



STATE OF WASHINGTON
Pharmacy Quality Assurance Commission
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**Pharmacy Quality Assurance Commission Meeting
March 24, 2022 - Minutes**

Convene: Chair, Teri Ferreira called the meeting to order March 24, 2022, 9:00 a.m.

Commission Members:

Teri Ferreira, RPh, Chair
Jerrie Allard, Public Member, Vice Chair
Uyen Thorstensen, CPhT
Hawkins DeFrance, Nuclear Pharmacist
Patrick Gallaher, BS, BPharm, MBA, MPH
Judy Guenther, Public Member
William Hayes, PharmD, CCHP
Helen H. Jung, PharmD, MBA
Ken Kenyon, PharmD, BCPS
Tim Lynch, PharmD, MS, FABC, FASHP
Craig Ritchie, RPh, JD
Matthew Ray, PharmD
Ann Wolken, PharmD, RPh

Commission Member Absent:

Bonnie Bush, Public Member

Staff:

Marlee O’Neill, Interim Executive Director,
Pharmacy Commission
Lindsay Trant, Interim Deputy Director,
Pharmacy Commission
Christopher Gerard, AAG
Hope Kilbourne, Policy Analyst
Joshua Munroe, Legislative and Rules
Consultant
Taifa “Nomi” Peaks, Pharmacist Consultant
Joanne Miller, Program Manager, Pharmacy
Amy L Robertson, Administrative Assistant,
Pharmacy

Guest:

Blake Maresh, OCS Director

1. Call to Order Teri Ferreira, Chair.

1.1 Meeting Agenda Approval – March 24, 2022.

MOTION: Craig Ritchie moved to approve the meeting agenda for March 24, 2022. Hawkins DeFrance, second. Motion carries, 13:0.

1.2 Meeting Minutes Approval – December 17, 2021

MOTION: Craig Ritchie moved to approve the meeting minutes for January 28, 2022 correcting Ken Kenyon as absent. Hawkins DeFrance, second. Motion carries, 13:0.

2. Consent Agenda

2.1 National Precursor Log Exchange Monthly Dashboard-December 2021

2.2 Pharmaceutical Firms Application Report

January 5, 2022, thru March 1, 2022

2.3 Ancillary Utilization Plans Approval

- 2.3.1 Hobson Clinic
- 2.3.2 Matrx LTC
- 2.3.3 Walgreens Pharmacy
- 2.3.4 Lakeside Pharmacy
- 2.3.5 Pharmaca
- 2.3.6 Cle Elum Pharmacy
- 2.3.7 Duvall Family Drug
- 2.3.8 Acasa Pharmacy
- 2.3.9 Whole Health
- 2.3.10 Inchelium Health Center Pharmacy
- 2.3.11 Omak Pharmacy
- 2.3.12 Pharmerica
- 2.3.13 Sound Specialty Pharmacy
- 2.3.14 Sumas Drug
- 2.3.15 Summit Pacific Medical Center Inpatient Pharmacy
- 2.3.16 Whitestone Pharmacy
- 2.3.17 Walmart Pharmacy
- 2.3.18 Ocean Shores Pharmacy

2.4 Pharmacy Technician Training Program Approval

- 2.4.1 Pharmerica
- 2.4.2 Olympic Pharmacy
- 2.4.3 Peace Health
- 2.4.4 Schaffner Pharmacy

William Hayes requested that items 2.3.3, 2.3.16, 2.3.18, 2.4.3, 2.4.4 be pulled from the Consent Agenda for discussion.

Teri Ferreira requested that Items 2.3.6, 2.3.13, 2.3.17, and 2.3.18 be pulled from the Consent Agenda for discussion.

Matthew Ray recuse 2.3.3
Patrick Gallaher recuse 2.4.1 and 2.3.12

MOTION: Craig Ritchie moved to approve Items 2.1, 2.2, 2.3.1, 2.3.2, 2.3.4, 2.3.5, 2.3.7, 2.3.8, 2.3.9, 2.3.10, 2.3.11, 2.3.14, 2.3.15, and 2.4.2. Hawkins DeFrance, second. Motion carries, 13:0.

MOTION: Craig Ritchie moved to approve 2.3.12 and 2.4.1 Hawkins DeFrance, second. Motion carries, 12:0 (Gallaher recused).

2.5 Regular Agenda/Items Pulled from 2.3 and 2.4. The commission will discuss items removed from the consent agenda and placed on the regular agenda for separate discussion.

MOTION: Craig Ritchie moved to approve the following, contingent on staff returning AUPs and the entities updating the language consistent with the [G003 Pharmacy Technician Administration Guidance \(wa.gov\)](#); secondly, on 2.3.3 missing appendices must be attached. Hawkins DeFrance, second. Motion carries, 13:0. **Note:** 2.3.3 Matthew Ray recused, motion passes 12:0.

- **2.3.3** Walgreens Pharmacy (Kenyon)
- **2.3.6** Cle Elum Pharmacy (Ferreira)

- **2.3.13** Sound Specialty Pharmacy (Ferreira)
- **2.3.16** Whitestone Pharmacy (Kenyon)
- **2.3.17** Walmart Pharmacy (Ferreira)

MOTION: William Hayes moved to approve the AUP for the following pharmacy with the modification of removing “O” on IV admixtures from the proposed AUP. Craig Ritchie, second. Motion carries, 13:0.

- **2.3.18** Ocean Shores Pharmacy (Ferreira; Kenyon)

MOTION: William Hayes moved to approve 2.4.3 and 2.4.4 contingent upon receipt of the required material staff identified as missing in the SBAR. Craig Ritchie, second. Motion carries, 13:0.

- **2.4.3** Peace Health (Kenyon)
- **2.4.4** Schaffner Pharmacy (Kenyon)

- 3. Old Business** – The commission will discuss, for clarification or decision, ongoing topics, and issues from previous meetings.

3.1 Office of Customer Service Credentialing Action Plan Overview - Blake Maresh, Director, Office of Customer Service

Blake Maresh reviewed the credentialing action plan and licensing information. The majority of staff will continue to work remotely with the exception of a few needing to be onsite regularly (call center, scan unit, FBI/Home care aid units, etc.). Communal spaces for employees will be available as needed. Technology will improve once HELMS is launched. Also working toward going paperless in the future to reduce paper copies stored onsite.

Concerns brought up by commissioners: timeline of license approval, why licensees are not utilizing online applications.

Jenny Arnold, WSPA – These DOH employees are essential workers. Credit card charge via online application is barrier when the licensee is asked to use the online system and then is charged for it. Kudos to the PQAC staff who have really helped with licensing delays and working through issues.

3.2 Opioid Treatment Program Mobile Unit Follow-up

MOTION: Craig Ritchie moved to authorize staff to file a CR-101 (permanent rulemaking) to amend WAC 246-945-060 to exempt mobile OTP mobile units from having to obtain separate registrations as long as they are covered under the OTP site’s controlled substance registration. Jerrie Allard, second. Motion carries, 13:0.

MOTION: Craig Ritchie moved to authorize staff to file a CR-105 (expedited rulemaking) to amend WAC 246-945-040 to update its incorporation of 21 CFR. Jerrie Allard, second. Motion carries, 13:0.

3.3 Revisit Policy Statement: Enforcement of USP 800 and USP 825

MOTION: Hawkins DeFrance moved to extend enforcement discretion of USP 800 for another six months (September 30, 2022). Craig Ritchie, second. Motion carries, 13:0.

3.4 Subcommittee Updates

MOTION: Craig Ritchie moved to approve the list of committees as set forth. Ken Kenyon, second. Motion carries, 13:0.

Committee	Commission Members
Recurring	
Budget Committee: <ul style="list-style-type: none"> • HELMS 	Chair: Patrick Gallaher Members: Judy Guenther, William Hayes, Helen Jung, Ken Kenyon Staff Lead: PQAC Executive Director and Finance Officer
Legislative Committee	Chair: William Hayes Members: Hawkins DeFrance, Craig Ritchie, Matthew Ray, Chair, Vice Chair Staff Lead: Rules and Legislative Consultant
Strategic Planning Committee	Chair: Jerrie Allard Members: Ann Wolken, Matthew Ray, Chair Staff Lead: Program Manager
Ad Hoc	
Compounding Committee: <ul style="list-style-type: none"> • FDA MOU • Self-Inspection Worksheets • White bagging 	Chair: Hawkins DeFrance Members: Ken Kenyon, Uyen Thorstensen, Judy Guenther Staff Lead: Pharmacist Consultant
Facility Committee <ul style="list-style-type: none"> • HPACs Committee • Suspicious Orders • Facility Enforcement Authority 	Chair: Ken Kenyon Members: Teri Ferreira, William Hayes, Helen Jung, Jerrie Allard Staff Lead: Pharmacist Consultant
Pharmacy Practice Committee <ul style="list-style-type: none"> • Misfill and Pharmacy Work Condition Workgroup • Sunrise Review • CDTA WMC Committee (Teri) • Sample AUP review 	Chair: Craig Ritchie Members: Hawkins DeFrance, Patrick Gallaher, Helen Jung, Ann Wolken, Matthew Ray Staff Lead: Pharmacist Consultant
Approved 03/24/22	

4. 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. Information/Action.

4.1 List and Label Requests

MOTION: Ken Kenyon moved to deny the University of Washington School of Nursing list and label application to DOH as it is not a request to use the list and label information for lists of labels for a commercial purpose. Ann Wolken, second. Motion carries, 13:0.

MOTION: Craig Ritchie moved to approve the Oregon Chapter of American College of Cardiology list and label application. Ann Wolken, second. Motion carries, 13:0.

4.2 Routine Inspections and Insufficient Staffing

Marlee O'Neill informed the commission that inspectors continue to be cognizant of issues within pharmacies due to lack of staffing or technology, etc. Inspectors will postpone routine inspections if patient care and/or day-to-day operations will be impacted.

Discussion focused around concern about notifying the pharmacy prior to arriving (particularly for long-distance inspections) one day prior, or two weeks to alleviate unnecessary travel/cost on the inspector. Marlee pointed out unannounced inspections help our inspectors adjust their schedules due to new business or delays; as well as capturing the "snap-shot" of the day-to-day. Pharmacies are able to contact the inspectors with blackout dates or other difficulties they might have.

MOTION: Craig moved to approve Option 2 to return to standard practice and encourage inspectors to be flexible. Patrick Gallaher, second. Motion carries, 13:0.

Option 2 - Return to standard practice: Inspectors have always had and utilized their discretion to reschedule routine inspections. Inspectors have rescheduled routine inspections due to staffing issues, pharmacy upgrading its software system, DEA inspectors being onsite, burst pipe, etc. The inspectors will continue to utilize their discretion and have an open dialogue with licensees when exceptional circumstances arise.

4.3 Non-resident Pharmacy Directive on Approved Inspection Reports: Tennessee Update

At the December PQAC business meeting, Tennessee was recognized as one of the states that inspect to substantially equivalent standards as Washington, and this is noted in the commission's Nonresident Pharmacy: Approved List of Recognized States directive. In January of 2022, the Tennessee Board of Pharmacy adopted the following policy: The Board interprets "applicable USP standards" under Official Compilation of the Rules and Regulations of the State of Tennessee 1140-07-.02 to mean a pharmacy engaged in prescription drug compounding under either: (1) the active proposed /revised version of a USP chapter or (2) the currently official chapter and version of the USP compendium. The Commission reviewed Tennessee's policy and determined that no action/motion needed by commission Tennessee remains a state that inspects to substantially equivalent standards as Washington.

4.4 Report back on Information on Compounding Non-resident Pharmacies

Lindsay Trant updated the commission that staff connected with other offices at the department and found that the best way to obtain the information is through a public records request, which generally have a 10-14 week turnaround.

Other options would include a reconfiguration of ILRS which is not feasible at this time. Staff did submit this ask to the HELMS team to try and add this feature to the new licensing system.

Stakeholders expressed concern that the state inspection programs listed as approved for nonresident compounding pharmacies include states that do not require adherence to USP 795, 797, or 800.

Commission tasks the staff to take this issue to the compounding subcommittee for further review.

4.5 Interpretation of Stocking for Pharmacy Assistants

Nomi Peaks informed the commission the potential benefits of utilizing pharmacy assistants to replenish ADDDs include personnel support for those pharmacies burdened by staffing shortages, the opportunity for assistants to gain professional aptitude and confidence, and improved productivity for high-volume pharmacies. The potential challenges include establishing the appropriate ADDD training for assistants, estimating the impact on pharmacists' duties as they supervise the ADDD replenishment, and determining if that supervision may occur remotely.

Commissioners discussed the definition of “stocking” and ADDDs and how they apply to the scope of practice for pharmacy assistants.

MOTION: Tim Lynch motioned to task the pharmacy practice subcommittee with engaging stakeholders to define what is permissible for a pharmacy assistant to stock inside and outside a pharmacy and review Guidance Document DOH 690-356, Access to Drugs Stored Outside of the Pharmacy, to see if any modification is necessary; Craig Ritchie, second. Motion carries, 13:0.

4.6 Euthanasia Training program approvals

Wenatchee Valley Humane Society submitted a requested reapproval of the euthanasia training program.

MOTION: Craig Ritchie moved to approve the proposed euthanasia training program with the requirement that they keep track of the administration of the medications documented. Hawkins DeFrance, second. Motion carries, 13:0.

5. Summary of Meeting Action Items – Commissioner and staff will revisit action items identified during today’s business meeting.

- 1.2 – make corrections to January minutes to reflect Ken’s absence.
- 2.3 – follow up with contingent approvals as directed.
- 2.4 – follow up with contingent approvals as directed.

- 3.2 – file the CR102 to amend WAC 246-945-060 to allow a controlled substance registration to extend for an OTP mobile unit; Also file CR105 to update the commission’s incorporation of 21CFR.
- 3.3 – revise policy statement to extend enforcement discretion on USP 800 for another six months; also to communicate commission’s through GovDelivery.
- 3.4 – make edits to subcommittee table as directed; and notify stakeholders of subcommittee meetings.
- 4.1 – staff will deny the University of Washington School of Nursing list and label application to DOH/PDRC as it is not a request to use the list and label information for commercial purposes; approved list/label request for Oregon Chapter of American College and Cardiology.
- 4.2 – return to Option 2 for routine inspections.
- 4.4 – revisit list of approved inspection programs in the commission’s directive through the compounding subcommittee.
- 4.5 – task pharmacy practice committee to engage in stakeholdering to define what is permissible for what a pharmacy assistant to stock both in and out of a pharmacy.
- 4.6 – Notify Wenatchee Humane Society euthanasia training program approved.

2:21 pm

Business Meeting Adjourned.