

STATE OF WASHINGTON Pharmacy Quality Assurance Commission

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Pharmacy Quality Assurance Commission Meeting December 14, 2023 – Minutes

Convene: Chair, Ken Kenyon called the meeting to order on December 14, 2023, 9:01 AM.

Commission Members:

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

Staff:

Shawna Fox, Office Director, Office of Health Professions
Marlee O'Neill, Executive Director
Lindsay Trant-Sinclair, Deputy Director
Christopher Gerard, Assistant Attorney General
Kseniya Efremova, Policy Analyst
Joshua Munroe, Legislative and Rules Consultant*
Taifa "Nomi" Peaks, Pharmacist Consultant
Haleigh Mauldin, Program Consultant
Si Bui, Pharmacy Inspector Supervisor
Julia Katz, Program Consultant
Keith Bond, Operations Manager
Irina Tiginyanu, Pharmacy Technician Consultant
Amy L Robertson, Communications Coordinator
and Program Support

*joined meeting at noon

1. Call to Order Action

Huey C. Yu, PharmD

1.1. Meeting Agenda Approval – December 14, 2023

MOTION: Craig Ritchie moved to approve the December 14, 2023, meeting agenda. William Hayes, second. Motion carries, 14:0.

1.2. Meeting Minutes Approval – October 19, 2023

MOTION: Craig Ritchie moved to approve the October 19, 2023, meeting minutes. William Hayes, second. Motion carries, 14:0.

1.3. Special Meeting Minutes Approval – November 13, 2023

MOTION: Craig Ritchie moved to approve the November 13, 2023, special meeting minutes. William Hayes, second. Motion carries, 14:0.

- 2. Consent Agenda Items listed under the consent agenda are considered routine and necessary commission matters and will be approved by a single motion of the commission without separate discussion. If separate discussion is desired, that item will be removed from the consent agenda and placed on the regular business agenda.
 - **2.1.** Correspondence
 - **2.1.1.** National Precursor Log Exchange Monthly Dashboard October November
 - 2.1.2. Pharmaceutical Firms Application Report
 - **2.1.3.** Washington Association of Naturopathic Physicians Correspondence
 - **2.2.** Ancillary Utilization Plans Approval
 - **2.2.1.** Bob Johnson's Pharmacy
 - **2.2.2.** Cascade Specialty Pharmacy
 - 2.2.3. Kaiser Permanente
 - **2.2.4.** Omnicare of Seattle
 - **2.2.5.** Spanaway Pharmacy
 - 2.2.6. Sumas Drug
 - **2.2.7.** Sunnyside Pharmacy
 - **2.2.8.** Swedish Medical Center
 - 2.2.9. Vashon Pharmacy
 - 2.2.10. Vital Care of Tacoma
 - 2.2.11. Virginia Mason
 - **2.3.** Pharmacy Technician Training Program Approval
 - **2.3.1.** Edmonds Community College
 - 2.3.2. Moses Lake Professional Pharmacy
 - 2.3.3. Yakima Valley Memorial Hospital

MOTION: Craig Ritchie moved to approve 2.1.1, 2.1.2, 2.1.3, 2.2.1, 2.2.2, 2.2.5, 2.2.6, 2.2.7, 2.2.11, 2.3.1, and 2.3.2. Teri Ferreira, second. Motion carries, 14:0.

- **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.
 - 2.2.3 Kaiser Permanente

MOTION: William Hayes moved to approve the 2.2.3 AUP contingent on clarification of item T27 to ensure it meets compliance with our guidance document on technician administration. Craig Ritchie, second. Motion carries, 14:0.

2.2.4 Omnicare of Seattle

MOTION: Teri Ferreira moved to approve the 2.2.4 AUP contingent on the removal of #6 and #13C in the assistant section as they are out of scope. Craig Ritchie, second. Motion carries, 14:0.

2.2.8 Swedish Medical Center

MOTION: William Hayes moved to approve 2.2.8 contingent on the removal of the outdated citation of WAC 246-901. Craig Ritchie, second. Motion carries, 14:0.

2.2.9 Vashon Pharmacy

MOTION: Teri Ferreira moved to approve 2.2.9 contingent on the removal of the last bullet on compounding in assistant section. Craig Ritchie, second. Motion carries, 14:0.

2.2.10 Vital Care of Tacoma

MOTION: William Hayes moved to approve 2.2.10 contingent on removing the outdated citations of chapters 246-871 and 246-878 WAC. Craig Ritchie, second. Motion carries, 14:0.

2.3.3 Yakima Valley Memorial Hospital

MOTION: Teri Ferreira moved to approve 2.3.3 contingent on the pharmacy adding the additional language commission notification and record retention. Craig Ritchie, second. Motion carries, 14:0.

3. Commission Member Reports

- **3.1.** Budget Subcommittee Report William Hayes reported the budget continues to be healthy. While the fund balance seems high, we expect this to come down over the next few years due to the commission being fully staffed. Commission payroll seems higher than normal because payouts from last biennium were not applied until this year. The forecast is positive with a projected end balance of \$4,174,935. However, litigation is always unknown and may fluctuate. Staff are also monitoring the impact moving to a two-year renewal cycle will have on the budget.
- **4. Old Business** The commission will discuss, for clarification or decision, ongoing topics, and issues from previous meetings.
 - **4.1.** Presentation from the Department's Office of Financial Services

Guests from the Office of Financial Services for the Department, Pam Ranes (Finance and Operations Manager) and Miceal Carnahan (Lead Finance Officer) presented on the process the department utilizes.

4.2. Presentation from the Board of Optometry Regarding SSB 5389

Kristina Bell (Program Manager, Board of Optometry) introduced members of the Board of Optometry (board). The board members and their staff presented draft changes to WAC 246-851-580, the codified drug list from which optometrists can prescribe.

- Bill Prothero, Optometrist (OD) Former Chair
- Melissa Dacumos, Optometrist (OD) Chair
- Riya Paranthan, Optometrist (OD)- Vice-Chair
- Theodore Kade, Optometrist (OD)

MOTION: Craig Ritchie moved to approve the medication list as proposed in WACs 246-851-580 and 246-851-590. Hawkins DeFrance, second. Motion carries, 14:0.

4.3. Revised USP Chapters and Nonresident Pharmacies

Taifa "Nomi" Peaks, Pharmacist Consultant, reminded the commission that in March 2023, the commission voted to begin enforcing the revised USP General Chapters <795>, <797>, and <800> in November 2023. This past year, the compounding subcommittee thoroughly reviewed and updated the directive, and the full commission voted to approve it this past summer. Because other boards of pharmacy may be in flux related to the enforcement of the revised USP <795> and <797>, and USP <800>, staff recommend that the commission start revisiting the directive in early 2024 with the hope that the full commission can adopt any revisions right after completion of the nonresident pharmacy renewal period in May 2024. This is because of the concern that approving a revised directive prior to that date could result in tremendous confusion for licensees and the potential for Washington residents not to receive their compounded medications from nonresident pharmacies in a timely fashion. In addition, all approved states have already been determined to at least be substantially equivalent to the former USP <795> and <797> chapters.

Commissioners discussed this and listened to stakeholder input. No action was taken.

4.4. Health Care Entity and 72-Hour Dispensing Limitation

Marlee O'Neill reviewed the draft FAQ regarding the 72-hour dispensing limitation for HCEs in RCW 18.64.450(4).

MOTION: Craig Ritchie moved to approve the FAQ as written. William Hayes, second. Motion carries, 14:0.

5. New Business The commission will review items of interest related to pharmacy practice for discussion, clarification, information, or action by or on behalf of the commission.

5.1. Pharmacy Intern Registration Renewal Limit

The commission received a question about WAC 246-945-155(3) pharmacist intern registration renewal limits at the October 2023 business meeting and asked to consider the topic at a future business meeting. The concern raised was that the two-renewal maximum makes it difficult for some pharmacy students to complete their internship hours before reaching the maximum renewal. An SBAR explaining the difference between previous and current rules about pharmacy internship renewal was included in the meeting materials.

5.2. Military Spouse Temporary Practice Permits for Pharmacy Interns

MOTION: Craig Ritchie moved to authorize staff to file a CR-101 on WACs 246-945-155, 246-945-156, and potentially adding a new WAC in chapter 246-945 WAC to consider changes to the commission's pharmacy intern registration limits and pharmacy intern temporary practice permit for military spouses. The motion also directed staff to draft a policy statement that allows pharmacy interns to request that the commission grant them more than the two renewals currently in rule and a policy statement that grants a 180-day temporary practice permit to military spouses seeking an intern registration. Teri Ferreria, second. Motion carries, 14:0.

6. Panel Review Study Plan (Panel B) – Hawkins DeFrance, Craig Ritche, Bonnie Bush, Matthew Ray, and Stephanie Bardin.

MOTION: Teri Ferreira moved to delegate the study plan reviews to Panel B: Hawkins DeFrance, Craig Ritchie, Bonnie Bush, Matthew Ray, and Stephanie Bardin. Teri Ferreira, second. Motion carries, 14:0.

6.1. PHRM.PH.61314899

MOTION: Craig Ritchie moved to approve the study plan review. Stephanie Bardin, second. Motion carries, 5:0.

6.2. PHRM.PH.61328969

MOTION: Bonnie Bush moved to approve the study plan review. Craig Ritchie, second. Motion carries, 5:0.

7. Rules and Legislative Updates

7.1. Significant Analysis Update: Accessible Labeling

Joshua Munroe provided an update on the accessible labeling rulemaking project.

7.2. Delegation of Commissioners for Weekly Office of Health Professions Legislative Call

MOTION: Teri Ferriera moved to delegate Hawkins DeFrance and Craig Ritchie to represent PQAC in the OHP legislative calls. William Hayes, second. Motion carries, 14:0.

7.3. Implementation Date for Health Equity Continuing Education

Joshua Munroe updated the commission on questions received from licensees on when they must comply with PQAC's health equity continuing education (CE) rule. The effective date for the CR-103p Rules Adoption package is 31 days after it is filed with the Code Reviser. Joshua explained that in August 2022, the commission voted that it will not take enforcement action and the department will not conduct CE audits until one full renewal cycle after October 27, 2022 (Reinstituting CE for Pharmacists and Pharmacy Technicians (govdelivery.com)). Even though the commission is not conducting continuing education audits, the commission does expect its licensees to comply with its CE rules. As a reminder, the department does have a list of free health equity CE trainings (Health Equity Continuing Education | Washington State Department of Health).

8. Presentations

8.1. Presentation from the Department's Legislative Team

Kelly Cooper, Director of Policy and Legislative Relations for the Department of Health, and Christie Spice, Deputy Assistant Secretary of Policy for the Health Systems Quality Assurance (HSQA) Division presented information on agency request legislation for the 2024 legislative session.

8.2. Presentation from the Office of Investigative and Legal Services

Judie Morton, Office Director for the Office of Investigative and Legal Services, Rayne Pearson, Deputy Director for the Office of Investigative and Legal Services, and Margaret Pagel, Supervising Staff Attorney for the Office of Investigative and Legal Services updated the commission on the work it does for the commission.

9. Rules and Legislative Updates

9.1. CR-103E: Refile Request for Medication Assistance

MOTION: Craig Ritchie moved to authorize the re-filing 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. William Hayes, second. Motion carries, 14:0.

9.2. Rules Workshop: Medication Assistance

Joshua Munroe reviewed the proposed rules for the commission regarding medication assistance. Marlee O'Neill reviewed feedback received on the draft rules. Staff will revise the rules based on the commission's discussion and hold another rules workshop at an upcoming business meeting.

9.3. Rules Workshop: Adding Certain Intramammary Antibiotics (WAC 246-945-507)

MOTION: Craig Ritchie moved to approve the rule language as presented and authorized staff to file a CR-102 on WAC 246-945-507. Hawkins DeFrance, second. Motion carries. 14:0.

9.4. Rules Petition Request: Patient Notification Requirements for Pharmacy Closures

MOTION: Craig Ritchie moved to approve the petition and task staff with filing a CR-101 Rules Inquiry package on WAC 246-945-480. Patrick Gallaher, second. Motion carries, 14:0.

9.5. Rules Petition Request: Pharmacists Continuing Education

MOTION: Ken Kenyon moved to deny the petition because RCW 18.64.005(8) requires the commission to adopt rules establishing and governing continuing education requirements for its licensees and the commission cannot delegate its authority. Also, Washington law requires pharmacists to complete continuing education in certain areas such as suicide assessment and health equity and the Commission cannot waive these requirements. The petition only benefits a limited group of licensees and does not prevent these licensees from maintaining BPS certification. Finally, the commission understands that some educational materials completed as part of BPS's certification is ACPE accredited so pharmacists may already be able to use this toward the CE required in WAC 246-945-178. Craig Ritchie, second. Motion carries, 14:0.

- **10. Open Forum** none.
- **Summary of Meeting Action Items** Commissioners and staff will revisit action items identified during today's business meeting.
 - 2. Consent Agenda
 - Follow up with approvals and contingent approvals as directed by the commission.
 - 4.1 Presentation from Office of Financial Services
 - Add tracking/accounting for HELMS and have a line item for that in budget report.
 - Circle back on credentialing line item as we would expect eventual decrease with transition to 2-year renewal cycle.
 - Host a presentation from the Office of Financial Services at least yearly moving forward.
 - 4.3 Revised USP Chapter Nonresident Pharmacies
 - Staff will begin review of nonresident pharmacy directive with the compounding subcommittee early next year.
 - 4.4 HCE and 72-Hour Dispensing Limitation
 - Post the approved FAQs to the commission's website and distribute through GovDelivery
 - 5.1 and 5.2 Pharmacy Intern Registration Renewal Limit Military Spouse Temporary Practice Permits for Pharmacy Interns

- File a CR-101 on WACs 246-945-155, 246-945-156, and potentially adding a new WAC in chapter 246-945 WAC to consider changes to the commission's pharmacy intern registration duration and pharmacy intern temporary practice permit.
- Draft interim policy to allow students to petition commission to exceed the two-renewal limit on intern registrations also allowing military spouses to hold a temporary practice permit for 180-days and bring to a future business meeting for review.

6 Panel Review

Communicate study plan approvals to credentialing.

7.2 OHP Weekly Legislative Calls

inform OHP Hawkins DeFrance and Craig Ritchie will represent PQAC.

9.1 Emergency Rules Medication Assistance

• Refile emergency rule on medication assistance

9.2 Medication Assistance Rules Workshop

• Make suggested edits to the rule language reviewed today. Bring back to a future commission meeting for another rules workshop.

9.3 Adding Certain Intramammary Antibiotics Rules Workshop

• File CR-102 on the updated list on the approved legend drugs and controlled substances for use by the WDFW chemical capture program

9.4 Rules Petition: Patient Notification Closures Send petition approval letter

• File CR-101 to amend WAC 246-945-480 related to patient notification requirements for facility closures.

9.5 Rules Petition: Pharmacists CE

• Send petition denial letter due to the reasons stated at today's meeting.

Business Meeting Adjourned at 3:01 p.m.