

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 May 4, 2023 - Minutes

Convene: Chair, Teri Ferreira called the meeting to order May 4, 2023, 9:01 AM.

Commission Members:

Teri Ferreira, RPh, Chair
Jerrie Allard, Public Member, Vice Chair
Uyen Thorstensen, CPhT
Hawkins DeFrance, Nuclear Pharmacist
Craig Ritchie, RPh, JD
Patrick Gallaher, BS, BPharm, MBA, MPH
Judy Guenther, Public Member
Matthew Ray, PharmD
Ken Kenyon, PharmD, BCPS
Ann Wolken, PharmD, RPh
William Hayes, PharmD CCHP
Timothy Lynch, PharmD, MS, FABC, FASHP (Joined at 9:17)

Staff:

Traci Orr, OHP Deputy Director
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
Desiré Gudmundson, Administrative Support
Amy L Robertson, Communications Coordinator
and Program Support

Commission Members Absent:

Bonnie Bush, Public Member

1. Call to Order Terri Ferreira, Chair.

1.1 Meeting Agenda Approval – May 4, 2023.

MOTION: Craig Ritchie moved to approve the business meeting agenda for May 4, 2023. Judy Guenther, second. Motion carries, 11-0.

1.2 Meeting Minutes Approval – March 2, 2023.

MOTION: Craig Ritchie moved to approve the meeting minutes for March 2, 2023. William Hayes, second. Motion carries, 11-0.

1.3 Meeting Minutes Approval – March 3, 2023.

MOTION: Craig Ritchie moved to approve the meeting minutes for March 3, 2023. William Hayes, second. Motion carries, 11:0.

2. Consent Agenda.

- 2.1 National Precursor Log Exchange Monthly Dashboard January- April 2023.
- 2.2 Pharmaceuticals Firms Application Report.

2.3 Ancillary Utilization Plans Approval.

- **2.3.1** Don's Pharmacy
- **2.3.2** Inchelium Pharmacy
- **2.3.3** Kadlec Pharmacy
- 2.3.4 Koru Pharmacy
- **2.3.5** Lincoln Pharmacy
- **2.3.6** Saver Pharmacy
- **2.3.7** Sid's Pharmacy, Sid's LTC Pharmacy
- **2.3.8** UWMC NW Outpatient Pharmacy
- **2.3.9** Viriginia Mason Pharmacy
- 2.3.10 Yakima Pharmacy
- 2.3.11 HealthPoint Update
- **2.3.12** CHAS Pharmacy
- **2.3.13** CVS Pharmacy

2.4 Pharmacy Technician Training Program Approval.

- **2.4.1** Aberdeen Pharmacy
- **2.4.2** Ferndale Pharmacy
- **2.4.3** Propac Payless Pharmerica
- 2.4.4 Seattle Children's Hospital
- **2.4.5** St. Joseph Medical Center
- **2.4.6** Whidbey Health Community Pharmacy
- 2.4.7 Yakima Valley Community College

2.1 Regular Agenda/Items Pulled from 2.3 and 2.4.

- 2.3.1 Don's Pharmacy
- 2.3.2 Inchelium Pharmacy
- 2.3.3 Kadlec Pharmacy
- 2.3.4 Kour Pharmacy
- 2.3.5 Lincoln Pharmacy
- 2.3.6 Saver Pharmacy
- 2.3.7 Sid's Pharmacy, Sid's LTC Pharmacy
- 2.3.8 UWMC NW Outpatient Pharmacy
- 2.3.10 Yakima Pharmacy
- 2.3.11 HealthPoint Update
- 2.3.12 CHAS Pharmacy
- 2.3.13 CVS Pharmacy
- 2.4.1 Aberdeen Pharmacy

- 2.4.6 Whidbey Health Community Pharmacy
- 2.4.7 Yakima Valley Community Pharmacy

Recusals:

Ken Kenyon: 2.3.8; Patrick Gallaher: 2.4.3.

MOTION: William Hayes moved to approve the consent agenda with the exception of the items that were pulled. Craig Ritchie, second. Motion carries, 12:0.

MOTION: William Hayes moves to approve item 2.3.1 contingent upon licensee updating its AUP to be compliant with the commission's guidance document on pharmacy technician administration and removal of the reconstitution by an assistant. Craig Ritchie, second. Motion carries, 12:0.

MOTION: Craig Ritchie moved to approve item 2.3.2 contingent upon amending the assistant portion of counting/pouring to include that it will be pulled by a pharmacist, intern, or technician. William Hayes, second. Motion carries, 12:0.

MOTION: William Hayes moved to approve item 2.3.3 contingent upon removal of old WAC citation 246-901-100. Craig Ritchie, second. Motion carries 12:0.

MOTION: William Hayes moved to approve item 2.3.4 contingent upon updating the AUP to include reference to complying with USP <795> and <797> where appropriate. Craig Ritchie, second. Motion carries, 12:0.

MOTION: Craig Ritchie moved to approve item 2.3.5 contingent upon updating the AUP to make it clear that assistants may only process refills in the pharmacy system to generate a label and updating the AUP to be compliant with the commission's guidance document on pharmacy technician administration. Ann Wolken, second. Motion carries, 12:0.

MOTION: Craig Ritchie moved to approve item 2.3.6 contingent upon including the language of pharmacy assistants processing refills to match what is in the commission's sample AUP. Ann Wolken, second. Motion carries, 12:0.

MOTION: Craig Ritchie moved to approve item 2.3.7 contingent on striking #18 and amending the assistant portion of counting/pouring to include that it will be pulled by a pharmacist, intern, or technician. Ann Wolken, second. Motion carries, 12:0.

MOTION: William Hayes moved to approve item 2.3.8 contingent upon removal of old WAC references and add reference USP <795> and <797> where appropriate when compounding is referenced. Craig Ritchie, second. Motion carries, 11:0. (Ken Kenyon recused).

MOTION: Craig Ritchie moved to approve item 2.3.10 contingent upon amending the assistant portion of counting/pouring to include that it will be pulled by a pharmacist, intern, or technician, removal of old WAC references, also change the word profile to demographic. Ann Wolken, second. Motion carries, 12:0.

MOTION: Craig Ritchie moved to approve item 2.3.11 contingent upon amending the assistant portion of counting/pouring to include that it will be pulled by a pharmacist, intern, or technician. Ann Wolken, second. Motion carries, 12:0.

MOTION: Craig Ritchie moved to deny approval of item 2.3.12 until entity revises its AUP to comply with current laws and rules. Judy Guenther, second. Motion carries, 12:0.

MOTION: William Hayes moved to approve item 2.4.1 contingent upon adding information on record retention and notifying the commission of significant program changes, having the AUP specify compounding, and updating references to USP <795> and <797>. Craig Ritchie, second. Motion carries, 12:0.

MOTION: Ann Wolken moved to approve item 2.4.3. Judy Guenther, second. Motion carries, 11:0. (Patrick Gallaher recused)

MOTION: William Hayes moved to approve item 2.4.6 contingent upon correcting information on record retention. Craig Ritchie, second. Motion carries, 12:0.

MOTION: William Hayes moved to approve item 2.4.7 contingent upon correcting information related to record retention. Craig Ritchie, second. Motion carries, 12:0.

3. Old Business.

3.1 Non-resident Pharmacy Directive.

MOTION: Craig Ritchie moved to approve the updates to the non-resident pharmacy directive. The updates will be in effect immediately for all new non-resident pharmacy applicants but will be in effect for the 2024 renewal cycle for existing nonresident pharmacy licensees. Hawkins DeFrance, second. Motion carries, 12:0.

3.2 Revisions to Current Self-Inspection Worksheets.

MOTION: Hawkins DeFrance moved to approve proposed revisions. Craig Ritchie, second. Motion carries, 12:0.

4. New Business.

4.1 Resolution for NABP Annual Meeting.

MOTION: Matthew Ray moved to approve the resolution presented by the Arizona State Board of Pharmacy regarding the pharmacy technicians on the board of pharmacy. Judy Guenther, second. Motion carries, 12:0.

MOTION: Matthew Ray moved to approve the North Dakota resolution regarding creating an industry standard of pharmacy technician scope of practice and entry-level requirements to support interstate portability. Uyen Thorstensen, second. Motion carries, 12:0.

4.2 Proposed Amendments to the NABP Constitution and Bylaws.

MOTION: Hawkins DeFrance moved to approve the amendment that one has to be a board member at the time of appointment to a NABP committee but can continue serving on that committee if their board term ends. Timothy Lynch, second. Motion carries, 12:0.

MOTION: Craig Ritchie moved to approve the proposed amendment that voting on proposed resolutions and amendments may be conducted electronically. Hawkins DeFrance, second. Motion carries, 12:0.

4.3 NABP Committee and Task Force.

MOTION: Hawkins DeFrance moved to approve Craig Ritchie's application and participation, if selected, on the committee on law enforcement. William Hayes, second. Motion carries, 12:0.

4.4 List and Label Requests.

MOTION: Timothy Lynch moved to recognize NetCE as an educational organization. Craig Ritchie, second. Motion carries, 12:0.

4.5 Leadership Elections Information.

Elections for Chair and Vice Chair will be held at the June Commission meeting.

4.6 Addresses for Six-Month Inspection Letters.

Marlee O'Neill addressed the concern of six-month letters being sent to both an entity's physical and listed mailing addresses. The commission requested staff amend the six-month inspection letter to add a sentence that directs corporate offices to ensure their pharmacies receive the letter.

4.7 Statement on Mifepristone.

MOTION: Hawkins DeFrance moved to approve statement on mifepristone with the addition of the following: "commission licensees should consider any obligations required under federal law including any requirements related to the REMS Program". Matthew Ray, second. Motion carries, 12:0.

5. Panel Review – Study Plan (Panel C- Uyen Thorstensen, William Hayes, Ann Wolken, Ken Kenyon, Jerrie Allard)

MOTION: Hawkins DeFrance moved to delegate the study plan review to Panel C (Uyen Thorstensen, William Hayes, Ann Wolken, Ken Kenyon, Jerrie Allard), Craig Ritchie, second. Motion carries, 12:0.

5.1 PHRM.PH.61321067

MOTION: Uyen Thorstensen moves to approve the study plan for PHRM.PH.61321067. Ann Wolken, second. Motion carries, 5:0.

6. Rules and Legislative Updates.

6.1 CR-103E: Refile Request for Medication Assistance.

MOTION: Craig Ritchie moved to approve the authorization to refile CR-103E. Ken Kenyon, second. Motion carries, 12:0.

6.2 CR-105: Approve Rule Language for Technical Fixes.

MOTION: Jerrie Allard moved to approve the rule language for the technical fixes rule language and to amend the scope of the rulemaking package to include edits to WAC 246-945-014, Judy Guenther, second. Motion carries, 12:0.

6.3 CR-103P: Request for CE (Old Rules) Repeal.

MOTION: Craig Ritchie moved to approve request to authorize staff to begin the CR-103P for this rules package, William Hayes, second. Motion carries, 12:0.

6.4 Guidance Document Review for Emergency Schedule II Oral Prescription.

MOTION: Jerrie Allard moved to approve the guidance document without revisions, to remain in effect until either the DEA's guidance is withdrawn, or the commission withdraws this guidance document at a meeting, whichever comes first. Ann Wolken, second. Motion carries, 12:0.

6.5 Rules Petition: Adding Certain Intramammary Antibiotics (WAC 246-945-507)

MOTION: Craig Ritchie moved to approve rules petition and authorize staff to file a CR-101 to amend WAC 246-945-507. Hawkins DeFrance, second. Motion carries, 12:0.

6.6 Rules Petition: Remove Fenfluramine from Schedule IV.

MOTION: Craig Ritchie moved to approve the petition request to remove Fenfluramine from the list of Schedule IV controlled substances and authorize the filing of CR-101 amending WAC 246-945-055 and adding a new WAC in chapter 246-945 to delete Fenfluramine from schedule IV. Jerrie Allard, second. Motion carries, 12:0.

6.7 CR-103E: OTC Designation for Narcan Nasal Spray.

MOTION: Craig Ritchie moved to authorize CR-103E to amend WAC 246-945-030 and add a new section of WAC in chapter 246-945 WAC classifying the 4 mg Narcan naloxone nasal spray as an over-the-counter drug and adopt the proposed rule language with the elimination of subsection 6. The commission also found that there is a need to increase the availability of naloxone to combat opioid overdose in Washington as it is a public health emergency in need of emergency rulemaking. Judy Guenther, second. Motion carries, 12:0.

6.8 CR-105: Approve Rule Language for Incorporations by Reference.

MOTION: Craig Ritchie moved to amend the scope of the expedited rule making package on updating the Commission's incorporation by reference to include amending WAC 246-945-030 and adding a new WAC in chapter 246-945 to classify the 4 mg Narcan naloxone nasal spray as an over-the-counter drug and to approve the rule language presented with the removal of subsection six. Ann Wolken, second. Motion carries, 12:0.

6.9 CR-103P Update: Retired Active Pharmacist License Status.

Joshua Monroe presented a brief update as to the status of the retired active pharmacist license status rule making project stating that the standard CR-103P for establishing a retired active pharmacist license status was filed on March 9, 2023, and went into effect 31 days later on April 9. WAC 246-945-171 allows pharmacists to obtain a retired active license status for the purpose of practicing pharmacy on an intermittent or emergent basis.

Similarly, the 103P was filed for the commission's expedited rule that removes an AIDS education requirement following the 2020 passage of Engrossed Substitute House Bill 1551.

6.10 CR-102 Rules Workshop: Remote Dispensing of OUD Medications (SSB 6086).

MOTION: Craig Ritchie moves to re-approve filing the CR-102 for the remote opioid use disorder dispensing program rule. Ann Wolken, second. Motion carries, 12:0.

6.11 Rules Workshop: Access to Drugs Stored Outside the Pharmacy.

MOTION: Ann Wolken moves to task the Facility Subcommittee with reviewing the draft rule language. Matthew Ray, second. Motion carries, 12:0.

7. Open Forum.

The purpose of the open forum is to provide the public an opportunity to address the commission on issues of significance to or affecting the practice of pharmacy. Discussion items may not relate to topics for which a hearing has or will be scheduled, or which are under investigation. **No comments received.**

8. Summary of Meeting Action Items.

- 2 Follow up with approvals and contingent approvals.
- 3.1 Post revised nonresident directive effective immediately for all new applications but will be in effect for 2024 renewal cycle. Staff will also investigate HELMS capabilities for adding designation on nonresident pharmacies not approved to provide compounded products in WA.
- 3.2 Revise current USP <795> and USP <800> self-inspection worksheets.
- 4.1 The voting delegate, Teri Ferriera, and alternate, Jerrie Allard will take the commission's positions with them to the annual meeting and vote in accordance with these positions on behalf of the commission.

- 4.2 Teri Ferriera and Jerrie Allard will also vote in accordance with the commission's position on amendments to NABP's constitution and bylaws to the annual meeting.
- 4.3 Craig Ritchie will submit a letter of interest and current resume to NABP to serve on the law enforcement and legislative task force by May 12th.
- 4.4 Staff will communicate decision recognizing NetCE as an educational organization to public records unit at the Department of Health.
- 4.5 Staff will send an email to commission on leadership elections at the June meeting.
- 4.6 Staff will amend the 6-month inspection letter to add a sentence that directs corporate offices to ensure their pharmacies receive the letter.
- 4.7 Staff will distribute the commission's statement on Mifepristone with edit to add sentence on requirements related to the REMS Program. Staff will also post the statement to the commission's website.
- 5.1 Communicate re-exam authorization to credentialing.
- 6.1 Refile emergency rules on Medication Assistance.
- 6.2 File the CR-105 with an amended scope to include WAC 246-945-014.
- 6.3 File CR-103P to repeal old continuing education rules.
- 6.4 Staff will make minor revision to guidance document on delivering a signed prescription when an emergency schedule II prescription is dispensed and post it to the commission's website as well as distribute it via GovDelivery.
- 6.5 Staff will send the official commission approval of the WDFW rules petition and file a CR-101 to amend WAC 246-945-507.
- 6.6 Staff will file CR–101 amending WAC 246-945-055 and adding a new WAC in chapter 246-945 WAC to delete Fenfluramine from Schedule IV. The legislative subcommittee may consider future legislative asks related to the drug schedules in chapter 69.50 RCW.
- 6.6b Staff will also file CR-102 to remove Fenfluramine from Schedule IV.
- 6.7 Staff will file a CR-103E to amend WAC 246-945-030 and add a new section of WAC in chapter 246-945 WAC classifying the four mg Narcan naloxone nasal spray as an overthe-counter drug and staff will remove subsection six from the draft rule language.
- 6.8 Staff will file the CR-105 with the rule language for the incorporations by reference rulemaking project as presented today with removing subsection (6) in WAC 246-945-030, some stylistic changes to the incorporations themselves, and adding 2 new sections of WAC (one for OTC Narcan and one to state where incorporated materials can be made available). Staff will bring a review of its incorporations by reference annually moving forward.
- 6.10 Staff will file CR–102 for the remote dispensing of opioid use disorder medications under RCW 18.64.600.
- 6.11 The facility subcommittee will review rule language on access to drugs stored outside of the pharmacy.

Business Meeting Adjourned

Teri Ferreira, Chair, called the meeting adjourned at 1:48 PM.