

Pharmacy Quality Assurance Commission February 6, 2025 - Minutes

Convene: Hawkins DeFrance, Chair, called the meeting to order February 6, 2025, 9:21 a.m.

Commission Members:

Hawkins DeFrance, Chair
Ann Wolken, Vice Chair
Jerrie Allard
Stephanie Bardin
Teri Ferreira
Patrick Gallaher
Judy Guenther
William Hayes
Kenneth Kenyon (absent: 10:56-
11:24 a.m. and 1:30-2 p.m.)
Matthew Ray
Craig Ritchie
Uyen Thorstensen
Huey Yu

Commission Members Absent:

Bonnie Bush

Staff:

Marlee O’Neill, Executive Director
Lindsay Trant-Sinclair, Deputy 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
Crystal Phipps
Justin Sisney
Michael Kelly

1. Call to Order, Hawkins DeFrance, Chair

1.1. Meeting Agenda Approval – February 6, 2025

MOTION: Craig Ritchie moved to approve the agenda without revisions. Jerrie Allard, seconded. Motion carried, 13:0.

1.2. Meeting Minutes Approval – December 12, 2024

MOTION: Craig Ritchie moved to approve the business meeting minutes without revisions for December 12, 2024. William Hayes, seconded. Motion carried, 13:0.

2. Consent Agenda

2.1. Correspondence

2.1.1. National Precursor Log Exchange Monthly Dashboard – December

2.1.2. Pharmaceutical Firms Application Report

2.2. Ancillary Utilization Plans Approval

2.2.1. Cascade Specialty Pharmacy LLC

2.2.2. Davenport Pharmacy

- 2.2.3. East Valley Pharmacy
- 2.3. Pharmacy Technician Training Program Approval
 - 2.3.1. Aequita Pharmacy
 - 2.3.2. Ostrom Enterprises, Inc. - multiple locations
 - 2.3.3. ReadyMeds Pharmacy
 - 2.3.4. Ritzville Drug Company
 - 2.3.5. Seamar

MOTION: Craig Ritchie moved to approve the consent agenda. Jerrie Allard, seconded. Motion carried, 13:0.

- 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.

No items were pulled from the consent agenda.

3. **Rulemaking for Dialysate and Dialysis Device Manufacturers and Wholesalers in Home Dialysis Programs**

- 3.1. **PUBLIC HEARING** The commission held a public hearing on proposed amendments to WAC 246-945-090, 246-945-091, 246-945-092, and 246-945-093 that were included as part of a supplemental notice filed on November 22, 2024 (WSR 24-24-028). The rulemaking was initiated in response to statutory changes made by Substitute House Bill (SHB) 1675 (chapter 23, Laws of 2022) that exempted a manufacturer of certain dialysate and dialysis devices used by home dialysis patients or a manufacturer’s agent from certain provisions of Chapters 18.64 and 69.41 RCW.

The public rules hearing began at 9:30am and was closed at 9:34am. The commission received one written comment during the public comment period and no oral comments during the public hearing.

- 3.2. **Approval of Comment Responses and Authorization to file CR-103P (Dialysate and Dialysis Device Manufacturers and Wholesalers)**

The commission discussed the comments received in writing during the public comment period and approved responses to those comments. There were no comments received during the public hearing for the Commission to respond to.

MOTION: Ann Wolken moved to approve the responses to the comments received, adopt the language as proposed in WSR 24-24-028, without edits, and authorize staff to file a CR-103P. Huey Yu, seconded. Motion carried, 13:0.

4. **Rulemaking for Permanent Facility Closure Requirements**

- 4.1. **PUBLIC HEARING** The commission held a public hearing on proposed amendments to WAC 246-945-480 and the addition of two new sections of WAC (WAC 246-945-231 and WAC 246-945-592) that were included in a CR-102 filed on December 11, 2024 (WSR 25-

01-067). The proposed rules would require additional reporting requirements provided to customers and the commission in advance of permanent closures, would add WAC 246-945-231 to consolidate the reporting requirement for pharmaceutical firms to report disciplinary action to the commission, and would add WAC 246-945-592 to establish reporting requirements for permanently closing manufacturers and wholesalers.

The public rules hearing began at 10:30am and was closed at 10:33am. There were no comments received during the public comment period and no oral comments during the public hearing.

4.2. Approval of Comment Responses and Authorization to File CR-103 (Permanent Facility Closure Requirements)

The Commission did not approve any response to comments because there were no written comments received during the public comment period and no oral comments received during the public rules hearing.

MOTION: William Hayes moved to adopt the as proposed in WSR 25-01-067, without edits, and authorize staff to file a CR-103P. Craig Ritchie, seconded. Motion carried, 13:0.

5. Presentations

5.1. Health Systems Quality Assurance (HSQA) Leadership Team

Sasha De Leon, Assistant Secretary for HSQA, Harold Wright Jr., Office Director (Acting) for the Office of Health Professions, Melissa Green, Deputy Director (Acting) for the Office of Health Professions, and Zach Patnode, QA/CQI Administrator for OHP provided updates on HSQA and OHP.

5.2. Presentation on an Act Relating to Health Care Benefit Managers E2SSB 5213

The Washington State Pharmacy Association (WSPA) CEO, Jenny Arnold, presented on WSPA's legislative efforts during the 2024 legislative session on E2SSB 5213 concerning health care benefit managers.

6. Old Business

6.1. Review Self-Inspection Worksheets

The Commission reviewed and discussed edits to self-inspection worksheets. Teri requested striking the following from question #6 of the USP Sterile Compounding Addendum, "for initial and ongoing training that is completed and documented."

MOTION: Craig Ritchie moved to approve the self-inspection worksheets with edit to question #6 of the USP Sterile Compounding Addendum proposed by Teri Ferreira. Jerrie Allard, seconded. Approved 12:0.

6.2. DSCSA Guidance Document and Self-Inspection Worksheet

MOTION: Craig Ritchie moved to approve the DSCSA assessing compliance guidance document and self-inspection worksheet, which is optional for licensees to complete in 2025, with formatting changes discussed and directed staff to post the two documents to the commission’s website and notify licensees through GovDelivery. Uyen Thorstensen, seconded. Approved 13:0.

7. Panel Review – Study Plan (Panel C)

MOTION: Jerrie Allard moved to delegate the study plan to Panel C (Uyen Thorstensen, Jerrie Allard, William Hayes, Ann Woken, and Ken Kenyon). Craig Ritchie, seconded. Approved 13:0.

7.1. PHRM.PH.61447824

MOTION: Uyen Thorstensen moved to approve the study plan. William Hayes, seconded. Approved 4:0.

8. Strategic Plan

8.1. Implementation Plan Update

Staff proposed the following edits to the strategic plan implementation plan.

- Objective 4: Advance health equity and mitigate health disparities
 - Add action items for staff to begin to develop an implementation plan for the accessible labeling rules
- Objective 6: Improve access to care for patients by reconsidering the roles of pharmacy professionals
 - Add an action item to reflect that staff have been continuing to draft rules related to pharmacy ancillary personnel to include putting the Ancillary Utilization Plans and the Administration of Drugs and Devices guidance document into rule.

MOTION: Craig Ritchie moved to approve revisions to the strategic plan implementation plan with the proposed edits. Huey Yu, seconded. Approved 13:0.

9. Rules and Legislation Updates

9.1. Listening Session: Considering Scheduling Kratom

The commission heard public comments from individuals on its rulemaking related to considering placing kratom in the list of Schedule I controlled substances.

MOTION: Matthew Ray moved to withdraw the CR-101 and asked staff to talk to the Department of Health about how to approach kratom regulation via legislation. Craig Ritchie, seconded. Approved 13:0.

9.2. DOH Sunrise Review: Pharmacist Scope of Practice

MOTION: Craig Ritchie moved to have staff prepare a draft comment in response to the pharmacist scope of practice sunrise review and bring the draft to the March 27, 2025, business meeting. Huey Yu, seconded. Approved 13:0.

9.3. Rules Workshop: Uniform Facilities Enforcement Framework

MOTION: Jerrie Allard moved to authorize staff to file a CR-102. Hawkins DeFrance, seconded. Approved 13:0.

9.4. Rules Workshop: Pharmacy Ancillary Personnel

Staff will send the draft rule out via GovDelivery for comments prior to the March 27, 2025, meeting.

9.5. Legislative Task Force Update

MOTION: Ken Kenyon moved to add reviewing RCW 18.64.600 and license of location to the list of possible legislative changes. Craig Ritchie, seconded. Approved 13:0.

MOTION: Ken Kenyon moved to approve the draft list as amended and tasked staff with determining the next steps. Craig Ritchie, seconded. Approved 13:0.

10. Open Forum

No public comments.

11. Commission Member Reports

11.1. Budget Report Out

Ashley May presented the commission budget report.

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

Hawkins DeFrance presented Uyen Thorstensen with a certificate of recognition for her service on the commission. Hawkins DeFrance also presented Jerrie Allard with a plaque for her service as Vice Chair on the commission.

12. Staff Reports

12.1. Executive Director – Marlee O’Neill

- Marlee advised the need to re-convene the Nonresident Pharmacy Directive Task Force and requested the same task for members as last year for continuity.

MOTION: Jerrie Allard moved to appoint Hawkins DeFrance as chair of the Nonresident Pharmacy Directive Task Force (Task Force), and appoint Uyen Thorstensen, Ann

Wolken, and Huey Yu as members of the Task Force. Judy Guenther, seconded.
Approved 13:0.

- The NABP Annual Meeting is in May 2025. The commission needs to select a voting delegate and an alternate. Hawkins DeFrance and Ann Wolken are attending the meeting.

MOTION: Jerrie Allard moved for Hawkins DeFrance to be the voting delegate and Ann Wolken to be the alternate voting delegate at the 2025 NABP Annual Meeting. Ken Kenyon, seconded. Approved 13:0.

12.2. Deputy Director – Lindsay Trant-Sinclair

- Lindsay advised staff has completed the new commissioner recruitment packet and interviews. The packet is being prepared to be sent to the governor’s office.
- Reminded staff and commission that there is credentialing freeze from Friday, February 14 from 5 p.m. to the morning of Wednesday, February 19 for system upgrades.

12.3. Pharmacist Supervisor – Si Bui

- Staff hired a new inspector, Michael P. Kelly.
- Staff are still searching for an inspector for Area 5.
- Si asked for continuing feedback on the self-inspection worksheets.

12.4. Assistant Attorney General – Christopher Gerard

- Nothing to report

13. Summary of Meeting Action Items

- **1.2 Meeting Minutes** – Staff will finalize the minutes and post them on the commission’s website.
- **2. Consent Agenda** – Staff will follow up on approvals.
- **3.2 Approval of Comment Responses and Authorization to file CR-103P (Dialysate and Dialysis Device Manufacturers and Wholesalers)** – Staff will file a CR-103P.
- **4 Rulemaking for Permanent Facility Closure Requirements** – Staff will file a CR-103P.
- **6.1 Self-Inspection Worksheet** – Staff will make the edits discussed by the commission and post the self-inspection worksheets on the website and send them out via GovDelivery and include language on how to submit comments.
- **6.2 DSCSA Guidance Document** – Staff will make the formatting corrections and post the document to the website and via GovDelivery noting that the worksheet is optional for 2025.
- **7.1 Panel Review – Study Plan (Panel C)** – Staff will convey the decision to credentialing.
- **8.1 Implementation Plan Update** – Staff will finalize the edits presented today and upload to Box.com.
- **9.1 Listening Session: Considering Scheduling Kratom** – Staff will withdraw the CR-101 and talk to the department about ways the commission can communicate to the legislature potential regulations on kratom.

- **9.2 DOH Sunrise Review: Pharmacist Scope of Practice** – Staff will draft comments in line with the discussion today and bring them back to the March 2025 business meeting for approval.
- **9.3 Rules Workshop: Uniform Facilities Enforcement Framework** – Staff will file a CR-102.
- **9.4 Rules Workshop: Pharmacy Ancillary Personnel** – Staff will distribute the draft rule language to interested parties through GovDelivery and bring back comments received at a future business meeting.
- **9.5 Legislative Task Force Update** – Staff will work with the department to determine the best way to move the commission’s legislative ideas forward.
- **12.1 Staff Reports** – Staff will work on scheduling the Nonresident pharmacy Directive Task Force meeting and communicate the voting delegates to NABP.

3:56 p.m. Business Meeting Adjourned