to the public interest. This rule will increase access to this lifesaving drug faster, which will help relieve some stress on affected communities in Washington state and attempt to reduce opioid overdoses.

Note: If any category is left blank, it will be calculated as zero. No descriptive text.

Count by whole WAC sections only, from the WAC number through the history note. A section may be counted in more than one category.

The number of sections adopted in order to comply with:

Federal statute:	New	0	Amended	0	Repealed	0
Federal rules or standards:	New	1	Amended	1	Repealed	0
Recently enacted state statutes:	New	0	Amended	0	Repealed	0

The number of sections adopted at the request of a nongovernmental entity:

New	0	Amended	0	Repealed	0

The number of sections adopted on the agency's own initiative:

New	0	Amended	0	Repealed	0

The number of sections adopted in order to clarify, streamline, or reform agency procedures:

New	0	Amended	0	Repealed	0

The number of sections adopted using:

Negotiated rule making:	New	0	Amended	0	Repealed	0
Pilot rule making:	New	0	Amended	0	Repealed	0
Other alternative rule making:	New	1	Amended	1	Repealed	0

Date Adopted: 4/5/2024	**Signature:** 
Name: Kenneth Kenyon, PharmD, BCPS	
Title: Pharmacy Quality Assurance Commission Chair	

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

WAC 246-945-030 Identification of legend drugs for purposes of chapter 69.41 RCW. (1) Those drugs determined by the FDA to require a prescription under federal law should be classified as legend drugs under state law because their toxicity, potential for harmful effect, methods of use, or collateral measures necessary to their use indicate they are only safe for use under the supervision of a practitioner.

(2) The commission finds that under state law, legend drugs are those drugs designated as legend drugs under federal law, as of the date of adoption of this rule, and listed in at least one of the following publications unless the drug is identified as an over-the-counter drug by the commission in WAC 246-945-034:

(a) The 39th Edition, including supplements, of the *Approved Drug Products with Therapeutic Equivalence Evaluations "Orange Book"* (available at https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book).

(b) The 2019 version, including monthly updates, of the *Approved Animal Drug Products "Green Book"* (available at https://www.fda.gov/animal-veterinary/products/approved-animal-drug-products-green-book).

(c) The 2019 *List of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations "Purple Book"* (available at https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/purple-book-lists-licensed-biological-products-reference-product-exclusivity-and-biosimilarity-or).

(3) Copies of the reference material listed in subsection (2) of this section are available for public inspection at the commission's office at Department of Health, Town Center 2, 111 Israel Road S.E., Tumwater, WA 98501.

(4) The commission also identifies those ephedrine products specified in WAC 246-945-031 as legend drugs under state law.

(5) There may be changes in the marketing status of drugs after the publication of the above references. Upon application of a manufacturer or distributor, the commission may grant authority for the over-the-counter distribution of certain drugs designated as legend drugs in these references. These determinations will be made after public hearing and will be published as an amendment to this chapter.

NEW SECTION

WAC 246-945-034 Identification of the over-the-counter drugs. Although listed as a legend drug in publications that are incorporated by reference in WAC 246-945-030(2), the commission identifies the following as an over-the-counter drug in Washington:

(1) 4 mg naloxone hydrochloride nasal spray, approved by the FDA for marketing as an OTC drug product.

(2) 3 mg naloxone hydrochloride nasal spray, approved by the FDA for marketing as an OTC drug product.

Mobile Opioid Treatment Program Units Language Draft
June 2024 Rules Workshop
PharmacyRules@doh.wa.gov

WAC 246-945-060 Other controlled substance registrants—

Requirements. (1) All persons and firms, except persons exempt from registration, must register with the commission in order to legally possess or use controlled substances.

(2) Persons or firms which are not classified as pharmacies, wholesalers, manufacturers, or researchers will be classified as other controlled substance registrants. Examples of persons or firms in this classification include analytical laboratories, dog handlers/trainers who use dogs for drug detection purposes, school laboratories, opioid treatment programs, and other agencies which have a legitimate need to use precursor chemicals as defined in WAC 246-945-053.

(3) The applicant for a controlled substance registration must complete and return an application form supplied by the commission. A list of the controlled substances to be used, the purpose for such use, and the names of the persons authorized to access the controlled substances must be listed on the application or on an addendum. Applicants for a controlled

substance registration who are an OTP must also identify any mobile units operated by the agency, if any, in the application or in an addendum.

(4) ~~All controlled substances must be stored in a substantially constructed locked cabinet. The registrant shall maintain records in sufficient detail in order to account for the receipt, use, and disposition of all controlled substances. The registrant shall inventory all controlled substances in the possession of the registrant every two years on the anniversary of the issuances of the registration and shall maintain the inventory list for two years. The registrant shall return unwanted, outdated, or unusable controlled substances to the source from which it was obtained or surrendered to the DEA.~~Other controlled substance registrants shall:

(a) Ensure all controlled substances are stored in a substantially constructed locked cabinet to prevent unauthorized access;

(b) Maintain records in sufficient detail in order to account for the receipt, use, and disposition of all controlled substances;

(c) Inventory all controlled substances in the possession of the registrant every two years on the anniversary of the issuance of the registration and shall maintain the inventory for two years;

(d) Return unwanted, outdated, or unusable controlled substances to the source from which it was obtained, surrendered to the DEA, or as otherwise permitted by state and federal law; and

(e) Affix a label to every box, bottle, jar, tube, or other container that is dispensed and delivered to an ultimate user that meets the labeling requirements in RCW 69.41.050 including:

(i) Name of prescriber;

(ii) Complete directions for use;

(iii) The brand or generic name of the drug;

(iv) Strength per unit dose;

(v) Name of patient; and

(vi) Date.

(5) Other controlled substance registrants that are OTPs, who have notified the department that they will be operating a mobile unit must:

(a) Notify the local DEA office and receive explicit written approval from the local DEA office prior to operating the mobile opioid treatment program unit;

(b) Possess valid county/city and Washington state vehicle licensing and registration prior to transporting controlled substances;

(c) Not reverse distribute, share, or transfer controlled substances from one mobile component to another mobile component while deployed away from the registered location;

(d) Establish policies and procedures to ensure, if the mobile unit becomes inoperable, that all controlled substances on the inoperable mobile unit are accounted for, removed, and secured at the registered location of the OTP;

(e) Return to the registered location at the completion of each operation and remove all controlled substances to secure within the registered location; and

(f) Notify the commission of any changes to the information provided on the application, including the addition or removal of a mobile unit.

(6) For the purposes of this section and WAC 246-945-250:

(a) "Mobile unit" means a component of an opioid treatment program that the DEA has approved to operate as a mobile narcotic treatment program pursuant to 21 C.F.R. § 1301.13.

(b) "Opioid treatment program(s)" or "OTP(s)" means a behavioral health agency that has been licensed or certified by the department as an opioid treatment program.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-060, filed 6/1/20, effective 7/1/20.]

WAC 246-945-250 Researcher and other controlled substance registration. (1) Applicants for initial registration and renewal for researcher or other controlled substance registrations shall submit to the commission a complete application, as described in WAC 246-945-060(3), with fees relevant to the registration type.

(a) Researcher:

(i) Noncontrolled legend drugs; or

(ii) Researchers requiring to purchase, possess, administer or dispense controlled substances shall apply for a controlled substance authority on its license with the commission and register with the DEA.

(b) Other controlled substance registrations:

(i) Opioid treatment programs;

(ii) Analytical laboratories;

(iii) Dog handler; and

(iv) Other agencies who have demonstrated a legitimate need to use precursor chemicals.

(2) OTPs who have notified the department they will be operating a mobile unit pursuant to WAC 246-341-0342 are not required to obtain a separate controlled substance registration for each mobile unit if the OTP's main fixed location has obtained an other controlled substance registration from the commission.

(3) Researcher and other controlled substance registrants must notify the commission within thirty days of any changes to the information provided on their application. ~~The application shall:~~

~~(a) List all legend drugs and controlled substances to be used and the purpose for its use;~~

~~(b) Name the primary registrant; and~~

~~(c) List the names of the individuals authorized to access the controlled substances.~~

(~~3~~4) Applicants for initial registration, renewal, and closure for researcher and other controlled substance registrations, including when an OTP removes a mobile unit from its registration, shall undergo an ~~initial~~ inspection. ~~and~~ Registrants will be subject to periodic inspections as deemed appropriate by the commission.

(5) Researcher and other controlled substance registrants will also be subject to:

(a) An inspection for any modification or remodel made by the registrant that affects security, location, and access to controlled substances, including when an OTP adds a mobile unit to their registration.

(b) An inspection fee as established in WAC 246-945-990(5)(a) for inspections under this subsection.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-250, filed 6/1/20, effective 7/1/20.]

PETITION FOR ADOPTION, AMENDMENT, OR REPEAL OF A STATE ADMINISTRATIVE RULE

Print Form

In accordance with RCW 34.05.330, the Office of Financial Management (OFM) created this form for individuals or groups who wish to petition a state agency or institution of higher education to adopt, amend, or repeal an administrative rule. You may use this form to submit your request. You also may contact agencies using other formats, such as a letter or email.

The agency or institution will give full consideration to your petition and will respond to you within 60 days of receiving your petition. For more information on the rule petition process, see Chapter 82-05 of the Washington Administrative Code (WAC) at http://apps.leg.wa.gov/wac/default.aspx?cite=82-05.

CONTACT INFORMATION *(please type or print)*

Petitioner's Name Jennifer Nicole Brandt

Name of Organization

Mailing Address [redacted]

City [redacted] State [redacted] Zip Code [redacted]

Telephone [redacted] Email [redacted]

COMPLETING AND SENDING PETITION FORM

- Check all of the boxes that apply.
- Provide relevant examples.
- Include suggested language for a rule, if possible.
- Attach additional pages, if needed.
- Send your petition to the agency with authority to adopt or administer the rule. Here is a list of agencies and their rules coordinators: http://www.leg.wa.gov/CodeReviser/Documents/RClist.htm.

INFORMATION ON RULE PETITION

Agency responsible for adopting or administering the rule: pharmacy quality assurance commission

☐ **1. NEW RULE - I am requesting the agency to adopt a new rule.**

☐ The subject (or purpose) of this rule is:

☐ The rule is needed because:

☐ The new rule would affect the following people or groups:

☒ **2. AMEND RULE - I am requesting the agency to change an existing rule.**

List rule number (WAC), if known: RCW 69.50.204

☒ I am requesting the following change: Kratom, including its active alkaloids mitragynine and 7-hydroxymitragynine, to be classified as a Schedule I controlled substance in the state of Washington

☒ This change is needed because: Abuse potential, lack of acceptable medical use, public hazards

☒ The effect of this rule change will be: A pause on the sale and use until regulated under current FDA food guidelines or outright banned

☐ The rule is not clearly or simply stated: _____

☐ **3. REPEAL RULE - I am requesting the agency to eliminate an existing rule.**

List rule number (WAC), if known: _____

(Check one or more boxes)

☐ It does not do what it was intended to do.

☐ It is no longer needed because: _____

☐ It imposes unreasonable costs: _____

☐ The agency has no authority to make this rule: _____

☐ It is applied differently to public and private parties: _____

☐ It conflicts with another federal, state, or local law or rule. List conflicting law or rule, if known: _____

☐ It duplicates another federal, state or local law or rule. List duplicate law or rule, if known: _____

☐ Other (please explain): _____

1. Kratom, including its active alkaloids mitragynine and 7-hydroxymitragynine, and all salts, isomers, and salts of isomers thereof whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, to be classified as a Schedule I controlled substance in the state of Washington.
2. Statement of Grounds for the Addition of Kratom to Schedule I

Introduction

This petition seeks to classify kratom (Mitragyna speciosa) and its active alkaloids, mitragynine and 7-hydroxymitragynine, as Schedule I controlled substances in Washington under RCW 69.50.204. This classification is warranted due to the significant abuse potential, lack of accepted medical use, and associated public health risks.

Abuse Potential

Kratom is known for its psychoactive properties, which contribute to its high potential for abuse. Users consume kratom for its stimulant effects at low doses and opioid-like effects at higher doses. This dual action raises substantial concerns about its potential for addiction and misuse. Several reports indicate that kratom is increasingly used as a recreational drug, leading to physical dependence and withdrawal symptoms similar to those of opioids.

Lack of Accepted Medical Use

Currently, kratom is not approved by the Food and Drug Administration (FDA) for any medical use. Although some anecdotal evidence suggests potential benefits for pain relief and opioid withdrawal management, these claims lack robust scientific validation and are not recognized by medical authorities. The absence of standardized dosing, potential for contamination, and variability in potency further undermines its legitimacy as a safe and effective medical treatment.

Public Health Risks

Kratom has been associated with numerous adverse health effects, including but not limited to:

- Nausea, vomiting, and constipation
- Respiratory depression
- Seizures
- Hallucinations and psychosis
- Liver damage
- Cardiovascular issues

The Centers for Disease Control and Prevention (CDC) and the FDA have reported multiple cases of kratom-related deaths, often involving the combination of kratom with other substances, but also in cases of kratom use alone. These adverse outcomes underscore the substance's potential to cause significant harm.

Supporting Data
Several studies and reports substantiate the need for kratom's classification as a Schedule I substance:
- The FDA has issued warnings about the safety risks associated with kratom, citing concerns over its opioid-like effects and the potential for abuse and dependency.
- The Drug Enforcement Administration (DEA) has identified kratom as a drug of concern, noting its abuse potential and the rising number of reports involving kratom misuse.
- A comprehensive review published in the Journal of Addiction Medicine outlines the pharmacology, toxicology, and adverse effects associated with kratom, highlighting the significant risks it poses to public health.

Impact on Affected Persons
Classifying kratom as a Schedule I substance would primarily impact:
- Individuals currently using kratom for self-medication
- Retailers and distributors of kratom products
- Healthcare providers who may encounter patients using kratom

The primary goal of this classification is to protect public health and safety by curbing the unregulated availability of a substance with high abuse potential and significant health risks.

Conclusion
In light of the substantial evidence demonstrating kratom's high potential for abuse, lack of accepted medical use, and severe public health risks, it is imperative to classify kratom as a Schedule I controlled substance. This action will help mitigate the risks associated with kratom use and align Washington's drug policy with public health and safety objectives.

Washington State Pharmacy Quality Assurance Commission

Strategic Plan 2024-2026

Approved: March 7, 2024

Document Version Control

#	Date	Description of changes	Owner
1.0	10/10/2023	First draft for ED and Deputy review	Keegan Curry
1.1	10/26/2023	ED and Deputy feedback on first draft	Marlee O'Neill Lindsay Trant-Sinclair
2.0	11/08/2023	Second draft discussed with ED and Deputy and forwarded to PQAC Strategic Planning Subcommittee	Keegan Curry
2.1	12/7/2023	Second draft for full commission review and feedback at Dec 15 business meeting	Marlee O'Neill Lindsay Trant-Sinclair
2.2	12/15/2023	Marked up second draft with commission's feedback	Keegan Curry
3.0	1/25/2024	Third draft for ED and Deputy review (current)	Keegan Curry
3.1	3/7/2024	Final draft presented to the commission, commission voted to approve and implement this version	Marlee O'Neill Lindsay Trant-Sinclair

Introduction

The Washington State Pharmacy Quality Assurance Commission (commission) developed this strategic plan to ensure its work aligns with its mission and vision. In addition, the strategic plan serves as a guide to staff and commissioners so that the breadth of work the commission and staff do is accessible and can be prioritized. The strategic plan will assist in identifying areas of success as well as areas needing improvement. It is a dynamic document that can be continually edited and updated.

Mission

The mission of the Washington State Pharmacy Quality Assurance Commission is to promote public health and safety by establishing the highest standards in the practice of pharmacy and to advocate for patient safety through effective communication with the public, profession, Department of Health, governor, and the legislature.

Vision

The Pharmacy Commission leads in creating a climate for the patient-focused practice of pharmacy as an integral part of an accessible, quality-based health system.

As a result, the citizens of Washington State:

- Are well informed about their medication therapy;
- Take responsibility and actively participate in their health outcomes;
- Utilize pharmacists and other healthcare providers appropriately; and
- Experience the highest level of health and wellness.

Strategic Goals

1.	2.	3.
Improve the commission's ability to impart change in legislation to promote the highest standards in the practice of pharmacy	Review and refine pharmacy rules to better reflect the current environment, technology, and innovation, and to promote health equity	Enhance the operational efficiency of the commission to ensure resources and business practices effectively support our regulatory and strategic priorities

Goal 1: Improve the commission's ability to impart change in legislation to promote the highest standards in the practice of pharmacy

Objective 1: Prepare commissioners and staff to pursue legislative change

a. Strategy: Establish short, mid, and long-range commission legislative priorities
b. Strategy: Increase coordination and communication around legislative priorities and proposals between the commission and DOH legislative staff
c. Strategy: Develop a legislative planning calendar to ensure commissioners are aware of key deadlines

Objective 2: Build a stronger relationship with DOH and HSQA legislative teams

a. Strategy: Invite DOH and HSQA legislative leadership to attend commission business meetings
b. Strategy: Hold regular check-ins for commission leadership and DOH/HSQA legislative teams, especially leading up to session
c. Strategy: Update the joint operating agreement (JOA) to enhance collaboration around the legislative process and priorities

Goal 2: Review and refine pharmacy rules to better reflect the current environment, technology, and innovation, and to promote health equity

Objective 3: Evaluate current and future rulemaking priorities and workload

a. Strategy: Maintain a list of rules in progress with actionable items for commissioners
b. Strategy: Establish a decision-making framework to prioritize current and future rulemaking
c. Strategy: Develop guiding principles for writing rule language to ensure that rules are equitable and forward-thinking
d. Strategy: Hold an annual rule making process training refresher for the commission

Objective 4: Advance health equity and mitigate health disparities

a. Strategy: Prioritize rulemaking for accessible labeling standards (CR-101)
b. Strategy: Continue rulemaking around mobile opioid treatment program (OTP) unit registration requirements (CR-101)

Objective 5: Optimize patient safety and ability to incorporate technology into practice

a. Strategy: Continue rulemaking for access to drugs stored outside of the pharmacy (CR-101)
b. Strategy: Continue rulemaking for prescription drug "White-Bagging" and "Brown-Bagging" transfer practices (CR-101)
c. Strategy: Research telepharmacy and consider rulemaking
d. Strategy: Implement revised USP chapters and Drug Supply Chain Security Act (DSCSA)
e. Strategy: Implement the Uniform Facilities Enforcement Framework (UFEF) once it passes the legislature (TBD 2024)

Objective 6: Improve access to care for patients by reconsidering the roles of pharmacy professionals

a. Strategy: Review pharmacy assistant's scope of practice and update rules if necessary

Objective 7: Contribute to pharmacy workforce development and retention

a. Strategy: Become more involved in L&I rulemaking
b. Strategy: Meet regularly with L&I and educate where needed on issues related to pharmacy
c. Strategy: Share well-being index and workplace initiatives from NABP with commissioners and stakeholders

Goal 3: Enhance the operational efficiency of the commission to ensure resources and business practices effectively support our regulatory and strategic priorities

Objective 8: Enhance the operational efficiency and effectiveness of the commission

a. Strategy: Establish realistic timeline expectations for tasks from the commission
b. Strategy: Create a task force to develop an orientation program for new commissioners

c. Strategy: Have a standard agenda item to review the strategic plan, monitor progress, revisit priorities and adjust as necessary
d. Strategy: Revise the “request for consideration form” on commission’s website for other boards, commissions, and programs who would like to present to the commission
e. Strategy: Update commission bylaws and improve the effectiveness of the committee structure