

## Pharmacy Quality Assurance Commission March 27, 2025 - Minutes

Convene: Hawkins DeFrance, Chair, called the meeting to order March 27, 2025, 9:03 a.m.

Commission Members:
Hawkins DeFrance, Chair
Ann Wolken, Vice Chair
Jerrie Allard
Stephanie Bardin
Teri Ferreira
Patrick Gallaher
Judy Guenther
Kenneth Kenyon
Matthew Ray
Craig Ritchie
Uyen Thorstensen (absent from 10:15am-10:38am)

Huey Yu

**Commission Members Absent:** William Hayes

Staff: Marlee O'Neill, Executive Director Si Bui, Inspector Supervisor Christopher Gerard, AAG Rachel Sahi Taifa "Nomi" Peaks Joshua Munroe Haleigh Mauldin Julia Katz Irina Harris Madison Washington Amy Robertson Scott Craig **Justin Sisney** Michael Kelly

## 1. Call to Order, Hawkins DeFrance, Chair

1.1. Meeting Agenda Approval – March 27, 2025

**MOTION**: Ann Wolken moved to amend the agenda to add that during lunch, Panel A of the commission will meet in closed session pursuant to RCW 42.30.140(1). Craig Ritchie, seconded. Motion carried, 12:0.

**MOTION**: Ken Kenyon moved to approve the amended agenda for the March 27, 2025, Business Meeting. Matthew Ray, seconded. Motion carried, 12:0.

**1.2.** Meeting Minutes Approval – February 6, 2025

**MOTION**: Ken Kenyon moved to amend the meeting minutes from February 6, 2025, with the corrections to the times he was absent from the meeting which was from 10:56 a.m. – 11:24 a.m. and 1:30 p.m. – 2:00 p.m. Matthew Ray, seconded. Motion carried, 12:0.

**MOTION**: Craig Ritchie moved to approve the amended business meeting minutes for February 6, 2025. Ken Kenyon, seconded. Motion carried, 12:0.

## 2. Consent Agenda

- 2.1. Correspondence
  - **2.1.1.** National Precursor Log Exchange Monthly Dashboard January and February
  - 2.1.2. Pharmaceutical Firms Application Report
- 2.2. Ancillary Utilization Plans Approval
  - 2.2.1. Arbor Health
  - 2.2.2. Columbia Valley Community Health
  - 2.2.3. Infusion Solutions
  - **2.2.4.** Paramount Pharmacy
  - 2.2.5. Peninsula Community Health Services
  - 2.2.6. Nordic Pharmacy
  - **2.2.7.** RX Pharmacy Long Term Care (LTC)
  - 2.2.8. Franciscan Hospice LTC
- 2.3. Pharmacy Technician Training Program Approval
  - 2.3.1. Cascade Specialty Pharmacy
  - **2.3.2.** Columbia Valley Community Health
  - 2.3.3. Family Health Centers Pharmacy
  - 2.3.4. Goldendale Pharmacy
  - **2.3.5.** Kuslers Compounding Pharmacy
  - 2.3.6. Moses Lake Community Health Center Pharmacy
  - 2.3.7. Nordic Pharmacy
  - 2.3.8. Rays Pharmacy
  - 2.3.9. RX Pharmacy LTC
  - 2.3.10. Sy Pharmacy and Wellness
  - 2.3.11. Tallmans Pharmacy
  - 2.3.12. Whitestone Pharmacy multiple locations
  - 2.3.13. Hoagland Pharmacy multiple locations

**MOTION**: Ann Wolken moved to approve the consent agenda except for items 2.2.2. Columbia Valley Community Health, 2.2.3. Infusion Solutions, and 2.2.4. Paramount Pharmacy. Teri Ferreira, seconded. Motion carried, 12:0.

- **2.4.** Regular Agenda Items Pulled from 2.1, 2.2, or 2.3. The commission discussed items removed from the consent agenda and placed them on the regular agenda for separate discussions.
- 2.2.2. Columbia Valley Community Health

**MOTION**: Teri Ferreira moved to approve item 2.2.2. Columbia Valley Community Health, contingent on striking "The Commission will be notified within 30 days of any changes to the program." Ken Kenyon, seconded. Motion carried, 12:0.

#### 2.2.3. Infusion Solutions

**MOTION:** Teri Ferreira moved to approve item 2.2.3. Infusion Solutions, contingent on changing the word "dispenses" to "hands out" in number 6 of the pharmacy technician AUP. Ken Kenyon, seconded. Motion carried, 12:0.

## **2.2.4.** Paramount Pharmacy

**MOTION**: Terri Ferreira moved to deny item 2.2.4. Paramount Pharmacy and to ask the entity to clarify letter K in the pharmacy assistant AUP and to have the entity change "dispenses" to "hands out" in letter G of both the pharmacy assistant and pharmacy technician AUP. Ann Wolken, seconded. Motion carried, 12:0.

#### 3. Presentations

# 3.1. Presentation on Healthcare Enforcement and Licensing Management System (HELMS)

Carly McCarthy, HELMS Communications Consultant, provided an update on HELMS.

Commissioners asked staff to send a GovDelivery advising licensees of a possible credentialing freeze around the end of April 2025.

#### 4. New Business

# 4.1. Resolutions for National Association of Boards of Pharmacy (NABP) Annual Meeting

**MOTION**: Ken Kenyon moved to support District 1's resolution on drugs lost in transit. Matthew Ray, seconded. Motion carried, 12:0.

**MOTION:** Ken Kenyon moved to support District 6's resolution (cosupported by Districts 7 and 8) on care coordination. Matthew Ray, seconded. Motion carried, 12:0.

**MOTION:** Ken Kenyon moved to support District 6's resolution (cosupported by Districts 7 and 8) on community health workers, but if additional information is presented at the NABP annual meeting, the commission gives the voting delegate permission not to support this resolution. Stephanie Bardin, seconded. Motion carried, 12:0.

**MOTION:** Ken Kenyon moved to support District 6's resolution (cosupported by Districts 7 and 8) on joint accountability for pharmacy compliance. Teri Ferreira, seconded. Motion carried, 12:0.

**MOTION:** Matthew Ray moved to support District 6's resolution (cosupported by Districts 7 and 8) on payer, processor, payment rates and methodologies impacting patient safety. Patrick Gallaher, seconded. Motion carried, 12:0.

**MOTION**: Patrick Gallaher moved to support District 6's resolution (cosupported by Districts 7 and 8) for national practice pharmacy standards. Ken Kenyon, seconded. Motion carried, 12:0.

**MOTION**: Ken Kenyon moved to support District 7's resolution (cosupported by Districts 6 and 8) that NABP partner with other pharmacy organizations and engage with the National Conference of State Legislatures, the Council of State Governments, and the National Governors Association and other policy organizations on current pharmacy issues. Stephanie Bardin, seconded. Motion carried, 12:0.

**MOTION**: Ken Kenyon moved to support District 8's resolution (cosupported by District 7) on the implementation of a standard of care regulatory model. Patrick Gallaher, seconded. Motion carried, 12:0.

**MOTION**: Ken Kenyon moved to support District 8's resolution (cosupported by Districts 7 and 8) on medications for opioid use disorder (MOUD). Patrick Gallaher, seconded. Motion carried, 12:0.

## 4.2. NABP 2025-2026 Committees and Task Forces

**MOTION**: Ken Kenyon moved to approve William Hayes' request to apply to participate on a NABP committee or task force of his choosing. Jerrie Allard, seconded. Motion carried, 11:0.

## 4.3. Frequently Asked Question on Sterile Hypodermic Syringes and Needles

**MOTION**: Ken Kenyon moved to adopt the FAQ with the edit of changing "can" to "may" and have staff research intramuscular needles as well as any other edits that may provide clarity and bring this back to the commission at a future business meeting. Ann Wolken, seconded. Motion carried, 12:0.

**MOTION:** Jerrie Allard moved to have staff bring the topic of RCW 70.115.050 to a future business meeting for discussion on whether the commission should seek a legislative change to this law. Patrick Gallaher, seconded. Motion carried, 12:0

### 5. Old Business

# 5.1. Rescinding of Policy Statement on Regulation of the Handling of Hazardous Drugs

**MOTION**: Matthew Ray moved to rescind the Policy Statement on the Regulation of the Handling of Hazardous Drugs, Number 60.1. Stephanie Bardin, seconded. Motion carried, 12:0.

## 6. Strategic Plan

## 6.1. Strategic Plan Implementation Update

Marlee O'Neill provided an update on the implementation of the strategic plan.

## 7. Rules and Legislation Updates

#### 7.1. Rules Tracker Update

**MOTION:** Ken Kenyon moved to rescind Policy Statement P008, Regulatory Standards Applicable to Manufacturers and Wholesalers of Dialysis Devices and Legend Drugs for Home Dialysis, on April 18, 2025, when the rulemaking on Manufacturers and Wholesalers of Dialysate and Dialysis Devices takes effect. Teri Ferreira, seconded. Motion carried, 12:0.

## 7.2. 2025 Weekly Legislative Update

Joshua Munroe reviewed bills pertinent to the commission.

# 7.3. Draft Comment on Department of Health Sunrise Review: Pharmacist Scope of Practice

**MOTION**: Hawkins DeFrance moved to delegate Ken Kenyon to provide comment at the public comment meeting on the Pharmacist Scope of Practice Sunrise Review. Judy Guenther, seconded. Motion carried, 12:0.

**MOTION**: Ann Wolken moved to approve the draft comment without edits. Teri Ferreira, seconded. Motion carried, 12:0.

#### 7.4. Rules Workshop: Utilization of Ancillary Personnel

**MOTION:** Patrick Gallaher moved to pause work on proposed new rule WAC 246-945-316 Pharmacy Technician Final Product Verification. Matthew Ray, seconded. Motion failed, 5:7.

**MOTION:** Teri Ferreira moved to task back proposed rule WAC 246-945-316 Pharmacy Technician Final Product Verification to staff to review data and comments received and bring another iteration of the rule to a future business meeting. Stephanie Bardin, seconded. Motion carried, 10:1:1.

## 7.5. Rules Workshop: Alternate Distribution Models

**MOTION:** Matthew Ray moved to approve the draft rule language as presented and direct staff to file a CR-102 on Alternate Distribution Models. Judy Guenther, seconded. Motion carried, 12:0.

## 7.6. Rules Workshop: Pharmacy Inspection Requirements for Modifications or Remodels

**MOTION**: Matthew Ray moved to approve the draft rule language as presented and direct staff to file a CR-102 on Pharmacy Inspection Requirements for Modifications or Remodels. Patrick Gallaher, seconded. Motion carried, 12:0.

## 8. Open Forum

No public comments were received.

## 9. Commission Member Reports

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

Hawkins DeFrance provided a reminder that the Nonresident Pharmacy Directive Task Force will meet from 1-2pm PST on Tuesday, April 29, 2025.

Hawkins DeFrance shared that Bonnie Bush has stepped down from her role as a commissioner and thanked Bonnie for her years of service and work on the commission.

Patrick Gallaher asked staff if there was a way for the commission to pay for a subscription to United States Pharmacopeia-National Formulary (USP-NF) Online for the commissioners.

Patrick Gallaher expressed concern about tariffs and the impact that might have on drugs.

Patrick Gallaher shared that the FDA no longer requires prescribers, pharmacies, and patients to participate in the REMS program for Clozapine and wants to ensure pharmacists are aware of the changes.

## 10. Staff Reports

#### 10.1. Executive Director – Marlee O'Neill

 Marlee shared that she attended Hawkins' and Patrick's senate confirmation hearings, which was the same day Jessica Todorovich, Interim Secretary for DOH, introduced herself to the Senate Health and Long-Term Care Committee.

- On February 19-20, 2025, Marlee participated in NABP's Interstate Privilege Workgroup meeting looking at ways to ensure licensure portability.
- At the OHP All Staff meeting last week, Lindsay Trant-Sinclair and Danielle Lee were recognized for their five years of state service.
- Continuing to work on commissioner recruitment.
- Additional resolution for the NABP annual meeting from the NABP Executive Committee about examining the use of the TOEFL-iBT as a requirement for FPGEC certification

**MOTION:** Hawkins DeFrance moved to support the NABP Executive Committee's resolution to evaluate the use of the TOEFL-iBT as a requirement for FPGEC certification. Ken Kenyon, seconded. Motion carried, 12:0.

### 10.2. Pharmacist Supervisor – Si Bui

- Marlee and Si presented to the Southwest Washington Pharmacy Association and, along with Lindsay and Nomi, presented at WSPA's New Drugs New Law.
- Reminded everyone that self-inspections must be completed during the month of March.

## 10.3. Assistant Attorney General - Christopher Gerard

 Christopher attended one of the FDA's Town Halls related to DSCSA implementation. Information was presented that indicated numerous trading partners were having success in the continued implementation of DSCSA requirements.

### 11. Summary of Meeting Action Items

- 1.2 Meeting Minutes Approval Staff will update and finalize the minutes to include the times Ken Kenyon was missing and post them on the commission's website.
- 2. Consent Agenda Staff will relay the decisions to the Office of Customer Service.
- 3.1 Presentation on Healthcare Enforcement and Licensing Management System (HELMS) Staff will send a GovDelivery letting licensees know about a likely credentialing freeze at the end of April.
- 4.1 Resolutions for National Association of Boards of Pharmacy (NABP)
   Annual Meeting Staff will provide Hawkins and Ann with the commission's decision on the resolutions ahead of the NABP Annual Meeting.
- 4.2 NABP 2025-2026 Committees and Task Forces Staff will let William
  Hayes know that he can apply to whichever committee or task force he
  chooses.

- policy statement to a future business meeting. Staff will bring RCW 70.115.050 to a future business meeting for a determination on whether the commission should seek a legislative change to this law.
- 5.1 Rescinding of Policy Statement on Regulation of the Handling of Hazardous Drugs Staff will rescind the policy statement and remove it from the web.
- 7.1 Rules Tracker Update Staff will rescind, and remove from the web, Policy Statement P008 on April 18, 2025, when the rulemaking on Manufacturers and Wholesalers of Dialysate and Dialysis Devices takes effect.
- 7.3 Draft Comment on Department of Health Sunrise Review: Pharmacist Scope of Practice Staff will submit the draft comment by April 1, 2025, and register Ken Kenyon to provide comment at the public comment meeting. Staff will also prepare talking points for Ken.
- 7.4 Rules Workshop: Utilization of Ancillary Personnel Staff will continue to refine this rule considering comments received and will continue to research this topic.
- **7.5 Rules Workshop: Alternate Distribution Models** Staff will file the CR-
- 7.6 Rules Workshop: Pharmacy Inspection Requirements for Modifications or Remodels Staff will file the CR-102.
- 9.1 Open Discussion Related to Items or Issues Relevant to Commission Business/Pharmacy Practice – Staff will send another GovDelivery message regarding the Nonresident Pharmacy Directive Task Force meeting. Staff will mail Bonnie Bush her certificate of service on the commission. Staff will research the cost of getting all commissioners a subscription to USP.

**4:17 p.m.** Business Meeting Adjourned

## 2.1.1. National Precursor Log Exchange Dashboard - March and April

## MONTHLY PROGRAM ADMINISTRATOR'S DASHBOARD - March

2 Logins - 0 Searches - 0 Report Queries - 20 Active Watches - 0 Active Watch Hits					
NEW USERS THIS MONTH					
New Users = 0	TOP USAGE AGENCIES	TOP AGENCIES BY ACTIVE WATCHES			
Total Accounts = 146	TOP USERS BY USAGE	1. ICE - King County (44)			
Active Users = 2					

## TRANSACTION SUMMARY STATISTICS (2025)

	JAN	FEB	MAR	TOTAL
PURCHASES	89,628	80,911	87,508	258,047
BLOCKS	3,655	3,072	3,863	10,590
GRAMS SOLD	160,732	146,822	170,909	478,463
BOXES SOLD	90,806	81,950	88,573	261,329
GRAMS BLOCKED	8,590	7,591	9,882	26,063
BOXES BLOCKED	3,867	3,270	4,064	11,201
AVG GRAMS PER BOX BLOCKED	2.22	2.32	2.43	2.32

## PHARMACY PARTICIPATION STATISTICS (Mar 2025)

Enabled Pharmacies	960
Pharmacies Submitting a Transaction	863
Pharmacies Logging in Without a Transaction	6
Inactive Pharmacies	91
Pharmacy Participation for Mar	90.52%

## MONTHLY PROGRAM ADMINISTRATOR'S DASHBOARD - April

## 10 Logins - 2 Searches - 16 Report Queries - 23 Active Watches - 1 Active Watch Hits

NEW USERS THIS MONTH

New Users = 1

Total Accounts = 147

Active Users = 2

TOP USAGE AGENCIES

1. DEA-Seattle Office

TOP USERS BY USAGE

1. Jalen Bynum, DEA-Seattle Office

TOP AGENCIES BY ACTIVE WATCHES

1. ICE - King County (44)

2. DEA-Seattle Office (2)

## TRANSACTION SUMMARY STATISTICS (2025)

	JAN	FEB	MAR	APR	TOTAL
PURCHASES	89,628	80,911	87,508	85,233	343,280
BLOCKS	3,655	3,072	3,863	3,942	14,532
GRAMS SOLD	160,732	146,822	170,909	173,669	652,132
BOXES SOLD	90,806	81,950	88,573	86,493	347,822
GRAMS BLOCKED	8,590	7,591	9,882	10,262	36,325
BOXES BLOCKED	3,867	3,270	4,064	4,156	15,357
AVG GRAMS PER BOX BLOCKED	2.22	2.32	2.43	2.47	2.36

## PHARMACY PARTICIPATION STATISTICS (Apr 2025)

Enabled Pharmacies	961
Pharmacies Submitting a Transaction	863
Pharmacies Logging in Without a Transaction	0
Inactive Pharmacies	98

Pharmacy Participation for Apr	89.8%

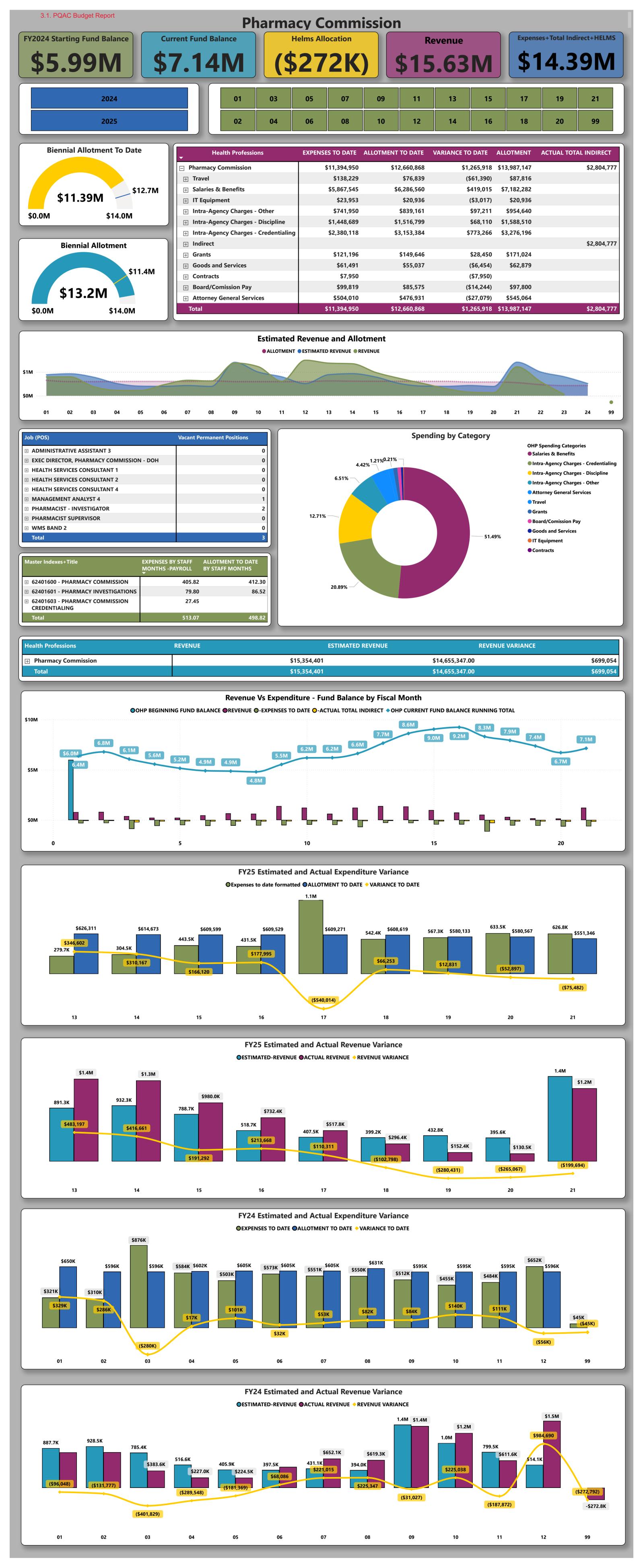
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## 2026 PQAC Business Meetings

Date	Time	Location
February 5, 2026	9:00 am – 4:00 pm	Zoom and TBD
April 2, 2026	9:00 am – 4:00 pm	Zoom and TBD
May 28, 2026	9:00 am – 4:00 pm	Zoom and TBD
July 23, 2026	9:00 am – 4:00 pm	Zoom and TBD
September 17, 2026	9:00 am – 4:00 pm	Zoom and TBD
November 5, 2026	9:00 am – 4:00 pm	Zoom and TBD
December 17, 2026	9:00 am – 1:00 pm	Zoom and TBD

All of the meetings are 8 weeks apart except for November and December's business meetings which are 7 and 6 weeks apart, respectively. We'd like to avoid the week of the Veteran's Day holiday (i.e. 11/12/26) as it would mean staff are not working the day before the commission meeting. Additionally, we thought it would be considerate to include a short December meeting, note the shorter timeframe, in order for AUPs, TTPs, study plans, etc. to avoid a long wait.



# Department of Health Pharmacy Quality Assurance Commission

## **Notice of Adoption – Policy Statement**

Title: Commission Approved Examinations and WAC 246-945-165 and 246-945-205 | P014

**Issuing Entity: Pharmacy Quality Assurance Commission** 

Subject Matter: Approved Examinations for Pharmacy Technicians and Pharmacists

Effective Date: December 12, 2024

Contact Person: Marlee B. O'Neill, Executive Director

wspqac@doh.wa.gov

OFFICE OF THE CODE REVISER STATE OF WASHINGTON FILED

DATE: February 06, 2025

TIME: 1:02 PM

WSR 25-05-009

## **Washington State Department of Health**

## **Pharmacy Quality Assurance Commission**

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## **Policy Statement**

Title:	Commission Approved Examinations and WAC 246-945-165 and 246-945-205	
Policy Statement Number:	P014	
References:	RCW 18.64.005; RCW 18.64.080; RCW 18.64A.020; WAC 246-945-165; WAC 246-945-205;	
Contact:	Contact: Marlee B. O'Neill, Executive Director	
Phone:	e: (360) 236-4946	
Email:	wspqac@doh.wa.gov	
Effective Date:	December 12, 2024	
Supersedes:	N/A	
Approved By:	Hawkins DeFrance, PharmD Pharmacy Quality Assurance Commission Chair	

This policy statement establishes the commission-approved examinations for pharmacy technicians and pharmacists described in WAC 246-945-165 and 246-945-205.

The Pharmacy Quality Assurance Commission (commission) requires in WAC 246-945-205(3)(c) an individual applying for a pharmacy technician license to "pass a national certification examination approved by the commission". The national certification examinations approved by the commission are the Pharmacy Technician Certification Board's (PTCB) Pharmacy Technician Certification Exam (PTCE) and the National Healthcareer Association's (NHA) Exam for the Certification of Pharmacy Technicians (ExCPT).

Pharmacist applicants must also satisfactorily pass exams approved by the commission. WAC 246-945-165(1) requires an individual applying for a pharmacist license to "take and pass a pharmacy licensure examination and jurisprudence examination approved by the commission". The commission-approved pharmacy licensure examination is the North American Pharmacist Licensure Examination (NAPLEX). The commission-approved jurisprudence examination is the Multistate Pharmacy Jurisprudence Examination (MPJE). Both exams are administered through the National Association of Boards of Pharmacy (NABP).

Washington State Department of Health Revised: 11/25/2024



STATE OF WASHINGTON

## DEPARTMENT OF HEALTH

Olympia, Washington 98504

## NOTICE OF ADOPTION OF A POLICY STATEMENT

**Title of Policy Statement:** Accreditation of Colleges of Pharmacy | Policy Number P007

**Issuing Entity:** Pharmacy Quality Assurance Commission

**Subject Matter:** This policy clarifies that the Pharmacy Quality Assurance Commission accredits schools and colleges of pharmacy accredited by the Accreditation Council for Pharmacy Education (ACPE) by meeting the 2016 ACPE standards.

Effective Date: May 29, 2020

**Contact Person**: Lindsay Trant

Rules & Legislative Consultant,

Pharmacy Quality Assurance Commission, Washington State Department of Health

360-236-2932

PharmacyRules@doh.wa.gov

OFFICE OF THE CODE REVISER STATE OF WASHINGTON FILED

DATE: February 01, 2021

TIME: 2:48 PM

WSR 21-04-120

# Department of Health Pharmacy Quality Assurance Commission

# **Policy Statement**

Revised - 10/18/11

Title:	Accreditation of Colleges of Pharmacy	Number: P007
References:	RCW 18.64.050(c)	
Contact:	Lauren Lyles-Stolz, PharmD, Executive Director	
Phone:	(360) 236-4946	
Email:	wspqac@doh.wa.gov	
Effective Date:	May 29, 2020 (reaffirmed)	
Supersedes:	July 20, 2006 (PQAC update July 2013)	
Approved By:	Tim Lynch, PharmD, MS, FABC, FASHP, Pharmacy Quality Assurance Commission Chair	

The Pharmacy Quality Assurance Commission (commission) accredits schools and colleges of pharmacy accredited by the Accreditation Council for Pharmacy Education (ACPE) by meeting the 2016 ACPE standards. This accreditation by the commission meets the requirement of RCW 18.64.080(1)(c).

The commission will review its policy on the accreditation of ACPE at any time there are changes to the accreditation standards.

## **2025** Legislative Session Bill Tracker

## **Link to Washington State Legislature Bill Information 2025**

Monday, January 13 – First day of session Friday, February 21 – Policy committee cutoff Friday, February 28 – Fiscal committee cutoff Wednesday, March 12 – House of origin cutoff Wednesday, April 2 – Policy committee cutoff (opposite house)
Tuesday, April 8 – Fiscal committee cutoff (opposite house)
Wednesday, April 16 – Opposite house cutoff
Sunday, April 27 – Sine die: Last day allowed for regular session under state constitution

TVW - <a href="http://www.tvw.org/">http://www.tvw.org/</a>

Focus Bills	Focus Bills					
Bill # /Companion	Short Title	Brief Description	Committee Action (subject to change)			
SHB 1009	Membership of the Pharmacy Quality Assurance Commission	SHB 1009 amends RCW 18.64.001 pertaining to individual eligibility to apply for a seat on the Pharmacy Quality Assurance Commission (commission). The bill changes one of the seats reserved only for a licensed pharmacist to allow for a public member who "may be an owner, officer, or operator of a pharmacy, but may not be licensed as a pharmacist or pharmacy technician" to also apply for the seat.  The substitute bill adds an additional seat to the commission reserved for a pharmacy technician.	HB 1009 Sponsor(s): Representatives Low, Ramel, and Eslick  Third Reading/Floor Vote (Senate): 3/26/2025, passed through chamber by majority vote (49/0/0/0). Concurrence (House): 4/19/2025, Senate amendments accepted and bill passed final passage (95/0/0/3). Signatures: House Speaker (4/22); Senate President (4/23). Delivered to Governor: 4/24/2025			
SHB 1186	Prepackaged medication distribution	RCW 70.41.480(3) creates restrictions for a practitioner or registered nurse to distribute prepackaged emergency medications to patients upon discharge from an emergency department. Effective January 1, 2025, these restrictions include no more than a 48-hour supply that can be dispensed to a patient except when:  • community or hospital pharmacy services will not be available within 48 hours; or	SHB 1186 Sponsor(s): Representatives Parshley, Rule, Low, Reed, Ramel, Macri, Obras, Farivar, Doglio, Fosse, Ormsby, Salahuddin, Bernbaum, and Hill			

Focus Bills	ocus Bills				
Bill # /Companion	Short Title	Brief Description	Committee Action (subject to change)		
		<ul> <li>human immunodeficiency virus postexposure prophylaxis (HIV PEP) drugs or therapies are required.</li> <li>SHB 1186 amends these exceptions to include when anti-infective drugs or therapies are required or when drugs are packaged directly by the manufacturer in quantities larger than 48 hours (that cannot be altered down to a 48-hour supply), in addition to the above list.</li> <li>The bill also amends RCW 18.64.450 to allow health care entities (HCEs) to dispense and deliver legend drugs and controlled substances beyond the 72-hour limit in the following situations:         <ul> <li>Community or hospital outpatient pharmacy services will not be available within 72 hours;</li> <li>Anti-infectives or human immunodeficiency virus postexposure prophylaxis (HIV PEP) drugs; or</li> <li>Drugs or therapies packaged directly by the manufacturer for a period longer than a 72-hour period.</li> </ul> </li> <li>The striker amendment, 1186-S AMS HLTC S2527.1, adds language clarifying that the amended statutes do not permit hospital emergency departments or HCEs to bill separately from the bundled payment for drugs or therapies dispensed pursuant to those sections.</li> </ul>	Third Reading/Floor Vote: 4/16/2025, passed through chamber by majority vote (49/0/0).  Concurrence (House): 4/21/2025, Senate amendments accepted and bill passed final passage (97/0/0/1).  Signatures: House Speaker (4/22); Senate President (4/23).  Delivered to Governor: 4/23/2025		
SHB 1720	Types of medication assistance in community-based care settings	This bill amends the definition of "medication assistance" in RCW 69.41.010(15) for the purpose of expanding the actions available to nonpractitioners providing medication assistance to individuals residing in a community-based or in-home care setting. Nonpractitioners would be allowed to set up diabetic devices for self-administration and would also be allowed to hand injectable medications to an individual for self-administration.	SHB 1720 Sponsor(s): Representatives Schmick and Low  Third Reading/Floor Vote (Senate): 3/26/2025, passed through chamber by majority vote (49/0/0). Signatures: House Speaker (3/31); Senate President (3/31). Delivered to Governor: 4/2/2025 Governor Signed: 4/7/2025 (effective date: 7/27/2025)		

Focus Bills					
Bill # /Companion	Short Title	Brief Description	Committee Action (subject to change)		
	Health care entity registry	This bill seeks to "develop a plan and recommendations with the goal of establishing a complete and interactive registry." The department is tasked with developing the plan and recommendations with consultation from the HCA, OIC, governor's office, and OFM, as well as input from stakeholders.  The plan and recommendations must identify health care entities that would be required to provide regular reports to the registry. These include but are not limited to "licensed and unlicensed facilities, providers, provider groups, systems, carriers, and health care benefit managers." The department must also identify information that must be reported and fees to be charged to registering entities.	(subject to change)  E2SHB 1686 Sponsor(s): Representatives Bronoske, Fosse, Reed, Scott, Nance, Hill, and Macri  Third Reading/Floor Vote (Senate): 4/14/2025, passed through chamber by majority vote (49/0/0/0). Signatures: House Speaker (4/15); Senate President (4/16) Delivered to Governor: 4/17/2025 Governor Signed: 4/22/2025 (effective)		
		The department must consider opportunities to streamline reporting and information sharing, strategies to "fully understand and monitor" the business structure of health care entities in Washington, including elements such as ownership, funding, and affiliations with external organizations. The department would need to provide an update to the legislature by December 31, 2027 and a final report by December 31, 2028. This bill is null and void if specific funding for the development of recommendations and a plan is not provided by June 30, 2025.	date: 7/27/2025)		

Agency Request Bills			
Bill # /Companion	Short Title	Brief Description	Committee Action (subject to change)
2SHB 1422	Modifying the drug take-back program	This bill amends various statutes in chapters 69.48 and 43.131 RCW relating to the drug take-back (i.e. safe medication return program) program. The bill expands the number of required elements that a program operator must submit via report to the department and updates the evaluation and approval standards for such reports.  The bill further updates enforcement mechanisms if a program operator is out of compliance and allows the department to set an annual operating fee. A new section is also created in chapter 69.48 RCW to further outline the duties and responsibilities of a drug take-back program operator.	HB 1422 Sponsor(s): Representatives Peterson, Davis, Thai, Ormsby, Hill, Macri, and Timmons  Executive Session (Ways & Means): 4/25/2025, passed through committee with a DO PASS recommendation. Third Reading/Floor Vote (Senate): 4/26/2025, passed through chamber by majority vote (46/0/0/2). Signatures: House Speaker (4/27); Senate President (4/27). Delivered to Governor: 4/27/2025
SB 5051	Consolidating regulatory authority for nursing assistants	This bill amends sections in chapters 18.79 and 18.88A RCW to consolidate the regulatory authority of nursing assistants under the Board of Nursing's jurisdiction.	SB 5051 Sponsor(s): Senators Bateman, Riccelli, Cleveland, Nobles, and Wellman  Third Reading/Floor Vote (House): 3/26/2025, passed through chamber by majority vote (98/0/0/0). Signatures: Senate President (3/28); House Speaker (3/31). Delivered to Governor: 4/1/2025 Signed by Governor: 4/4/2025 (effective date: 7/1/2026)

Agency Request Bills			
Bill # /Companion	Short Title	Brief Description	Committee Action (subject to change)
	WIC program staff exemptions for hematological screening tests	This bill adds a subsection to RCW 18.360.090 to include hematological tests and evaluations conducted by persons working at a special supplemental nutrition program for women, infants, and children (WIC) as exempt from other prohibitions or restrictions in chapter 18.360 RCW.	SB 5244 Sponsor(s): Senators Riccelli, Bateman, Nobles, Saldaña, and C. Wilson  Second Reading (Rules): 3/25/2025 Third Reading/Floor Vote: 3/27/2025; passed through chamber by majority vote (93/0/0/5). Signatures: Senate President (3/28); House Speaker (3/31). Delivered to Governor: 4/1/2025 Signed by Governor: 4/4/2025 (effective date: 7/27/2025)

Additional Bills to Watch		
Bill # /Companion	Short Title	Committee Action (subject to change)
SHB 1209	Transfer of sodium nitrite	HB 1209 Sponsor(s): Representatives Mena, Walen, Reed, Ryu, Berry, Alvarado, Macri, Farivar, Doglio, Pollet, Ormsby, Salahuddin, and Hill  Third Reading/Floor Vote (Senate): 3/26/2025, passed through chamber by majority vote (49/0/0/0).  Signatures: House Speaker (3/31); Senate President (3/31).  Delivered to Governor: 4/2/2025  Signed by Governor: 4/7/2025 (effective date: 4/7/2025)

Dead/dormant Bills (relevant if needed to pass the budget)			
Bill # /Companion	Short Title	Bill Summary	
ESSB 5594	Biosimilar and interchangeable biological product access	ESSB 5594 Sponsor(s): Senators Harris, Cleveland, Hasegawa, and Shewmake  Public Hearing (Health Care & Wellness): 3/26/2025 Executive Session (Health Care & Wellness): 4/1/2025, no action taken.  Missed cutoff: 4/2/2025, Opposite house policy committee	
HB 1725	Biosimilar product access	HB 1725 Sponsor(s): Representatives Thai, Shavers, Parshley, Duerr, and Macri  First Reading (House): 1/30/2025, referred to Health Care & Wellness Committee  Public Hearing (Health Care & Wellness): 2/12/2025  Missed cutoff: 2/28/2025, House-of-origin policy committee	
HB 1520	Pharmacists' scope of practice	HB 1520 Sponsor(s): Representatives Thai, Reed, Simmons, and Macri  First Reading (House): 1/22/2025, referred to Health Care & Wellness Committee.  Missed cutoff: 2/28/2025, House-of-origin policy committee	
SB 5513	Pharmacists' scope of practice	SB 5513 Sponsor(s): Senators Slatter, Chapman, Nobles, and Short  First Reading (Senate): 1/27/2025, referred to Health & Long-Term Care Committee.  Missed cutoff: 2/28/2025, House-of-origin policy committee	
HB 2072	Opioid impact fee on opioid manufacturers	HB 2072 Sponsor(s): Representative Davis  Introduced: 4/8/2025, referred to Appropriations committee.  Missed cutoff: 4/16/2025, Opposite house floor vote	

Dead/dormant Bills (relevant if needed to pass the budget)			
Bill # /Companion	Short Title	Bill Summary	
SSB 5019	Prepackaged medication distribution	SSB 5019 Sponsor(s): Senators Chapman, Bateman, Christian, Dhingra, Harris, Riccelli, Saldaña, Slatter, and Wellman Public Hearing (Health & Long-Term Care): 1/23/2025 Executive Session (Health & Long-Term Care): 2/6/2025, substitute bill adopted and passed through committee with a DO PASS recommendation; passed to Rules Committee for second reading (2/7). Missed cutoff: 3/12/2025, House-of-origin floor vote	
SSB 5112	Psychologist prescriptive authority certification	SSB 5112 Sponsor(s): Senators Bateman, Harris, Shewmake, Trudeau, Conway, Nobles, Riccelli, C. Wilson, Robinson, and Hasegawa  Executive Session (Health & Long-Term Care): 2/21/2025; substitute bill adopted and passed through policy committee with a DO PASS recommendation. Passed to Rules Committee for second reading. Second Reading (Rules): 3/7/2025  Missed cutoff: 3/12/2025, House-of-origin floor vote	
SB 5228 Agency request legislation	Governor's interagency coordinating council on health disparities updates	SB 5228 Sponsor(s): Senators Riccelli, Hasegawa, Conway, Nobles, and C. Wilson  First Reading (Senate): 1/13/2025, referred to Health & Long-Term Care Committee.  Public Hearing (Health & Long-Term Care): 1/24/2025  Missed cutoff: 2/28/2025, House-of-origin policy committee	
2SSB 5387	Corporate practice of health care (formerly medicine)	2SSB 5387 Sponsor(s): Senators Robinson, Hasegawa, Liias, Nobles, Riccelli, Stanford, and Valdez  Public Hearing (Ways & Means): 2/26/2025  Executive Session (Ways & Means): 2/28/2025, 2 <sup>nd</sup> substitute bill introduced, adopted, and passed through committee with a DO PASS recommendation. Passed to Rules Committee for second reading.  Missed cutoff: 3/12/2025, House-of-origin floor vote	

Dead/dormant Bills (relevant if needed to pass the budget)			
Bill # /Companion	Short Title	Bill Summary	
HB 1849	Unexpired prescription drug donation program eligibility	HB 1849 Sponsor(s): Representatives Graham, Griffey, Stuebe, Keaton, Volz, Eslick, and Obras  First Reading (House): 2/5/2025, referred to Health Care & Wellness Committee.  Missed cutoff: 2/28/2025, House-of-origin policy committee	
HB 1850	Replacement of continuous glucose monitoring equipment	HB 1850 Sponsor(s): Representatives Graham, Burnett, Griffey, Volz, Eslick, and Obras First Reading (House): 2/5/2025, referred to Health Care & Wellness Committee. Missed cutoff: 2/28/2025, House-of-origin policy committee	
HB 1638	Good Faith Pain Act	HB 1638 Sponsor(s): Representative Caldier  First Reading (House): 1/28/2025, referred to Health Care & Wellness Committee.  Missed cutoff: 2/28/2025, House-of-origin policy committee	
<u>SB 5201</u>	Access to psychedelic substances	SB 5201 Sponsor(s): Senators Salomon, Nobles, Bateman, Trudeau, Lovelett, Frame, Chapman, Hasegawa, Wellman, Holy, King, Saldaña, Schoesler, and J. Wilson  Public Hearing (Labor & Commerce): 2/18/2025, substitute version heard in committee  Executive Session (Labor & Commerce): 2/21/2025  Missed cutoff: 2/28/2025, House-of-origin policy committee	
<u>HB 1433</u>	Access to psychedelic substances	HB 1433 Sponsor(s): Representatives Macri, Couture, Ramel, Griffey, Lekanoff, Ormsby, Nance, Walen, Cortes, Fosse, Doglio, Reeves, Goodman, McEntire, Bernbaum, Waters, Street, Pollet, Gregerson, Rude, Simmons, Berry, Fitzgibbon, Parshley, Peterson, Reed, Farivar, Tharinger, and Hill  First Reading (House): 1/20/2025, referred to Health Care & Wellness Committee.  Public Hearing (Health Care & Wellness): 2/5/2025  Missed cutoff: 2/28/2025, House-of-origin policy committee	

Dead/dormant Bills (relevant if needed to pass the budget)			
Bill # /Companion	Short Title	Bill Summary	
SB 5713	Chemical abortion	SB 5713 Sponsor(s): Senator Fortunato  First Reading (Senate): 2/10/2025, referred to Law & Justice Committee.  Missed cutoff: 2/28/2025, House-of-origin policy committee	
HB 1124	Psychologist prescriptive authority certification	HB 1124 Sponsor(s): Representatives Simmons, Macri, Senn, Stonier, Ormsby, Tharinger, Kloba, Duerr, Ryu, Morgan, Reed, Callan, Obras, Doglio, Ortiz-Self, Goodman, Reeves, and Hill	
		Pre-filed: 12/23/2024 First Reading (House): 1/13/2025, referred to Health Care & Wellness Committee. Missed cutoff: 2/28/2025, House-of-origin policy committee	
HB 1034	Nonopioid drugs for the treatment of pain	HB 1034 Sponsor(s): Representatives Ortiz-Self, Peterson, Simmons, Kloba, Ormsby, Lekanoff, Donaghy, and Hill  First Reading (House): 1/13/2025, referred to Health Care & Wellness Committee.  Public Hearing (Health Care & Wellness): 1/21/2025  Missed cutoff: 2/28/2025, House-of-origin policy committee	
SB 5242	Interactive screening program for behavioral health service access	SB 5242 Sponsor(s): Senators Orwall, Harris, Hasegawa, Krishnadasan, Nobles, Shewmake, Valdez, and C. Wilson  First Reading (Senate): 1/14/2025, referred to Health & Long-Term Care Committee.  Public Hearing (Health & Long-Term Care): 1/28/2025  Missed cutoff: 2/28/2025, House-of-origin policy committee	
HB 1675	Corporate practice of medicine	HB 1675 Sponsor(s): Representatives Thai and Macri  First Reading (House): 1/28/2025, referred to Health Care & Wellness Committee.  Missed cutoff: 2/28/2025, House-of-origin policy committee	

Dead/dormant Bills (relevant if needed to pass the budget)			
Bill # /Companion	Short Title	Bill Summary	
SB 5452	Licensing psychiatric pharmacists as agency-affiliated counselors	SB 5452 Sponsor(s): Senators Slatter and Nobles  First Reading (Senate): 1/23/2025, referred to Health & Long-Term Care Committee.  Missed cutoff: 2/28/2025, House-of-origin policy committee	
SB 5765	Board-certified psychiatric pharmacists	SB 5765 Sponsor(s): Senator Slatter  First Reading (Senate): 2/18/2025, referred to Health & Long-Term Care Committee.  Missed cutoff: 2/28/2025, House-of-origin policy committee	
SB 5178	Transfer of sodium nitrite	SB 5178 Sponsor(s): Senators Trudeau, Harris, Frame, Hasegawa, Liias, Nobles, Orwall, Pedersen, Salomon, and Shewmake  Second Reading (Rules): 2/19/2025 Third Reading/Floor Vote (Senate): 3/3/2025, passed through chamber by majority vote (49/0/0/0)  First Reading (House): 3/5/2025, referred to Consumer Protection & Business Committee.  Missed cutoff: 2/28/2025, House-of-origin policy committee	

#### CERTIFICATION OF ENROLLMENT

## SUBSTITUTE HOUSE BILL 1720

Chapter 26, Laws of 2025

69th Legislature 2025 Regular Session

COMMUNITY-BASED CARE SETTINGS-MEDICATION ASSISTANCE

EFFECTIVE DATE: July 27, 2025

Passed by the House February 20, 2025 Yeas 97 Nays 0

### LAURIE JINKINS

# Speaker of the House of Representatives

President of the Senate

Passed by the Senate March 26, 2025 Yeas 49 Nays 0

#### DENNY HECK

Approved April 7, 2025 11:29 AM

#### CERTIFICATE

I, Bernard Dean, Chief Clerk of the House of Representatives of the State of Washington, do hereby certify that the attached is **SUBSTITUTE HOUSE BILL 1720** as passed by the House of Representatives and the Senate on the dates hereon set forth.

#### BERNARD DEAN

Chief Clerk

FILED

April 7, 2025

BOB FERGUSON

Governor of the State of Washington

Secretary of State State of Washington

#### SUBSTITUTE HOUSE BILL 1720

Passed Legislature - 2025 Regular Session

State of Washington 69th Legislature 2025 Regular Session

By House Health Care & Wellness (originally sponsored by Representatives Schmick and Low)

READ FIRST TIME 02/14/25.

- 1 AN ACT Relating to expanding the types of medication assistance
- 2 that may be provided to residents of community-based care settings;
- 3 and amending RCW 69.41.010.
- 4 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:
- 5 **Sec. 1.** RCW 69.41.010 and 2024 c 102 s 1 are each amended to 6 read as follows:
- As used in this chapter, the following terms have the meanings indicated unless the context clearly requires otherwise:
- 9 (1) "Administer" means the direct application of a legend drug 10 whether by injection, inhalation, ingestion, or any other means, to 11 the body of a patient or research subject by:
  - (a) A practitioner; or

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- 13 (b) The patient or research subject at the direction of the 14 practitioner.
- 15 (2) "Commission" means the pharmacy quality assurance commission.
- 16 (3) "Community-based care settings" include: Community 17 residential programs for persons with developmental disabilities,
- 18 certified by the department of social and health services under
- 19 chapter 71A.12 RCW; adult family homes licensed under chapter 70.128
- 20 RCW; and assisted living facilities licensed under chapter 18.20 RCW.

p. 1 SHB 1720.SL

- 1 Community-based care settings do not include acute care or skilled 2 nursing facilities.
  - (4) "Deliver" or "delivery" means the actual, constructive, or attempted transfer from one person to another of a legend drug, whether or not there is an agency relationship.
    - (5) "Department" means the department of health.
  - (6) "Dispense" means the interpretation of a prescription or order for a legend drug and, pursuant to that prescription or order, the proper selection, measuring, compounding, labeling, or packaging necessary to prepare that prescription or order for delivery.
    - (7) "Dispenser" means a practitioner who dispenses.
  - (8) "Distribute" means to deliver other than by administering or dispensing a legend drug.
    - (9) "Distributor" means a person who distributes.
    - (10) "Drug" means:

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- 16 (a) Substances recognized as drugs in the official United States
  17 pharmacopoeia, official homeopathic pharmacopoeia of the United
  18 States, or official national formulary, or any supplement to any of
  19 them;
- 20 (b) Substances intended for use in the diagnosis, cure, 21 mitigation, treatment, or prevention of disease in human beings or 22 animals;
  - (c) Substances (other than food, minerals or vitamins) intended to affect the structure or any function of the body of human beings or animals; and
  - (d) Substances intended for use as a component of any article specified in (a), (b), or (c) of this subsection. It does not include devices or their components, parts, or accessories.
  - (11) "Electronic communication of prescription information" means the transmission of a prescription or refill authorization for a drug of a practitioner using computer systems. The term does not include a prescription or refill authorization transmitted verbally by telephone nor a facsimile manually signed by the practitioner.
  - (12) "In-home care settings" include an individual's place of temporary and permanent residence, but does not include acute care or skilled nursing facilities, and does not include community-based care settings.
- 38 (13) "Legend drugs" means any drugs which are required by state 39 law or regulation of the pharmacy quality assurance commission to be

p. 2 SHB 1720.SL

- dispensed on prescription only or are restricted to use by practitioners only.
- (14) "Legible prescription" means a prescription or medication order issued by a practitioner that is capable of being read and understood by the pharmacist filling the prescription or the nurse or other practitioner implementing the medication order. A prescription must be hand printed, typewritten, or electronically generated.
- (15) "Medication assistance" means assistance rendered by a nonpractitioner to an individual residing in a community-based care setting or in-home care setting to facilitate the individual's selfadministration of a legend drug or <a href="legend drugs">legend drugs</a>, <a href="which may include a">which may include a</a> controlled substance or controlled substances. It includes reminding or coaching the individual, handing the medication container to the individual, opening the individual's medication container, using an enabler, or placing the medication in the individual's hand, and such other means of medication assistance as defined by rule adopted by the department. A nonpractitioner may help in the preparation of legend drugs ((or)), including controlled substances, for selfadministration where a practitioner has determined and communicated orally or by written direction that such medication preparation assistance is necessary and appropriate. Medication assistance shall not include assistance with intravenous medications or injectable medications, except ((prefilled insulin syringes)) setting up diabetic devices for self-administration or handing injectable medications to an individual for self-administration.
- (16) "Person" means individual, corporation, government or governmental subdivision or agency, business trust, estate, trust, partnership or association, or any other legal entity.
  - (17) "Practitioner" means:

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(a) A physician under chapter 18.71 RCW, an osteopathic physician or an osteopathic physician and surgeon under chapter 18.57 RCW, a dentist under chapter 18.32 RCW, a podiatric physician and surgeon under chapter 18.22 RCW, an acupuncturist or acupuncture and Eastern medicine practitioner to the extent authorized under chapter 18.06 RCW and the rules adopted under RCW 18.06.010(1)(m), a veterinarian under chapter 18.92 RCW, a registered nurse, advanced practice registered nurse ((practitioner)), or licensed practical nurse under chapter 18.79 RCW, an optometrist under chapter 18.53 RCW who is certified by the optometry board under RCW 18.53.010, a physician assistant under chapter 18.71A RCW, a naturopath licensed under

p. 3 SHB 1720.SL

chapter 18.36A RCW, a licensed athletic trainer to the extent authorized under chapter 18.250 RCW, a pharmacist under chapter 18.64 RCW, when acting under the required supervision of a dentist licensed under chapter 18.32 RCW, a dental hygienist licensed under chapter 18.29 RCW, a licensed dental therapist to the extent authorized under chapter 18.265 RCW, or a licensed midwife to the extent authorized under chapter 18.50 RCW;

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- (b) A pharmacy, hospital, or other institution licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or to administer a legend drug in the course of professional practice or research in this state; and
- (c) A physician licensed to practice medicine and surgery or a physician licensed to practice osteopathic medicine and surgery in any state, or province of Canada, which shares a common border with the state of Washington.
- 16 (18) "Secretary" means the secretary of health or the secretary's designee.

Passed by the House February 20, 2025. Passed by the Senate March 26, 2025. Approved by the Governor April 7, 2025. Filed in Office of Secretary of State April 7, 2025.

--- END ---

# Wholesaler Suspicious Orders and Zero Reports Language Draft Approved at March 2024 Business Meeting

WAC 246-945-585 Wholesaler—Suspicious orders and due diligence. (1) For the purposes of this section and WAC 246-945-590, "suspicious order" means an order(s) of a controlled substance or drug of concern that, relative to the customer's order history and the history of similarly situated customer, may include:

- (a) Unusual size;
- (b) Substantial deviation from a normal pattern; or
- (c) Unusual frequency.
- (2) Wholesalers shall design and operate a system to identify and report suspicious orders to the commission that resulted in customer termination.
- (a) Suspicious orders that resulted in customer termination shall be submitted electronically to the commission within five business days of the customer termination, and must include, but not necessarily be limited to:
  - (i) Customer name;
  - (ii) Customer address;

- (iii) Customer DEA registration number, if applicable;
- (iv) Washington state license number(s);
- (v) Order date;
- (vi) Drug name;
- (vii) NDC number;
- (viii) Quantity ordered; and
- (ix) The factual basis for the identification of the order as suspicious and customer termination.
- (b) Wholesalers may apply to the commission for an exemption from the reporting requirements if they do not distribute controlled substances or drugs of concern. (3) Except as provided in subsection (4) of this section, a wholesaler shall conduct due diligence on customers ordering or seeking to order controlled substances or drugs of concern, and establish the normal and expected transactions conducted by those customers, in order to identify and prevent the sale of controlled substances or drugs of concern that are likely to be diverted from legitimate channels. Such due diligence measures shall include, but are not limited to, the following, which shall be conducted prior to an initial sale and as necessary:

- (a) Questionnaires and affirmative steps by the wholesaler to confirm the accuracy and validity of the information provided, it shall be considered illegal for a customer to provide false or misleading information;
- (b) For a customer who is a prescriber, confirmation of prescriber type, specialty practice area, and if the prescriber personally furnishes controlled substances or drugs of concern, the quantity furnished;
  - (c) Review of drug utilization reports; and
  - (d) Obtaining and conducting a review of the following:
  - (i) Methods of payment accepted and in what ratios;
- (ii) The ratio of controlled versus noncontrolled
  prescriptions and overall sales;
- (iii) Orders for controlled substances or drugs of concern from other wholesalers U.S. DEA's Automation of Reports and Consolidated Orders System (ARCOS); and
- (iv) The ratio of out-of-state patients served compared to in-state patients.
- (4) A wholesaler receiving a request for an initial sale of a controlled substance or drugs of concern may conduct the sale

before complying with subsection (3) of this section if all of the following apply:

- (a) The sale is to a new customer;
- (b) The wholesaler documents that the order is to meet an emergent need;
- (c) The wholesaler completes the requirements of subsection(3) of this section no later than sixty business days from the date of sale.
- (5) Any potential customer that the wholesaler refuses to onboard due to a possible diversion risk shall be electronically reported to the commission within five business days of the wholesaler's refusal to onboard. Such reports shall include:
  - (a) Name of potential customer;
  - (b) Address of potential customer;
  - (c) Potential customer's DEA number, if applicable;
  - (d) Washington state license number(s); and
- (e) A detailed explanation of why the wholesaler identified the potential customer as a possible diversion risk.

(6) All information submitted under this section must be readable and accessible to the commission.

[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, § 246-945-585, filed 6/1/20, effective 7/1/20.]

# Washington State Department of HEALTH

## **Commission SBAR Communication**

Agenda Item/Title: Rulemaking Authorization: Timeframe for Reporting Disciplinary Action in WAC 246-945-231

Date SBAR Communication Prepared: May 8, 2025

Reviewer: Julia Katz

Action Information Follow-up Report only

**Situation:** Program staff request the commission consider authorizing rulemaking on <u>WAC 246-945-231 Reporting Disciplinary Action</u> to add a timeframe for pharmaceutical firms to report disciplinary action to the commission.

**Background:** The Pharmacy Quality Assurance Commission (commission) adopted WAC 246-945-231 as part of <u>WSR 25-07-097</u> which took effect on April 18, 2025. WAC 246-945-231 does not include timeframe guidance.

**Assessment:** WSR 25-07-097 established WAC 246-945-231 to require pharmaceutical firms to report disciplinary action to the commission and amended WAC 246-945-592 to establish reporting requirements for permanently closing manufacturers and wholesalers.

Staff often get questions from pharmaceutical firm licensees pertaining to the timeframe of reporting disciplinary action to the commission. Having a timeframe in rule will provide guidance and clarity to pharmaceutical firm licensees.

**Recommendation:** Program staff recommend the commission authorize rulemaking on WAC 246-945-231 to add a timeframe for pharmaceutical firms to report disciplinary action to the commission.

Follow-up Action: If approved, commission staff will initiate rulemaking by filing a CR-101.