

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 August 24, 2023 - Minutes

Convene: Chair, Ken Kenyon called the meeting to order on August 24, 2023, 9:11 AM.

Commission Members:

Kenneth Kenyon, PharmD, BCPS, Chair

Hawkins DeFrance, Nuclear Pharmacist, Vice Chair

Jerrie Allard, Public Member Bonnie Bush, Public Member

Teri Ferreira, RPh

Patrick Gallaher, BS, BPharm, MBA, MPH

Judy Guenther, Public Member William Hayes, PharmD CCHP

Timothy Lynch, PharmD, MS, FABC, FASHP

Matthew Ray, PharmD Craig Ritchie, RPh, JD Uyen Thorstensen, CPhT Ann Wolken, PharmD, RPh

Staff:

Marlee O'Neill, Executive Director Lindsay Trant-Sinclair, Deputy Director

Christopher Gerard, AAG

Irina Tiginyanu, Pharmacy Technician Consultant

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

Amy L Robertson, Communications Coordinator

and Program Support

1. Call to Order Ken Kenyon, Chair

1.1 Meeting Agenda Approval – August 24, 2023

MOTION: Craig Ritchie moved to approve the meeting agenda. Bonnie Bush, second. Motion carries, 13:0.

1.2 Meeting Minutes Approval – June 15, 2023

MOTION: Craig Ritchie moved to approve the meeting minutes for June 15, 2023. Bonnie Bush, second. Motion carries, 13:0.

1.3 Meeting Minutes Approval – June 16, 2023

MOTION: Craig Ritchie moved to approve the meeting minutes for June 16, 2023. Bonnie Bush, second. Motion carries, 13:0.

1.4 Special Meeting Minutes Approval – July 25, 2023

MOTION: Craig Ritchie moved to approve the special meeting minutes for July 25, 2023. Bonnie Bush, second. Motion carries, 13:0.

2. Consent Agenda

2.1 Correspondence

- 2.1.1 National Precursor Log Exchange Monthly Dashboard- June-July 2023
- 2.1.2 Pharmaceutical Firms Application Report
- 2.1.3 2024 Proposed Business Meeting Dates

2.2 Ancillary Utilization Plans Approval

- 2.2.1 Costco Pharmacy
- 2.2.2 Bartell Drugs Pharmacy
- 2.2.3 Aequita Pharmacy
- 2.2.4 Fiesta Pharmacy
- 2.2.5 Howards Drug
- 2.2.6 Jims Pharmacy
- 2.2.7 Navos Pharmacy
- 2.2.8 Pullman Regional Hospital Pharmacy
- 2.2.9 Rays Pharmacy
- 2.2.10 Vet-Ex Animal Health Supply
- 2.2.11 Newport Hospital

2.3 Pharmacy Technician Training Program Approval

- 2.3.1 CHAS
- 2.3.2 Clark College
- 2.3.3 Tims Pharmacy and Gift Shop
- 2.3.4 Woodinville Pharmacy

MOTION: Craig Ritchie moved to approve 2.1.1, 2.1.2, 2.1.3, 2.2.3, 2.2.4, 2.2.5, 2.2.6, 2.2.8, 2.2.9, 2.2.10, 2.2.11, and 2.3.2. Patrick Gallaher, second. Motion carries, 13:0.

MOTION: Craig Ritchie moved to approve 2.2.7. William Hayes, second. Motion carries, 12:0 (Timothy Lynch, recused).

2.4 Regular Agenda/Items Pulled from 2.3 and 2.4

2.2.1 Costco Pharmacy

MOTION: William Hayes moved to approve 2.2.1 contingent upon the submitter reviewing and ensuring that its AUP is aligned with the commission's guidance on technician administration. Craig Ritchie, second. Motion carries, 13:0.

2.2.2 Bartell Drugs Pharmacy

MOTION: Teri Ferreira moved to approve 2.2.2 contingent upon the submitter updating the AUP with the removal of the old WAC language and commission staff ensuring the AUP is aligned

with the commission's guidance on technician administration. Craig Ritchie, second. Motion carries, 13:0.

2.3.1 CHAS

MOTION: William Hayes moved to approve 2.3.1 contingent upon the submitter removing items K and L from the AUP which speaks to pharmacy assistants entering prescription information in the computer system. Craig Ritchie, second. Motion carries, 13:0.

2.3.3 Tims Pharmacy and Gift Shop

MOTION: William Hayes moved to approve 2.3.3 contingent upon the submitter updating item 17 so that it references the appropriate USP chapters instead of stating simple compounding. Craig Ritchie, second. Motion carries, 13:0.

2.3.4 Woodinville Pharmacy

MOTION: William Hayes moved to approve 2.3.4 contingent upon the submitter updating the AUP to ensure all WAC references are to the current rules instead of the old rules and to ensure the AUP is aligned with the commission's guidance on technician administration. Craig Ritchie, second. Motion carries, 13:0.

3. Old Business

- **3.1 Robert's Rules of Order and OPMA Training** Christopher Gerard, AAG, presented a training on Robert's Rules of Order and on the Open Public Meetings Act (OPMA).
- **3.2 FDA Proposed Rule: Patient Medication Information (PMI)** Christopher Gerard, AAG, presented information on the FDA's rulemaking to require a new type of Medication Guide for patients. The commission provided feedback on the information it wants to convey in the comment it submits on this rulemaking.
- **3.3 Review Self-Inspection Worksheets for Revised USP 795 and 797** Tina Lacey, Pharmacy Inspector, provided an overview of the draft worksheets.

MOTION: Craig Ritchie moved to approve the USP 795 and 797 Self-Inspection Worksheets. Timothy Lynch, second. Motion carries, 13:0.

4. New Business

4.1 Message from the Office Director of the Office of Health Professions – Shawna Fox, Director, Office of Health Professions, discussed changes in the Office of Health Professions and solicited feedback from the commission on how she can assist the commission and commission staff.

4.2 Commission Delegations for 2023-2024

MOTION: Matthew Ray moved to approve form 1-1-19A, Delegation of Signature Authority. Craig Ritchie, second. Motion carries, 13:0.

MOTION: Craig Ritchie moved to approve Form 1-1-19E: Determination of Maximum Daily Monetary Fine for Failing to Produce Documents under RCW 18.130.230. Timothy Lynch, second. Motion carries, 13:0.

MOTION: Craig Ritchie moved to approve Designation of Presiding Officer for Brief Adjudicative Proceedings. Teri Ferreira, second. Motion carries, 13:0.

MOTION: Timothy Lynch moved to approve Delegation and Authorization for Health Law Judges to Act as the Presiding Officer. Craig Ritchie, second. Motion carries, 13:0.

MOTION: Craig Ritchie moved to approve Delegation of Decision Making to Panels and Health Law Judges for Disciplinary Cases Involving Pharmaceutical Firms as edited by the commission. Patrick Gallaher, second. Motion carries, 13:0.

4.3 Euthanasia Training Program Approval

MOTION: Craig Ritchie moved to approve the Humane Society of Southwest Washington's euthanasia training program. William Hayes, second. Motion carries, 13:0.

5. Panel Review

MOTION: Craig Ritchie moved to delegate the study plan reviews to Panel A (Patrick Gallaher, Teri Ferreira, and Judy Guenther). Hawkins DeFrance, second. Motion carries, 13:0.

5.1 PHRM.PH.61295931

MOTION: Patrick Gallaher moved to approve the study plan. Teri Ferreira, second. Motion carries, 3:0.

5.2 PHRM.PH. 61198408

MOTION: Patrick Gallaher moved to approve the study plan. Teri Ferreira, second. Motion carries, 3:0.

5.3 PHRM.PH. 61318783

MOTION: Patrick Gallaher moved to approve the study plan. Teri Ferreira, second. Motion carries, 3:0.

5.4 PHRM.PH. 61302386

MOTION: Patrick Gallaher moved to approve the study plan. Teri Ferreira, second. Motion carries, 3:0.

5.5 PHRM.PH. 61306447

MOTION: Patrick Gallaher moved to approve the study plan. Teri Ferreira, second. Motion carries, 3:0.

5.6 PHRM.PH. 61306119

MOTION: Patrick Gallaher moved to approve the study plan. Teri Ferreira, second. Motion carries, 3:0.

6. Rules and Legislative Updates

6.1 Rules Workshops

- **6.1.1** Suspicious Orders and Zero Reports for Wholesalers Haleigh Mauldin, Program Consultant, presented the updated proposed rule language made since the June 2023 rules workshop. After discussion, the commission agreed to hold another rules workshop on this matter at a future business meeting.
- **6.1.2** Access to Drugs Stored Outside of the Pharmacy Haleigh Mauldin, Program Consultant, presented the updated proposed rule language made by the facility subcommittee in June 2023.

MOTION: Matthew Ray moved to instruct the staff to file a CR-102 on Access to Drugs Stored Outside of the Pharmacy language draft with the commission's edits. Craig Ritchie, second. Motion carries, 13:0.

6.2 CR-103E: Refile Request for Medication Assistance

MOTION: Teri Ferreira moved to authorize staff to refile emergency rule CR-103E: Refile Request for Medication Assistance because there is an emergent need for this rule to be extended for the health and safety of the public. Craig Ritchie, second. Motion carries, 13:0.

6.3 CR-105: Adding Opill and RiVive to Current Expedited Rulemaking

MOTION: Craig Ritchie moved to authorize the expansion of the CR105 to include RiVive three milligram nasal spray and the Opill tablet as over-the-counter medications. Hawkins DeFrance, second. Motion carries, 13:0.

6.4 Possible Future Legislative Ask: Name Change

MOTION: Timothy Lynch moved to join the dental commission in their effort to rename their commission and would support PQAC renaming itself the Washington State Pharmacy Commission. Craig Ritchie, second. Motion carries, 13:0.

7. Open Forum

Jenny Arnold, Washington State Pharmacy Association.

1. Requested the commission consider updating the wording in the Guidelines for the Implementation of a Washington Pharmacy Technician Program.

- 2. The WSPA would like to introduce legislation to allow the pharmacy commission to regulate based on a standard of care model (consistent with the medical commission).
- 3. WSPA is going to propose legislation to amend the definition of the practice of pharmacy. This legislation would allow pharmacists to prescribe under written guidelines/protocols, without the requirement that the written guidelines/protocols being approved by a prescriber for each pharmacist.

The commission thanked Jenny and the WSPA for the work on these matters.

8. Summary of Meeting Action Items

- 2.1 Staff will file the 2024 meeting dates with the Officer of the Code Reviser.
- 2.2 and 2.3 Staff will follow up with the contingent approvals on the AUPs and technician training programs from today.
- 3.2 Staff will draft comments to submit to the FDA on the patient medication information guides and forward for the commission to review at the October business meeting.
- 4.2 Finalize delegation forms, apply Ken's signature, and make edits to the policy statement reviewed today.
- 4.3 Staff will communicate the euthanasia training program approval to the applicant.
- 5 Staff will communicate study plan approvals to credentialing
- 6.1.1 Staff will distribute an updated draft on the suspicious orders rule and bring it back to the commission at a future meeting for another rules workshop.
- 6.1.2 Staff will file a CR-102 on the access to drug stored outside of the pharmacy rules package.
- 6.2 Staff will refile the emergency rule on medication assistance.
- 6.3 Staff will file an amended CR-105 with an amended scope to include Opill and RiVive as over-the-counter medications.
- 6.4 Staff will communicate to the dental commission staff of PQAC's desire to join their legislative effort and be named Washington State Pharmacy Commission.
- 7 Staff will bring technician training guidelines back to the commission for review at a future meeting.

Business Meeting Adjourned

Ken Kenyon, Chair, called the meeting adjourned at 2:20 PM.