



STATE OF WASHINGTON
Pharmacy Quality Assurance Commission
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**Pharmacy Quality Assurance Commission Meeting
October 22, 2021 - Minutes**

Convene: Chair, Teri Ferreira called the meeting to order October 22, 2021, 9:06 a.m.

Commission Members:

Teri Ferreira, RPh, Chair
Bonnie Bush, Public Member
Hawkins DeFrance, Nuclear Pharmacist
Patrick Gallaher, BS, BPharm, MBA, MPH
Judy Guenther, Public Member
William Hayes, PharmD, CCHP
Helen H. Jung, PharmD, MBA
Tim Lynch, PharmD, MS, FABC, FASHP
Craig Ritchie, RPh, JD
Ann Wolken, PharmD, RPh

Commission Member Absent:

Jerrie Allard, Public Member, Vice Chair
Ken Kenyon, PharmD, BCPS
Uyen Thorstensen, CPhT

Staff Members:

Trina Crawford, Interim Executive Director,
Pharmacy Commission
Lindsay Trant, Interim Deputy Director, Pharmacy
Commission
Christopher Gerard, AAG
Martin Pittioni, Director, OHP
Marlee O'Neill, Deputy Director, OILS
Blake Maresh, Deputy Director, Office of Health
Professions
Joshua Munroe, Legislative and Rules Consultant
Taifa "Nomi" Peaks, Pharmacy Consultant
Joanne Miller, Program Manager, Pharmacy
Amy L Robertson, Administrative Assistant,
Pharmacy

1. Call to Order Teri Ferreira, Chair **Action**

1.1 Meeting Agenda Approval – October 22, 2021

MOTION: Craig Ritchie moved to approve the meeting agenda for October 22, 2021. Bonnie Bush, second. Motion carries, 10:0.

1.2 Meeting Minutes Approval – September 2, 2021

MOTION: Craig Ritchie moved to approve the minutes for September 2, 2021. Patrick Gallaher, second. Motion carries, 10:0.

2. Consent Agenda

2.1 National Precursor Log Exchange January

2.2 Pharmaceutical Firms Application Report Approval

- August 16, 2021 thru October 4, 2021 – new and closed firms

2.3 Ancillary Utilization Plans Approval

2.3.1 CityScript Pharmacy

2.3.2 Geneva Woods Pharmacy

- 2.3.3 Jim's Pharmacy and Home Health
- 2.3.4 Mcleary Healthmart multiple locations
- 2.3.5 Memorial Pharmacy at Cornerstone
- 2.3.6 Seattle Cancer Care Alliance
- 2.3.7 Willapa Harbor Hospital

2.4 Pharmacy Technician Training Program Approval

2.3.1 Credena Health

MOTION: Craig Ritchie moved to approve the consent agenda with the removal of item 2.3.2 Geneva Woods Pharmacy per Patrick Gallaher's request. William Hayes, second. Motion carries, 10:0.

2.5 Regular Agenda/Items Pulled from 2.1-2.4. The commission will discuss items removed from the consent agenda and placed on the regular agenda for separate discussion.

2.3.2 – Geneva Woods Pharmacy

MOTION: William Hayes moved to return the AUP to the pharmacy for review, correction, and update the AUP. Patrick Gallaher, second. Motion carries, 10:0.

3. **Old Business** – The Commission will discuss, for clarification or decision, ongoing topics and issues from previous meetings. *Information/Action.*

3.1 USP 800 & 825 (self-inspection worksheets) *Action*

Shelley Feldner-Schuerman is unable to present this today. This item will be discussed at the December meeting.

3.2 Overview of case load and timeline *information only*

Marlee O'Neill updated the commission that OILS is working to put a plan in place to more consistently meet case disposition timelines set out in chapter 246-14 WAC. Marlee will have more information at the December meeting about this plan. Due to staffing issues, pandemic, etc., it has been challenging for staff attorneys and commissioners to timely get their disciplinary work completed. For application cases, there are options for the commission in order to assist in moving these cases timelier. Options for the commission:

Distribute all materials for review to entire CMT panel via Box.com.

Assign a case to a specific commission member for presentation to the CMT panel.

Commissioners agree option two is the preferred action. In addition, if needed, allowing the presenter to have a written statement prepared for a staff member to read in the case the presenter cannot attend the CMT.

3.3 FDA MOU Update- *information only*

Christopher Gerard, AAG, provided commissioners with a summary of Wellness Pharmacy vs United States Health and Human Services (2021). A coalition of compounding pharmacies filed this action and challenged the FDA's Memorandum of Understanding Addressing Certain

Distributions of Compounded Human Drug Products (MOU). The Court remanded the MOU back to the FDA to either certify the MOU will not have a significant economic effect on small business or prepare a regulatory flexibility analysis. No action is required by PQAC at this time.

3.4 Subcommittee Chair volunteers *Action*

MOTION: Craig Ritchie moved to change membership and assign chairs as outlined during the meeting. Bonnie Bush, second. Motion carries, 10:0.

Committee	Commission Members
Leadership Committee: <ul style="list-style-type: none"> • Commission Recruitment • Staffing/Training and SOP 	Chair: Teri Ferreira Members: Jerrie Allard, William Hayes
Budget Committee: HELMS	Chair: Patrick Gallaher Members: Judy Guenther, William Hayes, Helen Jung, Ken Kenyon
Compounding Committee: <ul style="list-style-type: none"> • FDA MOU • Self-Inspection Worksheets • Whitebagging 	Chair: Hawkins DeFrance Members: Tim Lynch, Ken Kenyon, Uyen Thorstensen
Strategic Planning Committee	Chair: Jerrie Allard (tentative) Members: Bonnie Bush, Ann Wolken
Pharmacy Practice Committee <ul style="list-style-type: none"> • Misfill and Pharmacy Work Condition Workgroup • Sunrise Review • CDTA WMC Committee (Tim/Teri) • Sample AUP review 	Chair: Craig Ritchie Members: Hawkins DeFrance, Patrick Gallaher, Helen Jung, Ann Wolken
Facility Committee <ul style="list-style-type: none"> • HPACs Committee • Suspicious Orders • Facility Enforcement Authority 	Chair: Ken Kenyon (tentative) Members: Teri Ferreira, William Hayes, Helen Jung, Tim Lynch
Legislative Committee	Chair: William Hayes Members: Hawkins DeFrance, Tim Lynch, Craig Ritchie
Updated 10/27/21	

3.5 Review Policy on Approved List of Recognized States for Nonresident Pharmacies *Action*

MOTION: Craig Ritchie moved to include Illinois to the states that are substantially equivalent to Washington while PQAC’s policy statement “Enforcement of USP Chapters <800> and <825>” is in effect, and for this directive to be reapproved at the December meeting. Bonnie Bush, second. Motion carries, 10:0.

4. New Business-- The commission will discuss, for clarification or decision, ongoing topics and issues from previous meetings. *Information/Action.*

4.1 List and label request *Action*

MOTION: Craig Ritchie moved to ask the requestor whether they still need the list and if yes, submit a declaration stating that the list will not be used for a commercial purpose. Judy Guenther, second. Motion carries, 10:0.

4.2 Midwives legend drugs and devices consult *Action?*

Kathy Weed presented proposed changes to administrative rules addressing legend drugs and devices that midwives can purchase and use (WAC 246-834-250). The secretary of health is required to consult with PQAC before adopting these rules pursuant to RCW 18.50.115.

MOTION: Tim Lynch moved to accept the changes as suggested. Patrick Gallaher, second. Motion carries, 10:0.

4.3 Opioid Treatment Programs mobile unit credential *information only*

Lindsay Trant updated the commission that the DEA has completed rules allowing OTPs to add a mobile component to their existing DEA registration. The department is pursuing licensing options for these mobile units. Currently, mobile components of OTPs will need to obtain separate “other controlled substance registrations” from PQAC. Staff will amend application to accommodate mobile licensing needs.

Michelle Weatherly and Julie Tomaro informed the PQAC that the Behavioral Health Agencies Program within the Department of Health are working on rules to regulate mobile components of OTPs. The timeline for those rules to be implemented is approximately July 2022.

Recommendations:

- License mobile OTPs as “other controlled substance” registrants
- Make the following changes to the application:
 - Add field for license plate number
 - Add field for VIN number
- Modifications to ILRS as needed to identify mobile units
- Applicant would need to apply for new credential for each OTP mobile unit

MOTION: Craig Ritchie moved approve the recommendations in the SBAR to move forward with the rule-making process. In the interim direct staff to investigate a legal analysis and present to the commission on a new rule that would exempt OTPs from a separate credential with the commission that mirrors the DEA OTP new regulation. Hawkins DeFrance, second. Motion carries, 10:0.

5. Rules and Legislative Session Updates - Information/Action.

5.1 Rules Petition: Accessible Labeling *Action*

MOTION: Craig Ritchie moved to approve the petition and begin the rulemaking process regarding accessible labeling. Hawkins DeFrance, second. Motion carries, 10:0.

5.2 Reauthorize Retired Pharmacist Emergency Rules *Action*

MOTION: Craig Ritchie moved to reauthorize the retired pharmacist emergency rules. Hawkins DeFrance, second. Motion carries, 10:0.

6. Panel Review:

6.1 Study Plan review PHRM.PH.61170886

MOTION: Tim Lynch moved to accept the study plan and authorize applicant to retake the MPJE exam for a fourth time. Craig Ritchie, second. Motion carries, 10:0.

7. Open Forum (10 minutes)

8. Commission Member Reports - *Information/Action.*

8.1 Commissioner Reports - No reports provided.

8.2 Commissioners' open discussion related to items or issues relevant to Commission business/pharmacy practice.

Patrick Gallaher will work with pharmacy staff to develop needle stick safety and prevention for the technician training program, FAQ, and guidance document.

9. Staff Reports *Information/Action.*

9.1 Interim Executive Director- Trina Crawford

- Trina Crawford shared the state auditor's office (SAO) has started an audit of the prescription monitoring program (PMP) system. This audit also includes prescribing boards and PQAC. Conference with SAO on October 11. Tim Lynch, Patrick Gallaher and some staff attended the conference. Overall to see if it could be better used to monitor opioid prescribing/dispensing patterns and help reduce opioid abuse/misuse. The recommendation will be completed by summer 2022. The recommendations are not legislatively mandated. They will be recommendations PQAC can consider if any changes are needed.

Tim Lynch added that this was a good meeting and a great opportunity to educate our auditors on what the PQAC's role is in the PMP program and educate on pharmacy practice.

Patrick agreed with Tim, and volunteered to act as a point of contact.

- Secondly, SSB 5092 passed and requires sexual transmitted infection workgroup to be formed by the DOH and within that workgroup, it specifically asks for a pharmacy staff member to participate. Nomi Peaks will be that member and reporting to PQAC.

9.2 Interim Deputy Director – Lindsay Trant

9.3 OILS Deputy Director– Marlee O'Neill

- Pharmacy Inspector Stephanie Martin has been activated to DOH's incident management team (IMT). Tentatively she will return as inspector in early 2022 after maternity leave.

- Currently interviewing for the project pharmacy inspector positions. These should be completed in the next few weeks.
- Thank you to inspectors for being kind and patient.

9.4 Assistant Attorney General – Christopher Gerard

- A hearing on the John Worthington case will take place on November 19. PQAC will be provided an additional update at the December meeting.

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

- 2.5 – Geneva Woods Pharmacy – contact the pharmacy to update the AUP and application.
- 3.1 – moved to the December meeting
- 3.2 – option 2 on SBAR on 3.2
- 3.4 – Volunteers for subcommittees for the chair so staff will prepare and document update. Distribute to website and commissioners.
- 3.5 – policy on approved list of recognized states – staff will notify credentialing that we are accepting Illinois. Staff will bring the full list back to December meeting to be reviewed and/or approved
- 4.1 – List and Labels – staff contact the requestor to see if this documentation is still needed. If yes, please confirm and provide declaration this will not be used for commercial purposes.
- 4.3 – Opioid Treatment Program mobile unit credential – staff will approve the recommendation in the SBAR. Staff will look into options for exempting OTP mobile units from separate registration requirement.
- 5.1 – Rule Petition – staff will begin rule-making process
- 5.2 – reauthorizing the emergency rule
- 6.1 – Joanne will notify credentialing as well as NABP the panel’s decision to approve the retake of the MPJE.
- Patrick to work with staff regarding current guidance document on technician immunization / needle safety.

**12:46 pm (approximately)
Business Meeting Adjourned.**