



STATE OF WASHINGTON
Pharmacy Quality Assurance Commission
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**Pharmacy Quality Assurance Commission Meeting
March 2, 2023 - Minutes**

Convene: Chair, Teri Ferreira called the meeting to order March 2, 2023, 9:01 AM.

Commission Members:

Teri Ferreira, RPh, Chair
Jerrie Allard, Public Member, Vice Chair
Uyen Thorstensen, CPhT (*Joined at 9:30 AM*)
Hawkins DeFrance, Nuclear Pharmacist
Craig Ritchie, RPh, JD
Patrick Gallaher, BS, BPharm, MBA, MPH
Judy Guenther, Public Member
Tim Lynch, PharmD, MS, FABC, FASHP
Matthew Ray, PharmD
Ken Kenyon, PharmD, BCPS
Ann Wolken, PharmD, RPh
William Hayes, PharmD CCHP
Bonnie Bush, Public Member

Staff:

Marlee O’Neill, Executive Director
Lindsay Trant-Sinclair, Deputy Director
Kristi Knieps, Assistant Attorney General
Irina Tiginyanu, Pharmacy Technician Consultant
Joshua Munroe, Legislative and Rules Consultant
Taifa “Nomi” Peaks, Pharmacist Consultant
Haleigh Mauldin, Program Consultant
Joanne Miller, Program Manager
Desire Gudmundson, Administrative Support
Amy L Robertson, Communications Coordinator
and Program Support

Staff Members Absent:

Christopher Gerard, Assistant Attorney General

1. Call to Order Terri Ferreira, Chair.

1.1 Meeting Agenda Approval – March 2, 2023.

MOTION: Tim Lynch moved to approve the business meeting agenda for March 2, 2023. Jerrie Allard, second. Motion carries, 12-0.

1.2 Meeting Minutes Approval – January 12, 2023.

MOTION: Jerrie Allard moved to approve the meeting minutes for January 12, 2023. Kenneth Kenyon, second. Motion carries, 12-0.

1.3 Meeting Minutes Approval – January 13, 2023.

MOTION: William Hayes moved to approve the meeting minutes for January 13, 2023. Kenneth Kenyon, second. Motion carries, 12-0.

2. Consent Agenda.

2.1 Ancillary Utilization Plans Approval.

- 2.1.1 Chehalis Pharmacy
- 2.1.2 Country Doctor Pharmacy
- 2.1.3 DOC Pharmacy Services
- 2.1.4 Doctors Pharmacy – Multiple locations
- 2.1.5 Easterns Pharmacy
- 2.1.6 Goldendale Pharmacy
- 2.1.7 Seebers Pharmacy
- 2.1.8 Sixth Avenue Medical
- 2.1.9 Suncrest Pharmacy
- 2.1.10 Tick Klock Drug
- 2.1.11 Yokes Food

2.2 Pharmacy Technician Training Program Approval.

- 2.2.1 Koru Pharmacy
- 2.2.2 Matrux LTC Pharmacy

2.3 Regular Agenda/Items Pulled from 2.1 and 2.2.

Items pulled:

- 2.1.1 Chehalis Pharmacy
- 2.1.3 DOC Pharmacy
- 2.1.4 Doctors Pharmacy
- 2.1.6 Goldendale Pharmacy
- 2.1.7 Seebers Pharmacy
- 2.1.9 Suncrest Pharmacy
- 2.2.1 Koru Pharmacy
- 2.2.2 Matrux LTC Pharmacy

Recusals:

Jerrie Allard: 2.1.9; William Hayes: 2.1.3.

MOTION: William Hayes moved to approve the consent agenda with the exception of items 2.1.1, 2.1.3, 2.1.4, 2.1.6, 2.1.7, 2.1.9, 2.2.1, 2.2.2. Kenneth Kenyon, second. Motion carries, 12:0.

MOTION: Teri Ferreira moved to approve AUP item 2.1.1 contingent upon approval that the licensee understands that simple compounding must follow USP <795> in the absence of FDA approved labeling. William Hayes, second. Motion carries, 12:0.

MOTION: Ken Kenyon moved to ask staff to get clarification on compounding in 2.1.3 AUP and bring back to the commission tomorrow. Tim Lynch, second. Motion carries, 11:0. (William Hayes recused)

MOTION: William Hayes moved to approve AUP 2.1.4 contingent upon correcting the AUP to include the appropriate information regarding administration by technicians and providing clarification to item number 15 on the assistant AUP section regarding collection of patient history information. Kenneth Kenyon, second. Motion carries, 13:0.

MOTION: Teri Ferreira moved to approve AUP item 2.1.6 contingent upon approval that the licensee understands that simple compounding must follow USP <795> in the absence of FDA approved labeling. William Hayes, second. Motion carries, 13:0.

MOTION: Teri Ferreira moved to approve AUP 2.1.7 contingent upon removal of reconstitution from the assistant AUP. Judy Guenther, second. Motion carries, 13:0.

MOTION: Kenneth Kenyon moved to approve AUP 2.1.9 contingent upon approval that the licensee understands that simple compounding must follow USP 795 in the absence of FDA approved labeling. Judy Guenther, second. Motion carries, 12:0. (Jerrie Allard recused.)

MOTION: William Hayes moves to approve Pharmacy Technician Training Programs 2.2.1 and 2.2.2 contingent upon updating the technician training documents with the missing information listed in the approval form SBAR's. Craig Ritchie, second. Motion carries, 13:0.

3. Executive Session – CLOSED to the Public.

The Commission will meet in executive session to discuss with legal counsel representing the Commission matters relating to litigation or potential litigation to which the Commission is, or is likely to become, a party, when public knowledge regarding the discussion is likely to result in an adverse legal or financial consequence to the Commission pursuant to RCW 42.30.110(1)(i).

4. Old Business.

4.1 Revised USP Chapters <795> and <797>.

4.1.1. Compliance Expectations.

MOTION: Kenneth Kenyon moved that the commission begin enforcement of revised USP Chapters <795> and <797> on November 1, 2023, and allow for phased early adoption. Craig Ritchie, second. Motion carries, 13:0.

MOTION: Kenneth Kenyon moved to approve staff file a CR-105 to update the commission's incorporation by reference of USP <795> and <797> in WAC 246-945-100. Craig Ritchie, second. Motion carries, 13:0.

4.1.2 Policy Statement (#65.4): Enforcement of USP Chapters <800> and <825>.

MOTION: Tim Lynch moved to withdraw Policy Statement 65.4 on USP <800>, effective November 1, 2023. Hawkins DeFrance, second. Motion carries, 13:0.

4.1.3 Self-Inspection Worksheets for Revised Chapters.

MOTION: Tim Lynch moved to task the compounding subcommittee to review the draft self-inspection sheets for revised USP Chapters <795> and <797>. Kenneth Kenyon, second. Motion carries, 13:0.

4.1.4 Policy Statement (#61): United States Pharmacopeia General Chapter <795>.

MOTION: Craig Ritchie moved to rescind PQAC Policy Statement document #61 on nonsterile compounding. Kenneth Kenyon, second. Motion carries, 13:0.

4.2. Guidance Document on Technician Administration.

During the discussion of the USP <800> self-inspection worksheets at the January business meeting, commissioners raised a concern regarding the ability of pharmacy technicians to administer hazardous drugs. Currently, the commission guidance document on Technician Administration states “Pharmacy technicians may provide administration of medications or devices under the immediate supervision of a pharmacist and if the Pharmacy Quality Assurance Commission (Commission) has authorized the pharmacy technician to administer medications or devices by approving an ancillary utilization plan (AUP).”

The term “drugs and devices” is interpreted to include hazardous drugs. While the commission can amend its guidance document, it would be difficult to narrow the scope of policy without engaging in rulemaking as guidance documents are not enforceable.

No action deemed necessary by the commission.

4.3. White Bagging (Follow-up from Legislative Subcommittee).

MOTION: Kenneth Kenyon moved to direct staff to file a CR-101 related to the regulation of white/brown bagging or any other transfer of a prescription or drug for the purpose of re-dispensing for subsequent administration to a patient. Craig Ritchie, second. Motion carries, 13:0.

4.4. Sample AUP (Follow-up from Pharmacy Practice Subcommittee).

The Pharmacy Practice Subcommittee met on January 26, 2023, to review the most recent version of the Sample Ancillary Personnel Utilization Plan (AUP). As a reminder, the AUP is a document that pharmacies licensed by the commission must submit to the commission for approval, prior to the utilization of pharmacy assistants and technicians. The Sample AUP is designed to be a tool to assist licensees in creating plans for utilizing their pharmacy personnel.

The Sample AUP is being revised and will be presented to the commission during the March 5th business meeting.

5. New Business.

5.1 NABP Annual Meeting.

5.1.1. Voting Delegates.

MOTION: Tim Lynch moved to delegate Teri Ferreira the voting delegate at the NABP annual meeting and Jerrie Allard the alternate delegate. William Hayes, second. Motion carries, 13:0.

5.1.2. Resolutions

MOTION: Tim Lynch moved to support District One's resolution related to point-of-care testing and treatment by pharmacists. William Hayes, second. Motion carries, 13:0.

MOTION: Tim Lynch moved to support District One's resolution related to standards of care initiative. Kenneth Kenyon, second. Motion carries, 13:0.

MOTION: Tim Lynch moved to support District Two's resolution related to a task force on examination limits. Jerrie Allard, second. 13:0.

MOTION: Tim Lynch moved to support District Two's resolution related to the Drug Supply Chain Security Act education and compliance assessment. William Hayes, second. Motion carries, 13:0.

MOTION: Tim Lynch moved to support District Two's resolution related to increasing access to Buprenorphine. Kenneth Kenyon, second. Motion carries, 13:0.

MOTION: Tim Lynch moved not to support the District Eight's resolution related to identifying challenges in aligning renewal cycles across the country for individuals and businesses. Kenneth Kenyon, second. Motion carries, 13:0.

6. Rules and Legislative Updates.

6.1 CR-105: Review Additional Edit to Rule Language for WAC 246-945-040.

MOTION: Craig Ritchie moved to approve the addition of 21 CFR section 1301.28 to WAC 246-945-040 as being exempt from the incorporation by reference to Title 21 CFR. William Hayes, second. Motion carries, 13:0.

6.2 Rulemaking Related to Prescription Transfers WAC 246-945-345.

MOTION: Timothy Lynch moved to authorize staff to file a CR-101 to consider revisions to WAC 246-945-345, prescription transfers. Kenneth Kenyon, second. Motion carries, 13:0.

7. Panel Review – Study Plan (Panel C – Uyen Thorstensen, William Hayes, Jerrie Allard, Kenneth Kenyon, Ann Wolken)

MOTION: Tim Lynch moved to delegate Commission decision-making for agenda items 7.1 and 7.2 to Panel C (Uyen Thorstensen, William Hayes, Jerrie Allard, Kenneth Kenyon, and Ann Wolken). Judy Guenther, second. Motion carries, 13:0.

7.1 PHRM.PH.61312798

MOTION: Uyen Thorstensen moved to approve the study plan. William Hayes, second. Motion carries, 5:0.

7.2 PHRM.PH.61314820

MOTION: Uyen Thorstensen moved to approve the study plan. William Hayes, second. Motion carries, 5:0.

8. Open Forum.

No comments.

9. Commission Member Reports.

9.1 Pharmacy Practice Subcommittee – Craig Ritchie, Subcommittee Chair.

The Pharmacy Practice Subcommittee met on January 26, 2023, to discuss the sample AUP and pharmacy assistants' scope of practice. The first hour of the meeting was dedicated to reviewing edits from staff and further refining the sample AUP document to present at this month's business meeting. The second hour of the meeting involved consideration of the assistant's scope of practice, with a particular focus on the topic of stocking. PQAC staff members were tasked with researching how other state boards of pharmacy have addressed this topic and compiling that research in an SBAR. Staff members expect that their research findings will be ready to present to the Pharmacy Practice Subcommittee at the meeting on March 23, 2023. The subcommittee will review what staff present and develop a recommendation to bring to the full commission at a future business meeting.

9.2 Budget Subcommittee – William Hayes (for Subcommittee Chair).

At the January meeting, the commission voted to retain a reserve of 15% of biennial expenditures. The reserve has been adjusted. As a reminder, the commission's last fee increase for personnel and facilities was in 2018. When the commission moved to a two-year renewal cycle for personnel with its rules rewrite, the yearly fee doubled to account for the two-year renewal cycle. We anticipate a drop in revenue every odd fiscal year beginning in 2023 as there will be substantially less renewals for personnel due to the transition to the 2-year renewal cycle. Staff are monitoring the budget now that we have returned to a more routine working environment with in-person meetings and travel to ensure we are managing our funds effectively. As a reminder, at the July 2022 business meeting, Marlee told us that the commission has a lot of work that is critical to the profession and patient safety (rule writing, inspections), and we simply do not have the staff needed to keep up with the work. Marlee and Lindsay were able to work with the department and received permission to hire nine additional staff. We will probably need to do a decision package during the 2024 legislative session so allotments we will be using for these new hires may be reallocated. The department does not think this will be a problem since the commission's budget is so healthy. The legislature is usually concerned only if the decision package requires a fee increase (which ours will not). Our

fiscal team looked out to FY 2030 when making this assessment. We cannot perfectly predict the future. We cannot say that there will never be a fee increase. We feel good that the fiscal team looked out to FY 2030, and we are excited that we will be able to better and more timely manage our workload. While adding these staff will impact our budget, again, the fiscal team looked out to FY 2030 when making this assessment and felt that the commission's budget would still be in a good place to accomplish our important work. Marlee and Lindsay will provide staffing updates during their reports. We are not seeing a huge costs savings in the services provided by the staff attorneys. There are likely several reasons for this. The staff attorneys stopped routinely completing case reviews in October. It has only been 4 months and staff attorneys were still working on case reviews that had been assigned prior to this change. The Office of Investigative and Legal Services (OILS) has had a backlog due to vacancies. OILS has been able to fill those vacancies and the staff are now catching up on the backlog which includes drafting charging documents that the commission has authorized.

9.3 Compounding Subcommittee – Hawkins DeFrance, Subcommittee Chair.

The Pharmacy Commission's Compounding Subcommittee met on February 23 to discuss the *Nonresident Pharmacy: List of Approved Inspection Programs* Directive. Commissioners reviewed eight states: Arkansas, Indiana, Massachusetts, Missouri, Texas, Vermont, West Virginia, and Wyoming, as well as four states that they tasked staff members with researching following the December 2022 subcommittee meeting. Those states were Mississippi, New Mexico, South Dakota, and Tennessee. The subcommittee has reviewed and gathered stakeholder feedback on a total of 18 states. The collective data gathered at the subcommittee meetings will be used by staff to prepare an updated version of the directive for the full commission's review. The subcommittee members agreed during the February meeting that a more in-depth analysis is required for Massachusetts, New Mexico, Texas, and West Virginia. Staff will conduct the appropriate research and present their findings to the subcommittee at its next scheduled meeting.

9.4 Senate Confirmation Hearings – Teri Ferreria

On February 14 and 16, eight commissioners (Ann, Matthew, Patrick, Ken, Jerrie, Hawkins, Uyen, and I) appeared before the Senate Health and Long Term Care Committee for their confirmation hearings. The hearings went well. We were able to share the good work the commission has done and continues to do, and the senators asked good questions. The committee voted to confirm all eight commissioners and move the Gubernatorial Appointments on for a vote before the full Senate.

10. Staff Reports

10.1 Executive Director – Marlee O'Neill.

HCE FAQ will be ready for a future meeting. We are in the process of reviewing applications for the Pharmacy Inspector Supervisor position.

10.2 Deputy Director – Lindsay Trant-Sinclair.

Haleigh Mauldin's position has become permanent as an HSC4. The public member recruitment packet is with the Governor's office.

12.3 Assistant Attorney General – Kristi Knieps.

Nothing to report.

13. Summary of Meeting Action Items.

- 2 – Follow up with contingent approvals. Reach out to 2.1.3 for clarification. Add to agenda tomorrow if possible.
- 4.1.1 – The commission will prepare to begin enforcement of the revised USP <795> and USP <797> on November 1, 2023. In the meantime, the commission will allow a phased early adoption approach. Staff will file a CR-105 to update the commission's incorporation by reference of USP <795> and <797> in WAC 246-945-100.
- 4.1.2 – Staff will withdraw the commission's policy #65.4 on the enforcement of USP <800> and 825 on November 1, 2023.
- 4.1.3 – Staff will schedule compounding subcommittee meetings to review and take comment on the self-inspection worksheets for the revised USP <795> and <797>. Once the review is complete, we will bring the revised self-inspection worksheets to the full commission.
- 4.1.4 – Staff will rescind the commission's guidance document #61 on the current USP <795>.
- 4.4 – Staff will file CR-101 related to regulation of white bagging, brown bagging, or any other transfer of a prescription or drug for the purpose of re-dispensing for subsequent administration to a patient.
- 4.5 – Revise Sample AUP and bring back to the commission for review at tomorrow's meeting (if possible).
- 5.1.1 – Staff will communicate to NABP that Teri Ferreira is the commission's voting delegate with Jerrie Allard as the alternate voting delegate at the NABP annual meeting.
- 5.1.2 – Marlee and the voting delegates will take the commission's positions on the resolutions discussed today with them to the NABP annual meeting.
- 6.1 – Staff will file the CR-105 with the amended language to exclude 21 CFR 1301.28 related to the x-waiver requirement on buprenorphine in WAC 246-945-040.
- 6.2 – File CR-101 to consider revisions to WAC 246-945-345 regarding prescription transfer requirements.
- 7 – Communicate study plan approvals to credentialing so individuals can re-site for exams.
- 9.2 – Staff will bring back definitions of line items included in the budget report.
- 9.5 – Staff will also upload the PDF version of the self-inspection worksheets posted on the commission's website as soon as possible. Bring back 6-month letter to future meeting for discussion of which addresses the letters are sent to.

Business Meeting Adjourned

Teri Ferreira, Chair, called the meeting adjourned at 3:07 PM.