

Pharmacy Quality Assurance Commission October 10, 2024 - Minutes

Convene: Hawkins DeFrance, Chair, called the meeting to order October 10, 2024, 9:01 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
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 Tiginyanu
Madison Washington
Amy Robertson

1. Call to Order Hawkins DeFrance, Chair

1.1. Meeting Agenda Approval – October 10, 2024

MOTION: Craig Ritchie moved to approve the business meeting agenda for October 10, 2024. Ken Kenyon, seconded. Motion carried, 13:0.

1.2. Meeting Minutes Approval – August 22, 2024

MOTION: Craig Ritchie moved to approve the business meeting minutes for August 22, 2024. William Hayes, seconded. Motion carried, 13:0.

1.3. Meeting Minutes Approval – October 4, 2024

MOTION: Craig Ritchie moved to approve the special meeting minutes for October 4, 2024. Uyen Thorstensen, seconded. Motion carried, 13:0.

2. Consent Agenda

2.1. Correspondence

- 2.1.1. National Precursor Log Exchange Monthly Dashboard – August and September
 - 2.1.2. Pharmaceutical Firms Application Report
- 2.2. Ancillary Utilization Plans Approval
 - 2.2.1. Evergreen Pharmaceutical LLC
 - 2.2.2. Kalama Pharmacy
 - 2.2.3. Safeway Pharmacy
 - 2.2.4. Safeway Pharmacy 4405
 - 2.2.5. Sea Mar Community Health Centers
- 2.3. Pharmacy Technician Training Program Approval
 - 2.3.1. Harbor Drug and Gifts
 - 2.3.2. Raymond Pharmacy
 - 2.3.3. Chinook Pharmacy, Inc.
 - 2.3.4. Coram CVS Specialty Infusion Services

MOTION: Craig Ritchie moved to approve the consent agenda except for items, 2.2.1 Evergreen Pharmaceutical, LLC and 2.2.3 Safeway Pharmacy. William Hayes, seconded. Motion carried, 12:0, with 1 recusal.

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

- 2.2.1. Evergreen Pharmaceutical, LLC

MOTION: William Hayes moved to approve item 2.2.1 Evergreen Pharmaceutical, LLC. Craig Ritchie, seconded. Motion carried, 13:0.

- 2.2.3. Safeway Pharmacy

MOTION: Hawkins DeFrance moved to approve item 2.2.3 Safeway Pharmacy contingent on changing “check and print pending TIPs ...” to “access and print pending TIPs ...” on the pharmacy assistant AUP. Ann Wolken, seconded. Motion carried, 12:0, with 1 recusal.

3. Rulemaking for Drugs Stored Outside of the Pharmacy

- 3.1. **PUBLIC HEARING** The commission held a public rule hearing on the rulemaking to propose amending WAC 246-945-455 which currently limits access to drugs stored outside of the pharmacy to only licensed health care professionals and may disrupt supply chain management in health care facilities.

The public rule hearing began at 9:30am and was closed at 9:31am. The commission received no comments during the public hearing.

- 3.2. Approval of Comment Responses and Authorization to File CR-103 (Drugs Stored Outside of the Pharmacy).

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

MOTION: Ken Kenyon moved to approve the draft responses to the comments received, adopt the language for WAC 246-945-455 without edits, and authorized staff to file a CR-103P. Matthew Ray, seconded. Motion carried, 13:0.

4. Presentations

4.1. Washington State Health Workforce Data

Renee Fullerton, Health Workforce Council Policy Analyst for the Workforce Training and Education Coordinating Board; Susan Skillman, Senior Deputy Director of the UW Center for Health Workforce Studies; and Benjamin Stubbs, Program Director of the Sentinel Network for the UW Center for Health Workforce Studies presented on Washington State Health Workforce Data.

5. Rulemaking for Pharmacy Intern Credentials

5.1. PUBLIC HEARING

The commission held a public rules hearing on the rulemaking and proposed to amend a section of rule, WAC 246-945-155 and 246-945-156 related to pharmacy intern registration requirements. Specifically, the commission proposed amending WAC 246-945-155 to grant additional renewals to pharmacy interns to address concerns raised by interested parties. Additionally, the commission proposed amending WAC 246-945-156 to extend the duration of pharmacy intern temporary practice permits to 180 days to comply with Second Substitute House Bill (2SHB) 1009 (chapter 165, Laws of 2023).

The public rules hearing began at 10:30am and was closed at 10:33am. The commission received no comments during the public hearing.

5.2. Approval of Comment Responses and Authorization to file CR-103 (Pharmacy Intern Credentials).

No written or oral comments were received.

MOTION: Ken Kenyon moved to approve WAC 246-945-155 and WAC 246-945-156 without edits and authorized staff to file a CR-103P. Huey Yu, seconded. Motion carried, 13:0.

MOTION: Ann Wolken moved to rescind policy statements numbered P012: Extension Process for Pharmacy Intern Renewal Limitation and P011 Temporary Practice Permits for Military Spouse Pharmacy Interns once the rule is effective. Ken Kenyon, seconded. Motion carried, 13:0.

6. Rules Update

6.1. Utilization of Pharmacy Ancillary Personnel

Haleigh Mauldin provided an overview of research done for the rulemaking project on pharmacy ancillary personnel and requested direction from the commission to inform the draft rule language. The commission discussed what it wants to see in the draft rule language.

MOTION: Judy Guenther moved to not include a provision allowing pharmacy assistants to pull medications in the draft rule language. Patrick Gallaher, seconded. Motion carried, 6:3:3.

7. Presentations

7.1. Updates from the Deans of Washington Colleges of Pharmacy

The Dean of the University of Washington School of Pharmacy, Jayanth Panyam, PhD, and the Dean of the Washington State University College of Pharmacy and Pharmaceutical Sciences, Mark Leid, PhD, presented updates on their respective programs.

8. Panel Review – Study Plan (Panel A)

MOTION: Craig Ritchie moved to delegate study plans to Panel A: Patrick Gallaher, Judy Guenther, Teri Ferreira, and Huey Yu. Ann Wolken, seconded. Motion carried, 13:0.

8.1. PHRM.PH.60917547

MOTION: Patrick Gallaher moved to approve the study plan. Teri Ferreira, seconded. Motion carried, 4:0.

8.2. PHRM.PH.61306447

MOTION: Patrick Gallaher moved to approve the study plan. Teri Ferreira, seconded. Motion carried, 4:0.

8.3. PHRM.PH.61314899

MOTION: Patrick Gallaher moved to approve the study plan. Teri Ferreira, seconded. Motion carried, 4:0.

9. Strategic Plan

9.1. Guiding Principles

MOTION: Jerrie Allard moved to approve the guiding principles for rule writing without edits. Ann Wolken, seconded. Motion carried, 13:0.

9.2. New Commissioner Orientation Program Draft

MOTION: Ann Wolken moved to approve the New Commissioner Orientation Handbook with edits to the travel guidelines. Ken Kenyon, seconded. Motion carried, 13:0.

9.3. Strategic Plan Implementation Update

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

10. Rulemaking for Prescription Transfers

10.1. PUBLIC HEARING

The commission held a public rule hearing on the rulemaking to propose amending a section of rule, WAC 246-945-345 and adding a new section WAC 246-945-346 in chapter 246-945 WAC to establish the expectations of pharmacies related to noncontrolled and controlled substance prescription transfers upon patient request.

The public rules hearing began at 1:30pm and was closed at 1:37pm. The commission received two oral comments during the public hearing.

10.2. Approval of Comment Responses and Authorization to file CR-103 (Prescription Transfers).

MOTION: Ken Kenyon moved to approve the responses to the oral comments, adopt WAC 246-945-345 and WAC 246-945-346 without edits, and authorized staff to file a CR-103P. Craig Ritchie, seconded. Motion carried, 13:0.

11. Rules Update

11.1. Prescription Transfer Policy Statement and CMS Final Rule Update

MOTION: Ken Kenyon moved to approve the draft policy statement without edits and to publish it once the rule is effective. Craig Ritchie, seconded. Motion carried, 13:0.

11.2. Rules Workshop: Uniform Facility Enforcement Framework for Pharmacy

The commission discussed the draft fining severity matrix and what metric to use to define operation size for its facility types. Staff will continue to refine the matrix based on the discussion.

11.3. Supplemental Rules Workshop: Dialysate and Dialysis Devices Manufacturers and Wholesalers

MOTION: Craig Ritchie moved to approve the draft supplemental rule language without revisions and to include the language in the supplemental CR-102 package. Teri Ferreira, seconded. Motion carried, 13:0.

11.4. Rulemaking Authorization: DSCSA

MOTION: William Hayes moved to authorize staff to file a CR-102 Exception Rules Proposal for the purpose of incorporating federal language around the DSCSA. Ken Kenyon, seconded. Motion carried, 13:0.

12. Open Forum

No public comments.

13. Commission Member Reports

13.1. Budget Report Out

Ashley May presented the commission budget report.

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

William Hayes participated in NABP's task force to review institutional pharmacy and compounding model rules in September. The recommended rules will be presented at NABP's 2025 Annual Meeting.

The commission recognized Teri Ferriera and Ken Kenyon for their leadership as prior chairs of the commission.

Teri Ferriera noted how productive it was to have so many commissioners attend the meeting in person.

14. Staff Reports

14.1. Executive Director – Marlee O’Neill

- Attended the Executive Officer Forum in September at NABP headquarters in Illinois.

- Will be attending the NABP District 6, 7, & 8 Meeting in New Mexico in November 2024 with Ann Wolken.
- Marlee and Lindsay will be meeting Amanda Hunt, HSQA Workforce and Employee Engagement Manager, about possible commission and staff team building activities.
- Marlee, Nomi, and Si will be presenting at the WSPA annual meeting on November 9, 2024.
- Reviewed RCW 69.41.095 and the standing order on Naloxone and that a practitioner can lawfully prescribe, dispense, distribute, and deliver naloxone to any natural person and a pharmacist may dispense it pursuant to the standing order, prescription, CDTA, or protocol.

14.2. Deputy Director – Lindsay Trant-Sinclair

- Nothing to report

14.3. Pharmacist Supervisor – Si Bui

- Still working to fill two inspector vacancies in Areas 2 and 5.
- The inspection team has made significant progress with getting all facilities caught up on routine inspections. Expect to be caught up by the second quarter of 2025.
- Continuing to build positive relationships with our licensees.
- Most common violations documented in 2024 is not properly documenting allergies and chronic conditions and expired medications remaining on shelves.

14.4. Assistant Attorney General – Christopher Gerard

- Nothing to report

14.5. Pharmacist Consultant – Taifa “Nomi” Peaks

- Nothing to report

14.6. Rules and Legislative Consultant – Joshua Munroe

- Nothing to report

15. Summary of Meeting Action Items

- **1.2 Meeting Minutes** – Staff will finalize the minutes and post them on the commission’s website.
- **1.3 Meeting Minutes** – Staff will finalize the minutes and post them on the commission’s website.
- **2. Consent Agenda** – Staff will convey the decisions to the applicants and the Office of Customer Service.
- **3.2 Rulemaking for Drugs Stored Outside the Pharmacy** – Staff will file a CR-103p.
- **5.2 Rulemaking on Pharmacy Intern Credentials** – Staff will file a CR-103p and will rescind the two policy statements on interns when the rule becomes effective.
- **6.1 Rulemaking on the Utilization of Pharmacy Ancillary Personnel** – Staff will begin a draft of the rule with the guidance the commission provided.

- **7.1 Updates from the Deans of Washington Colleges of Pharmacy** – Staff will invite the deans back to a future business meeting.
- **8. Panel Reviews** – Staff will convey the decisions to the credentialing team.
- **9.1 Guiding Principles** – Staff will finalize the principles and provide them to the commissioners.
- **9.2 New Commission Orientation Program** – Staff will look into the reimbursement table and finalize the new commissioner handbook and provide it to the commission via Box.com.
- **10. Rulemaking on Prescription Transfers** – Staff will file a CR-103p.
- **11.1 Prescription Transfer Policy Statement** – Staff will file the policy statement with the code revisor to correspond with the finalization of the rule project.
- **11.2 Rules Workshop: Uniform Facility Enforcement Framework for Pharmacy** – Staff will make edits to the matrices discussed with the commission and bring back an updated draft at a future commission meeting.
- **11.3 Supplemental Rules Workshop: Dialysate and Dialysis Devices Manufacturers and Wholesalers** – Staff will use the rule language approved today to file a supplemental CR-102.
- **11.4 Rulemaking Authorization: DSCSA** – Staff will file a CR-102 exception rulemaking to incorporate the DSCSA by reference.

5:05pm Business Meeting Adjourned