



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  
October 19, 2023 – Minutes**

Convene: Chair, Ken Kenyon called the meeting to order on October 19, 2023, 9:05 AM.

**Commission Members:**

Ken Kenyon, PharmD, BCPS, Chair  
Hawkins DeFrance, PharmD, 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  
Craig Ritchie, RPh, JD  
Uyen Thorstensen, CPhT  
Ann Wolken, PharmD, RPh

**Absent:**

Matthew Ray, PharmD

**Staff:**

Marlee O’Neill, Executive Director  
Lindsay Trant-Sinclair, Deputy Director  
Shawna Fox, Director, Office of Health Professions  
Harold Wright, Jr., Deputy Director, Office of  
Health Professions  
Christopher Gerard, Assistant Attorney General  
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  
Irina Tiginyanu, Pharmacy Technician Consultant  
Amy L Robertson, Communications Coordinator  
and Program Support

**Guests:**

Bob Nicoloff, Executive Director of the Chiropractic  
Quality Assurance Commission.  
Kyle Karinen, Executive Director of the Washington  
Medical Commission  
Allison Bradywood, Executive Director of the  
Washington State Board of Nursing  
Karl Hoehn, Assistant Director of Legal Services for  
the Washington State Board of Nursing

**1. Call to Order Ken Kenyon, Chair**

**1.1 Meeting Agenda Approval – October 19, 2023**

**MOTION:** Hawkins DeFrance moved to amend the agenda: add Section 9.3, CR105 Expedited Rulemaking on Incorporations by Reference and OTC Drug Products; Craig Ritchie, second; Motion carries, 11:0:1. Abstain: Bonnie Bush.

**MOTION:** Craig Ritchie moved to approve the October 19, 2023, meeting agenda. Uyen Thorstensen, second. Motion carries, 12:0.

### **1.2 Meeting Minutes Approval – August 24, 2023**

**MOTION:** Craig Ritchie moved to approve the August 24, 2023, meeting minutes. William Hayes, second. Motion carries, 12:0.

### **1.3 Meeting Minutes Approval – August 25, 2023**

**MOTION:** Craig Ritchie moved to approve the August 25, 2023, meeting minutes as amended by William Hayes. Teri Ferreira, second. Motion carries, 12:0.

## **2. Consent Agenda**

### **2.1 Correspondence**

- 2.1.1 National Precursor Log Exchange Monthly Dashboard – August-September 2023
- 2.1.2 Pharmaceutical Firms Application Report

### **2.2 Ancillary Utilization Plans Approval**

- 2.2.1 Moses Lake Pharmacy
- 2.2.2 New Health Programs Association Pharmacy
- 2.2.3 North Olympic Healthcare Network
- 2.2.4 Quynhs Pharmacy
- 2.2.5 Sea Mar
- 2.2.6 Sound Prescriptions dba Custom Prescriptions
- 2.2.7 Tukwila Station Pharmacy
- 2.2.8 Wellfound
- 2.2.9 Bellegrove Pharmacy
- 2.2.10 The Vancouver Clinic

### **2.3 Pharmacy Technician Training Program Approval**

- 2.3.1 Howard's Drug
- 2.3.2 Tick Clock Drug
- 2.3.3 Vashon Pharmacy
- 2.3.4 Vet Ex Animal Supply

**MOTION:** Craig Ritchie moved to approve 2.1.1, 2.1.2, 2.2.1, 2.2.2, 2.2.5, 2.2.7, 2.2.10, and 2.3.1. Teri Ferreira, second. Motion carries, 12:0.

### **2.4 Regular Agenda Items Pulled from 2.1, 2.2, or 2.3. The commission will discuss items removed from the consent agenda and placed on the regular agenda for separate discussion.**

### 2.2.3 North Olympic Healthcare Network

**MOTION:** Teri Ferreira moved to approve contingent on updating the language for vaccine or other medication and device administration per the commission's guidance document. Craig Ritchie, second. Motion carries, 12:0.

### 2.2.4 Quynhs Pharmacy

**MOTION:** William Hayes moved to approve contingent staff confirming with licensee to ensure all typographical and grammatical errors are corrected. Craig Ritchie, second. Motion carries, 12:0.

### 2.2.6 Sound Prescriptions dba Custom Prescriptions

**MOTION:** Teri Ferreira moved to approve 2.2.6. Craig Ritchie, second. Motion carries, 11:0. (Hawkins DeFrance, recused).

### 2.2.8 Wellfound

**MOTION:** Teri Ferreira moved to approve 2.2.8. Craig Ritchie, second. Motion carries, 11:0. (Timothy Lynch, recused).

### 2.2.9 Bellegrove Pharmacy

**MOTION:** Timothy Lynch moved to take no action on 2.2.9 pending staff analysis of the AUP submission and a formal agenda item at a future commission meeting for the commission to dedicate the requisite time to discuss technician final product verification. Craig Ritchie, second. Motion carries, 12:0.

### 2.3.2 Tick Clock Drug

**MOTION:** Ann Wolken moved to approve the TTP contingent upon staff ensuring the following edits get made: (1) add language to reflect that the TTP will notify the commission in writing or via email prior to any significant changes to the program, including change in the director, course content, and time frames; (2) remove the statement that the pharmacy is a Class A pharmacy; and (3) add language to ensure compounding is done in compliance with USP 795 and 797. Craig Ritchie, second. Motion carries, 12:0.

### 2.3.3 Vashon Pharmacy

**MOTION:** Ann Wolken moved to approve contingent upon staff ensuring the following edits get made: (1) add language to reflect that the TTP will notify the commission in writing or via email prior to any significant changes to the program; (2) add language that all student-specific records must either be retained on-site and kept for a minimum of 2 years, as well as be made

available within 72 hours upon request; and (3) add language to ensure compounding is done in compliance with USP 795 and 797. Craig Ritchie, second. Motion carries, 12:0.

### **3. Rulemaking for the Remote OUD Dispensing Sites**

#### **3.1 Public Hearing – WAC 246-945-457. The hearing opened at 9:32 AM.**

Joshua Munroe provided an overview of the rules package on SSB6086 – RCW 18.64.600 requiring the commission to adopt rules establishing minimum standards of remote OUD dispensing sites.

Joshua reported that no public comments directly pertaining to the project topic were received during the public comment period. A public comment email was received prior to the hearing, but the commission determined that the subject of inquiry and the requested changes focused on sections of rule (chapter 246-341 WAC) that were neither mentioned in the rulemaking package nor were under the commission’s regulatory jurisdiction.

The public rules hearing was opened for public testimony at 9:32 AM. The Commission requested to receive oral testimony from the public, but no oral testimony from the public was received. The public rules hearing was closed at 9:35 AM.

#### **3.2 Approval of Comment Responses and Authorization to file CR-103P (SSB 6086 Rulemaking).**

The only suggested change during the commission’s discussion of the rules package was to change the term “using this registration” to “holding this registration” in the rule language to more accurately reflect how licensees seeking to extend their licenses to manage a remote OUD dispensing site would interact with the registration.

**MOTION:** Craig Ritchie moved to approve the draft responses to comments received, ”, moved to adopt the rule language including the change to the term “using this registration” to “holding this registration” in the rule language to more accurately reflect how licensees seeking to extend their licenses to manage a remote OUD dispensing site would interact with the registration, and moved to authorize staff to file the CR103p. Patrick Gallaher, second. Motion carries, 12:0.

### **4. Rulemaking for Health Equity CE Standards**

#### **4.1 Public Hearing – CR-102 rules proposal amending WACs 246-945-178 and 246-945-220. Hearing opened at 10:31**

Joshua Munroe provided a brief overview on the rules package focused on establishing health equity continuing education standards for pharmacists and pharmacy technicians. Joshua reported that no written comments were received during the public comment period.

The public rules hearing was opened for public testimony at 10:31 AM. The Commission requested to receive oral testimony from the public, but no oral testimony from the public was received. The public rules hearing was closed at 10:34 AM.

#### **4.2 Approval of Comment Responses and Authorization to file CR 103P (Health Equity CE Rulemaking**

**MOTION:** Craig Ritchie moved to adopt the rule language to WACs 246-945-178 and 246-945-220 and authorize staff to file the CR103p. Bonnie Bush, second. Motion carries, 12:0.

### **5. Old Business.**

#### **5.1 Title 21 CFR 1306.08: Transfer of Controlled Substance Prescriptions**

**MOTION:** Craig Ritchie moved to approve the FAQ without edits and to publish it on the commission website. Bonnie Bush, second. 12:0.

#### **5.2 FDA Proposed Rule: Patient Medication Information**

**MOTION:** Craig Ritchie moved to approve the letter with staff updating the commission's phone number. Hawkins DeFrance, second. 12:0

**MOTION:** Craig Ritchie moved to add the additional language to the approved letter noting that the proposed regulation imposes an unworkable mandate and does not adequately facilitate the availability of PMI to those that are visually impaired, print disabled, or limited English proficiency. Hawkins DeFrance, second. 12:0.

#### **5.3 Policy Statement on Compliance with Revised USP General Chapters <795> and <797>**

**MOTION:** Craig Ritchie moved to approve the policy statement. Teri Ferreira, second. 12:0

### **6. Informational Session**

#### **6.1 Presentation from the Executive Directors for the Chiropractic Commission, Medical Commission, and Board of Nursing for the purpose of future PQAC strategic planning.**

Marlee O'Neill introduced guests:

- Bob Nicoloff, Executive Director of the Chiropractic Quality Assurance Commission.
- Kyle Karinen, Executive Director of the Washington Medical Commission
- Allison Bradywood, Executive Director of the Washington State Board of Nursing
- Karl Hoehn, Assistant Director of Legal Services for the Washington State Board of Nursing.

The guests presented information on how their respective boards and commissions operates as partner boards and commissions within the Department of Health.

### **7. Panel Review.**

**MOTION:** Teri Ferreira moved to delegate the study plan reviews to Panel C (William Hayes, Jerrie Allard, Uyen Thorstensen, Ken Kenyon, and Ann Wolken). Patrick Gallaher, second. Motion carries, 12:0.

## **7.1 PHRM.PH. 61348645**

**MOTION:** Uyen Thorstensen moved to approve the study plan review Ken Kenyon, second. Motion carries, 5:0.

## **8. New Business**

### **8.1 RCW 18.130.077 (2SHB 1724, Section 8) and Substantial Equivalency**

**MOTION:** Hawkins DeFrance moved to follow the current procedures for pharmacy assistants and pharmacy interns, respectively, for out-of-state applicants. Craig Ritchie, second. Motion carries, 12:0.

**MOTION:** Patrick Gallaher moved that the eight hours of guided study are a core licensing requirement, which results in no other state being substantially equivalent for out-of-state pharmacy technician applicants. Uyen Thorstensen, second. Motion carries, 12-0.

**MOTION:** Craig Ritchie moved that there may be other states that have substantially equivalent standards to Washington, but the Commission is unable to “waive” the Washington MPJE requirement as required by RCW 18.130.077 because of the mandate in RCW 18.64.080(5), and directed staff to proceed with the license transfer application process when applicable for out-of-state pharmacist applicants. Jerrie Allard, second. Motion carries, 12:0.

## **9. Rules and Legislative Updates.**

### **9.1 CR-103P Authorization: Title 21 CFR Incorporation by Reference (WAC 246-945-040)**

**MOTION:** Craig Ritchie moved to approve the filing of the CR-103p rules adoption for the incorporation by reference of sections Title 21 CFR sections into WAC 246-945-040. Uyen Thorstensen, second. 12:0

### **9.2 OTC Naloxone Emergency Rule Refile Request**

**MOTION:** Jerrie Allard moved to approve the refiling of the emergency rule language with the updated language. Craig Ritchie, second. 12:0

**MOTION:** Craig Ritchie moved to also find that there is an opioid public health crisis in the state of Washington and the lifesaving OTC naloxone products proposed in the rule will save lives and aid in addressing this public health emergency. As a result, the Commission findings that refiling the emergency rule is necessary for the preservation of the public health, safety, and general welfare, and that observing the time requirements of notice and opportunity to comment upon adoption of a permanent rule would be contrary to the public interest. William, second. 12:0.

### **9.3 CR-105: Expedited Rulemaking on Incorporations by Reference and OTC Drug Products**

**MOTION:** Bonnie Bush moved to approve the new language in the CR-105. Craig Ritchie, second. 12:0

## 10. Open Forum.

- **Dr. Julie Akers, Washington State University College of Pharmacy and Pharmaceutical Sciences**  
Dr. Akers asked the commission to consider amending WAC 246-945-155(3) to allow pharmacy interns to renew their credentials more than twice.

**MOTION:** Teri Ferreira moved to add Dr. Akers' request to a future agenda. Craig Ritchie, second. 12:0

- **Dr. Gail Elliot, Kaiser Family Foundation of Washington** – Dr. Elliot asked the commission to consider providing clarification on RCW 18.64.450(4).

Marlee O'Neill informed the commission and Dr. Elliot this topic is already in our queue and tentatively on the December business meeting .

## 11. Commission Member Reports

### 11.1 Budget

Patrick Gallaher informed the commission that overall the fund balance is healthy. Recent legislation, among other things, is impacting accounting staff but they are making progress on updating items affected. There is a discrepancy between estimated revenue and actual revenue for September 2023. We were able to see that license counts remain steady. This is due to the move to the 2-year renewal cycle that began in December 2021. We anticipate seeing more renewal revenue starting in December 2023. WE noticed a decrease in HCE licenses which may be due to closures or the consolidation of HCEs.

### 11.2 Open Discussion

- Patrick Gallaher requested staff provide clarification on WAC 246-945-310 and the designated responsible person in USP.
- Jerrie Allard requested the following items be on the December agenda.
  - Debrief of the partner board and commission panel discussion.
  - Update on accessible labeling and significant analysis and small business impact statement

## 12. Staff Reports

### 12.1 Executive Director

- Attended the NABP executive officer, compliance officer, and legal counsel forum with Si Bui. There were sessions on artificial intelligence, the DSCSA, and other emerging topics.
- Lindsay, Si, and Marlee will present at the WSPA annual meeting on November 4.
- Marlee will present at the SWPA meeting later in November.

## 12.2 Deputy Director

- Staffing
  - Joanne Miller's last day was August 31
  - New Staff: Julia Katz, Program Support
  - OILS - Ashley Maxwell no longer with DOH
  - Rayne Pearson will take over as deputy director for OILS.
  - Rayne and Judie Morton will attend the December business meeting to update the commission on OILS.
- Commissioner Candidates – Staff submitted a public packet to the Governor.
- SSB1009 – Military Spouse – mandatory training NLT December 31. Staff send reminders to commissioners.

## 12.3 Pharmacist Inspector Supervisor

- New inspector Justin Sisney started on October 1.
- Attended the NABP executive officer, compliance officer, and legal counsel forum in Chicago with Marlee

## 12.4 Assistant Attorney General

## 13. Summary of Meeting Action Items.

- 1.3 – Meeting Minutes Approval 8/25: Make proposed edit to minutes before posting on the commission's website.
- Consent Agenda
  - Convey the decisions on AUPs and TTPs to the applicants and the Office of Customer Service.
  - Staff will provide an analysis related to the AUP submitted today on technician final product verification and add it as a future agenda item for further discussion.
- 3.2 – Approval of Comment Responses and Authorization to file CR-103P: File CR-103P with minor edit to rule language on "holding the registration" rather than "using this registration".
- 4.2 – Approval of Comment Responses and Authorization to file CR-103P: File CR-103P on health equity continuing education.
- 5.1 – Title 21 CFR 1306.08 Transfer of CS Prescriptions: Replace the commission's FAQ on transfer of controlled substances on its website to the one presented today related to 21 CFR 1306.08
- 5.2 – FDA Proposed Rule: Patient Medication Information: Make two minor edits as well as add the additional statement revisited today to the letter to the FDA on patient medication information discussed today and begin department review process. Will submit to the FDA by November 27
- 5.3 – Policy Statement on Compliance with Revised USP General Chapters 795 and 797: Post policy statement on Compliance with Revised USP General Chapters 795 and 797 after Department review
- 7.1 – PHRM.PH.61345645: Communicate approval to credentialing
- 8.1 – Carry out the commission's determinations related to RCW 18.130.077
- 9.1 – File CR-103P on the incorporation by reference of Title 21 CFR in WAC 246-945-040.



- 9.2 – Refile emergency rule language on designation of OTC naloxone with updated rule language.
- 9.3 – File CR-105 on incorporations by reference and designation of OTC drug products with updated language
- Staff will send out instructions on how to complete the military spouse training.

**Business Meeting Adjourned, 3:50 PM.**