

Pharmacy Quality Assurance Commission December 12, 2024 - Minutes

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

Commission Members:

Hawkins DeFrance, Chair
Ann Wolken, Vice Chair
Stephanie Bardin
Patrick Gallaher
Judy Guenther
William Hayes
Kenneth Kenyon
Craig Ritchie
Huey Yu

Commission Members

Absent:

Jerrie Allard
Bonnie Bush
Teri Ferreira
Matthew Ray
Uyen Thorstensen

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
Crystal Phipps
Scott Craig
Justin Sisney
Mariam Boulos

1. Call to Order Hawkins DeFrance, Chair

1.1. Meeting Agenda Approval – December 12, 2024

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

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

1.2. Meeting Minutes Approval – October 10, 2024

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

1.3. Meeting Minutes Approval – October 11, 2024

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

2. **Consent Agenda**

2.1. Correspondence

2.1.1. National Precursor Log Exchange Monthly Dashboard – October and November

2.1.2. Pharmaceutical Firms Application Report

2.2. Ancillary Utilization Plans Approval

2.2.1. Chinook Pharmacy

2.2.2. Evergreen Professional Center Pharmacy

2.2.3. Family Pharmacy

2.2.4. Prosser Memorial Hospital Pharmacy

2.2.5. Whidbey Health Community Pharmacy

2.3. Pharmacy Technician Training Program Approval

2.3.1. CityScript Pharmacy, LLC

2.3.3. Peninsula Community Health Services

2.3.4. QuickRX LLC (Brewster Pharmacy)

2.3.5. Skyline Hospital Pharmacy

2.3.6. Sumas Drug

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

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

2.3.3. Peninsula Community Health Services

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

3. **Rulemaking for Medication Assistance**

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

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

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

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

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

4. Presentations

4.1. Health Systems Quality Assurance (HSQA) Legislative Team

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

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

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

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

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

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

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

5. New Business

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

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

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

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

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

5.3. Update Signature Authority Delegation

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

6. Strategic Plan

6.1. Annual Review of Commission Bylaws

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

6.2. Strategic Plan Implementation Update

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

7. Rules Update

7.1. Refresher on the Rules Process and Rules Tracker Spreadsheet

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

7.2. Emergency Rule Refile Request for Medical Assistance

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

7.3. Overview of State Regulation of Kratom

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

7.4. Update on Permanent Facility Closure Requirements

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

7.5. Rules Workshop: Utilization of Ancillary Personnel

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

7.6. Rules Workshop: Uniform Facilities Enforcement Framework

This item was moved to the February 2025 business meeting.

7.7. Rules Workshop: Alternate Distribution Models

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

7.8. PQAC Bill Report

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

8. Open Forum

No public comments.

9. Commission Member Reports

9.1. Legislative Task Force Report Out

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

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

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

10. Staff Reports

10.1. Executive Director – Marlee O’Neill

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

10.2. Deputy Director – Lindsay Trant-Sinclair

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

10.3. Assistant Attorney General – Christopher Gerard

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

11. Summary of Meeting Action Items

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

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

5:03pm Business Meeting Adjourned