



STATE OF WASHINGTON
Pharmacy Quality Assurance Commission
PO Box 47852 – Olympia, Washington 98504-7852
Tel: 360-236-4030 – 711 Washington Relay Service

**Pharmacy Quality Assurance Commission Meeting
September 2, 2021 - Minutes**

Convene: Chair, Teri Ferreira called the meeting to order September 2, 2021, 9:00 a.m.

Commission Members:

Teri Ferreira, RPh, Chair
Jerrie Allard, Public Member, Vice Chair
Craig Ritchie, RPh, JD
Judy Guenther, Public Member
Hawkins DeFrance, Nuclear Pharmacist
Ken Kenyon, PharmD, BCPS
Patrick Gallaher, BS, BPharm, MBA, MPH
William Hayes, PharmD, CCHP
Uyen Thorstensen, CPhT

Commission Member Absent:

Tim Lynch, PharmD, MS, FABC, FASHP
Bonnie Bush, Public Member

Staff Members:

Trina Crawford, Interim Executive Director,
Pharmacy Commission
Lindsay Trant, Interim Deputy Director,
Pharmacy Commission
Christopher Gerard, AAG
Marlee O'Neill, Deputy Director, OILS
Hope Kilbourne, Policy Analyst
Blake Maresh, Deputy Director, Office of
Health Professions
Joanne Miller, Program Manager, Pharmacy
Amy L Robertson, Administrative Assistant,
Pharmacy

1. Call to Order

1.1 Meeting Agenda Approval – September 2, 2021

MOTION: Craig Ritchie moved to approve the amended agenda. Patrick Gallaher, second. Motion carries, 9:0

1.2 Meeting Minutes Approval – July 16, 2021

MOTION: Craig Ritchie moved to approve the meeting minutes for July 16, 2021. Patrick Gallaher, second. Motion carries, 9:0

2. Consent Agenda

2.1 National Precursor Log Exchange January

2.2 Pharmaceutical Firms Application Report Approval

- July 1, 2021 thru August 14, 2021 – new and closed firms

2.3 Ancillary Utilization Plans Approval

- 2.3.1 CHAS
- 2.3.3 Fred Meyer Pharmacy
- 2.3.5 Overlake Pharmacy
- 2.3.6 Peninsula Community Health Services (Multiple locations)
- 2.3.7 Pharmacy Plus
- 2.3.8 QFC Fred Meyer

2.4 Pharmacy Technician Training Program Approval

- 2.4.5 Brewster Multiple Locations
- 2.4.6 Charter College

MOTION: Craig Ritchie moved to approve the consent agenda except for items 2.3.2, 2.3.4, and 2.3.9. Jerrie Allard, second. Motion carries, 9:0

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.

William Hayes requested the following be pulled for further discussion:

- 2.3.2 Doctors Telepharmacy

MOTION: Craig Ritchie moved to approve the AUP contingent on the pharmacy amending the AUP to reflect that the pharmacist is the person to offer counseling; William Hayes, second. Motion carries, 9:0.

- 2.3.4 Harbor Health Apothecary

MOTION: William Hayes moved to approve AUP while also informing the licensee that citation to WAC 246-901 should be removed as the rules chapter no longer exists; Craig Ritchie, second. Motion carries, 9:0.

Patrick Gallaher requested the following be pulled for further discussion:

- 2.3.9 Sea Mar Community Health

MOTION: Patrick Gallaher moved to approve AUP with #9 “Reconstitution under the pharmacy assistants” being stricken; Craig Ritchie, second. Motion carries, 9:0.

3. Old Business

3.1 2022 Business Meeting Dates

MOTION: Craig Ritchie moved to approve 2022 business meeting dates; Hawkins DeFrance, second. Motion carries, 9:0.

3.2 Review Policy Statement on Enforcement of USP 800 & 825

MOTION: Craig Ritchie moved to extend policy statement #65.1 on USP 800 through March 31, 2022; excluding USP 825 as it will be immediately enforced on October 1; Patrick Gallaher, second. Motion carries, 9:0. (Hawkins second?)

Stakeholder Jenny Arnold, WSPA, supports delay enforcement of USP 800, but requests PQAC educate the pharmacy community about the existence of L&I's hazardous drug rules in chapter 296-62 WAC.

Stakeholder Richard Molitor, expanded on Jenny Arnold's remarks that in addition to L&I the environmental protection agency is interested in "key drugs."

3.3 Out-of-State OTC-only Wholesaler

MOTION: Ken Kenyon moved we approve Option 1 as amended below; Jerrie Allard, second. Motion carries, 9:0.

Option 1: Resume the option of in-state OTC wholesaler inspections AND refer people to NCDQS for an out-of-state inspection—especially for those states that require licensure for OTC wholesalers. If a state does not require licensure then the commission may need to develop guidance and future rulemaking to address this gap. This guidance may provide out-of-state applicants with an option to submit a letter in lieu of the inspection report and proof of licensure from their regulatory authority stating that they are not required to be licensed in their resident state. Secondly, the commission authorized rulemaking to either remove or modify WAC requirements, WAC 246-945-246(3)(a) and (b), for out-of-state OTC-only wholesalers.

3.4 HCE Self-Inspection Worksheet Public Comment

MOTION: Ken Kenyon moved to approve the HCE self-inspection worksheet as amended during the meeting, direct staff to expeditiously post with revisions, and clarify that licensees must complete before March 2022. Hawkins DeFrance, seconds. Motion carries, 9:0.

- Page 8, Question 9: add clarifying statement regarding freezer temperature ranges - "or acceptable standard range" and correct grammar.
- Page 13, Question 31-33: switch 31 and 32

MOTION: Ken Kenyon moved initiate rule-making under the expedited process that is currently open for WAC 246-945-417 to correct subsection 7 as noted; Craig Ritchie, second. Motion carries, 9:0.

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

4.1 Reauthorize emergency rules deleting Epidiolex from Schedule V.

MOTION: Craig Ritchie moved to reapprove the refiling of the emergency rule; Patrick Gallaher, second. Motion carries, 9:0.

4.2 Emergency rules for prescribing Schedule II drugs during COVID-19.

MOTION: Craig Ritchie moved to approve the refiling of the emergency rule for prescribing Schedule II drugs during COVID-19; Ken Kenyon, second. Motion carries, 9:0.

4.3 Reauthorize medication assistance emergency rules.

MOTION: Patrick Gallaher moved to approve jointly refiling medication assistance emergency rules with the Department of Health; Craig Ritchie, second. Motion carries, 9:0.

4.4 Rules prioritization and strategizing for interim.

MOTION: Jerrie Allard moved to approve the prioritizations of rules list as presented; Patrick Gallaher, second. Motion carries, 9:0.

4.5 2022 Legislative Proposal Update

Blake Maresh presented an overview of the Board/Commission (BCC) Expansion bill. Key points:

- Change some qualifications to be a member of a BCC – removes US citizenship as a prerequisite to serve on BCCs. However, must be Washington State resident for at least five years.
- Changed the definition of a quorum – “a majority of members appointed and serving.”
- Harmonizes all BCC as Class 5 groups under Chapter 43.03 – proposed compensation increase from \$50/day to \$250/day for attendance at official meetings or performance of statutorily prescribed duties.
- Gives PQAC authority to delegate to panels of three, four, etc. for facilities work.
- Gives PQAC authority to delegate to a health law judge for facilities.
- Gives the ability to do a more national search for Executive Director position without immediately being licensed in Washington State. Not effective immediately for this current recruitment.
- Additional housekeeping with old language, etc.

4.6 Review Uniform Facilities Enforcement Framework Recommendations

MOTION: Hawkins DeFrance moved to adopt the proposed recommendations with the additional comments (below); Patrick Gallaher, second. Motion carries, 9:0.

- Fine Limits listed are only a high-level overview from other sources. Not specific at this time.
- Consider a provision for reimbursement for costs of investigation.
- Scope and Severity Matrix will be of help for future use.

5. **Open Forum** (10 minutes) – None.

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

6.1 Commissioner Reports

Teri Ferreira, Jerrie Allard, and Trina Crawford were unable to attend the NABP regional meeting due to travel restrictions.

Jerrie Allard recognized Martin Pittioni for all his support and help to the commission during all of the recent staff changes.

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

PQAC Commission vacancies

Hawkins DeFrance –the fifteen-member commission currently shows four vacancies and three expire in January. What is the plan for filling these positions?

Per Joanne Miller:

- 2021 recruitment (3 positions) is now at the Governor's office
- 2022 recruitment has just been announced.

Blake Maresh confirmed members can serve until there is a replacement appointment made.

Licensing

Ken Kenyon raised the concern regarding the significantly extended time stakeholders are seeing their licensing completed.

Blake Maresh acknowledges there is delay, but the office of customer service is taking many different approaches to expedite licensing. Through the federal recovery act, we are bringing on inspectors on a temporary basis. The credentialing unit is also bringing on

staff to help expedite. We are also looking into LiveScan for fingerprinting, but the challenge is other states having it available.

Thanks to Staff

Patrick Gallaher, thanks Lindsay, Trina, and Marlee taking on these critical roles and taking on the extra work. All the staff should be commended on how they have stepped up with all the changes.

7. Staff Reports *Information/Action*.

7.1 OHP Deputy Director – Blake Maresh

- Status of PQAC transition and recruitment

Executive Director Position – recruitment is underway for this position. Applications review will begin September 17. Review panel: Jerrie Allard, Teri Ferreira, William Hayes

Deputy Director Position – While Lindsay is interim deputy director, we are trying to back-fill the rules coordinator. Candidates are in place, but not confirmed at the moment.

Pharmacy Consultant Position – interviews set for tomorrow. Panelist of seven (3 commissioners, 3 OHP, 1 HR).

Supervising Pharmacist – recruitment for this position is on hold.

Pharmacy Inspectors – One-time funding has come through and allows us to secure three inspectors in a non-permanent basis. Recruitment to begin later.

7.2 OILS Deputy Director– Marlee O’Neill

- Return to Routine Inspections Update

Routine Inspections – Inspectors will resume routine inspections soon. We are coordinating with the Office of Health Systems Oversight to ensure practices/procedures are consistent. Stakeholders will be receiving new “six-month notice” letters.

CMT Materials – Kirby will begin using Box.com to distribute CMT materials to panels.

Ivermectin Information – Thanks to the investigators and inspectors for distributing the ivermectin information so quickly.

7.3 Interim Executive Director- Trina Crawford

- FDA MOU Update – the FDA has extended the deadline to sign the MOU to Oct 27, 2022. If rulemaking is started, it can be pulled at any time.

Chris Gerard reminded the commission the MOU is required to be developed between the FDA and NABP. In short, it addresses the interstate shipping of compounded human drug products. If states decide to enter this MOU, they are subject to the significant data reporting to the FDA. Alternative to not signing restricts the amount of compounded human drug products that can be shipped in state to 5%. The MOU will not be tailored to each state.

MOTION: Hawkins DeFrance motioned to move forward with rulemaking to adopt/sign the MOU; Ken Kenyon, second. Motion carries, 9:0.

7.4 Interim Deputy Director – Lindsay Trant

- Sample AUP – would like to schedule the pharmacy practice committee to start the revision work on the sample AUP.

7.5 Assistant Attorney General – Christopher Gerard – nothing to report.

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

- 2.3.2 – Consent agenda Doctor’s Telepharmacy – approved with restrictions.
- 2.3.4 – Consent agenda approved but strike 246-901. Irina will follow-up
- 2.3.9 – Sea Mar – strike #9 reconstitution by pharmacy assistants. Irina will follow-up
- 3.2 – Policy Statement –
 - Update Policy Statement
 - Staff create and FAQ and send via newsletter
- 3.3 – Out of State Wholesalers
 - Staff develop guidance letter for out of state wholesalers for the states that do not conduct inspections.
 - File CR101 with authorization rule making for WAC 246-945-246 in consideration of requiring self-inspections.
- 3.4 – HCE self-inspection sheets
 - Post revisions to the worksheet
 - Clarify self-inspection worksheets due by March 2022.
 - File CR105 to correct the technical error in WAC 246-945-417
- Refile Emergency rules for 4.1, 4.2, 4.3
- 4.6 – Uniform Facilities Enforcements
 - Make edits made during the meeting
- 7.3 – MOU FDA – file the CR101
- 7.4 – Sample AUP – schedule meeting of the pharmacy practice committee for review.

Business Meeting Adjourned. 12:15 p.m.

Pharmacy Quality Assurance Commission

Mission Statement

The mission of the Pharmacy Quality Assurance Commission is to promote public health and safety by establishing the highest standards in the practice of pharmacy and to advocate for patient safety through effective communication with the public, profession, Department of Health, Governor, and the Legislature.

Vision Statement

The Washington State Pharmacy Quality Assurance Commission leads in creating a climate for the patient-focused practice of pharmacy as an integral part of an accessible, quality-based health care system.

- As a result, the citizens of Washington State:
- Are well informed about medications;
- Take responsibility for their health;
- Utilize pharmacists and other health care providers appropriately; and
- Experience the highest level of health and wellness.

Next scheduled business meeting: October 22, 2021

Business Meetings

9:00 a.m.

Virtual – by Webinar

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