

## Pharmacy Quality Assurance Commission June 27, 2024 - Minutes

Convene: Vice Chair, Hawkins DeFrance called the meeting to order June 27, 2024, 9 a.m.

### **Commission Members:**

Hawkins DeFrance, Vice Chair  
Jerrie Allard  
Bonnie Bush (departed at noon)  
Patrick Gallaher  
Judy Guenther  
Matthew Ray  
Craig Ritchie  
Uyen Thorstensen  
Ann Wolken  
Huey Yu

### **Commission Members**

#### **Absent:**

Stephanie Bardin  
Teri Ferreira  
William Hayes  
Kenneth Kenyon, Chair

### **Staff:**

Marlee O’Neill, Executive Director  
Lindsay Trant-Sinclair, Deputy Director  
Si Bui, Inspector Supervisor  
Chris Gerard, AAG  
Rachel Sahi  
Taifa “Nomi” Peaks  
Joshua Munroe  
Haleigh Mauldin  
Julia Katz  
Irina Tiginyanu  
Amy Robertson

## **1. Call to Order Hawkins DeFrance, Vice Chair**

### **1.1. Meeting Agenda Approval – June 27, 2024**

**MOTION:** Craig Ritchie moved to approve the amended business meeting agenda removing agenda item number 4, panel review, for June 27, 2024. Huey Yu, seconded. Motion carried, 11:0.

### **1.2. Meeting Minutes Approval – May 2, 2024**

**MOTION:** Craig Ritchie moved to approve the business meeting minutes for May 2, 2024. Ann Wolken, seconded. Motion carried, 11:0.

### **1.3. Meeting Minutes Approval – May 3, 2024**

**MOTION:** Craig Ritchie moved to approve the business meeting minutes for May 3, 2024. Ann Wolken, seconded. Motion carried, 11:0.

## **2. Consent Agenda**

### **2.1. Correspondence**

- 2.1.1.** National Precursor Log Exchange Monthly Dashboard – April and May
- 2.1.2.** Pharmaceutical Firms Application Report
- 2.1.3.** 2025 Proposed Business Meeting Dates

**2.2. Ancillary Utilization Plans Approval**

- 2.2.1.** Cardinal Health
- 2.2.2.** Cascadia Pharmacy – Wallingford
- 2.2.3.** QFC Pharmacy – multiple locations
- 2.2.4.** Hoagland Pharmacy
- 2.2.5.** Key Compounding Pharmacy
- 2.2.6.** Ralph’s Thriftway Pharmacy
- 2.2.7.** Community Health Care

**2.3. Pharmacy Technician Training Program Approval**

- 2.3.1.** Community Health Care
- 2.3.2.** HealthPoint
- 2.3.3.** Klickitat Valley Health
- 2.3.4.** Mega Pharmacy
- 2.3.5.** North Olympic Healthcare Network
- 2.3.6.** Pullman Regional Hospital
- 2.3.7.** Valu Drug

**MOTION:** Craig Ritchie moved to approve the consent agenda with the exception of items 2.1.3 2025 Proposed Business Meeting Dates, 2.2.5 Key Compounding Pharmacy, and 2.3.1 Community Health Care. Ann Wolken, seconded. Motion carried, 11:0.

**2.4. Regular Agenda Items Pulled from 2.1, 2.2, or 2.3.**

**2.1.3 2025 Proposed Business Meeting Dates**

**MOTION:** Jerrie Allard moved to approve item 2.1.3 2025 Proposed Business Meeting Dates. Craig Ritchie, seconded. Motion carried, 11:0.

**2.2.5 Key Compounding Pharmacy**

**MOTION:** Ann Wolken moved to approve 2.2.5 Key Compounding Pharmacy. Craig Ritchie, seconded. Motion carried, 11:0.

**2.3.1 Community Health Care**

**MOTION:** Uyen Thorstensen moved to approve 2.3.1 Community Health Care contingent on removal of the statement “should any changes occur, the commission will be notified within 30 days” from the AUPs attached to the TTP. Patrick Gallaher, seconded. Motion carried, 11:0.

### 3. Presentations

#### 3.1. National Association of Boards of Pharmacy (NABP) – Workplace Conditions

Neal Watson (NABP Member Relations/Government Affairs Director) and Andrew Funk (PharmD, Member Relations/Government Affairs Director) presented information on work NABP has done around workplace conditions.

#### 3.2. Office of Financial Services – Budget Report

Ashley May, Budget Analyst with the Office of Financial Services, presented the budget report.

#### 3.3. HELMS Update (Healthcare Enforcement and Licensing Management System)

Elizabeth Geisler, HELMS Business Deputy Project Director, provided an update on the HELMS project. HELMS will replace the current system, ILRS (Integrated Licensing and Regulatory System).

#### 3.4. Office of Community Health Systems Approach to Fine Severity Matrix Rulemaking

Julie Tomaro, Facilities Program Manager in the Office of Community Health Systems, presented her experience conducting rulemaking to develop a fining severity matrix for both psychiatric and acute care hospitals.

#### 3.5. ESHB 1503 – Health Professionals Licensure Information Collection

Kevin Ninkovich, Deputy Director of Operations in the Office of Health Professions, discussed the implementation of ESHB 1503 that requires the department to collect certain demographic data from licensees.

### 4. Panel Review – Removed from the agenda.

### 5. New Business

#### 5.1. List and Label Request

Haleigh Mauldin presented the list and label request from the Institute of Natural Resources.

**MOTION:** Jerrie Allard moved to recognize the Institute of Natural Resources as an educational organization. Ann Wolken, seconded. Motion carried, 10:0.

### 6. Old Business

#### 6.1. Presentation on DSCSA

Christopher Gerard, AAG, presented on the Drug Supply Chain Security Act (DSCSA).

**MOTION:** Matthew Ray moved to direct staff to research how other states are implementing the DSCSA and bring the information back to a future commission meeting. Judy Guenther, seconded. Motion carried, 10:0.

## 6.2. Nonresident Pharmacy Directive

Taifa “Nomi” Peaks, PharmD, consultant, presented the nonresident pharmacy directive and led a discussion on substantial equivalency.

**MOTION:** Matthew Ray moved that requiring compliance with USP <800> is necessary for an inspection program to be approved as having substantially equivalent standards to those of the commission for the purposes of RCW 18.64.360(1)(b)(i). Craig Ritchie, seconded. Motion carried, 10:0.

**MOTION:** Jerrie Allard moved that inspection programs will be approved as having substantially equivalent standards to those of the commission for the purposes of RCW 18.64.360(1)(b)(i) even if the inspection program has implemented a policy of delaying enforcement of the revised USP chapters <795> and <797>.Matthew Ray, seconded. Motion carried, 10:0.

**MOTION:** Matthew Ray moved that inspection programs that exclude the addition of flavoring from the definition of “compounding” and compliance with USP chapter <795> would not be approved as having substantially equivalent standards to those of the commission for the purposes of RCW 18.64.360(1)(b)(i). Jerrie Allard, seconded. Motion carried, 10:0.

## 6.3. Overview of Regulations on Telepharmacy

Taifa “Nomi” Peaks, PharmD, consultant, presented on telepharmacy regulations in other states and Canadian provinces.

## 7. Rules Updates

### 7.1. Ancillary Pharmacy Personnel Rulemaking Update

Haleigh Mauldin, Program Consultant, requested the Pharmacy Technician Final Product Verification and the Pharmacy Assistant Scope of Practice rules projects be combined into one CR-101.

**MOTION:** Jerrie Allard moved to authorize combining the Pharmacy Technician Final Product Verification rules project and the Pharmacy Assistant Scope of Practice rules project into a single CR-101. Matthew Ray, seconded. Motion carried, 10:0.

**7.2. Emergency Rule (CR-103E) Refile Request: Naloxone**

Haleigh Mauldin, Program Consultant, requested authorization to refile the emergency rule CR-103E on Naloxone as over-the-counter status while permanent rulemaking is ongoing.

**MOTION:** Craig Ritchie moved to authorize the refiling the CR-103E on Naloxone as over the counter status as there is an emergent need to extend this rule for the health and safety of the public based upon the ongoing opioid crisis. Patrick Gallaher, seconded. Motion carried, 10:0.

**7.3. Rules Workshop: Mobile Opioid Treatment Program Units**

Haleigh Mauldin, Program Consultant, presented the draft rule language for mobile opioid treatment program units.

**MOTION:** Matthew Ray moved that this topic be placed on the August 2024 meeting agenda in order to allow more time to solicit public feedback. Craig Ritchie, seconded. Motion carried, 10:0.

**7.4. Rules Petition Request: Classifying Kratom as a Schedule I Controlled Substance**

Joshua Munroe, Rules and Legislative Consultant, presented a petition request to classify kratom—including its active alkaloids mitragynine and 7-hydroxymitragynine as a Schedule I controlled substance.

**MOTION:** Craig moved to approve the rules petition and authorize staff to file a CR-101 to consider kratom, including its active alkaloids mitragynine and 7-hydroxymitragynine, as a Schedule I controlled substance. Jerrie Allard, seconded. Motion carried, 10:0.

**8. Strategic Plan Update.**

Marlee O'Neill, Executive Director and Lindsay Trant-Sinclair, Deputy Director, updated the commission on the strategic plan implementation and reviewed the recurring dates calendar.

**MOTION:** Jerrie Allard moved to approve the calendar adding the JOA and bylaws review, Craig Ritchie, seconded. Motion carried, 10:0.

**9. Leadership Elections**

The commission entertained nominations for Chair and Vice Chair and the following individuals accepted nominations for those positions.

**MOTION:** Matthew Ray moved to approve Hawkins DeFrance's nomination as Chair for the Washington State Pharmacy Quality Assurance Commission effective July 1, 2024. Huey Yu, second. Motion carries, 10:0.

**MOTION:** Jerrie Allard moved to approve Ann Wolken’s nomination for Vice Chair for the Washington State Pharmacy Quality Assurance Commission effective July 1, 2024. Matthew Ray, second. Motion carries, 10:0.

**10. Open Forum**

- Jenny Arnold, Washington State Pharmacy Association addressed the commission regarding the technician training endorsement.
- Cindi Hoenhouse, Washington Patients in Intractable Pain addressed the commission regarding the difficulty chronic pain patients are having in obtaining their prescription medication.
- Boris Zhang, Washington State Pharmacy Association addressed the commission noting that the MPJE study guide was recently removed from the website.

**11. Commission Member Reports**

**11.1. NABP Annual Meeting Report Out**

Hawkins DeFrance reported that he, Ken Kenyon, Marlee O’Neill, and Lindsay Trant-attended the 120<sup>th</sup> annual NABP meeting. Meeting attendees, in addition to routine business, discussed numerous topics including healthcare provider wellbeing and AI in healthcare.

**11.2. Alternate Distribution Model Task Force Report Out**

The Alternate Distribution Model Task Force met on June 13th. Staff prepared a preliminary outline and received feedback from the public as well as task force members.

**11.3. Open Discussion Related to Items or Issues Relevant to Commission Business/Pharmacy Practice**

- Matthew Ray addressed the commission regarding the wellbeing of pharmacy personnel and overlap with the Department of Labor and Industries (L&I).

**MOTION:** Matthew Ray moved to have staff contact L&I staff and invite L&I staff to present to the commission regarding its regulations. Teri Ferreira, second. Motion carries, 10:0.

**12. Staff Reports**

**12.1. Executive Director – Marlee O’Neill**

- Attended the NABP meeting with Hawkins DeFrance, Ken Kenyon, and Lindsay Trant-Sinclair.

- Attended the Office of Health Professions Board, Commission, and Committee leadership conference.
- Kudos to the commission’s rules staff who were highlighted during a recent agency rules training.

**12.2. Deputy Director – Lindsay Trant-Sinclair**

- Northwest Pharmacy Convention in Coeur d’Alene – Lindsay presented with Joshua Munroe and Shelly Feldner-Schuerman.
- Staffing
  - Desiré Gudmundson will be transitioning to a credentialing specialist position.
  - The AA3 position has been posted.

**12.3. Pharmacist Supervisor – Si Bui**

With Inspector Stephanie Martin’s departure, there is one inspector vacancy we will be working to fill.

**12.4. Pharmacist Consultant – Taifa “Nomi” Peaks**

The Board of Nursing created an interagency aesthetics work group that will be meeting regularly to address issues across professions related to the aesthetics industry.

**12.5. Assistant Attorney General – Christopher Gerard – nothing to report.**

**13. Summary of Meeting Action Items**

- **1.2 Meeting Minutes** – staff will finalize the minutes and post them on the commission’s website.
- **2 Consent Agenda** – staff will convey the decisions to the applicants and the Office of Customer Service and file the 2025 commission business meetings dates with the code revisor and add it to our website.
- **5.1 List and Label Request** – staff will convey the decision to the public disclosure unit.
- **6.1 DSCSA Presentation** – staff will research what other states are doing and bring it back to the commission at a future business meeting.
- **6.2 Nonresident Pharmacy Directive** – staff will revise the nonresident pharmacy directive as voted on today and bring it back to the commission at a future meeting.
- **6.3 Overview of Telepharmacy Regulations** – staff will continue to follow the strategic plan for telepharmacy.
- **7.1 Ancillary Pharmacy Personnel Rulemaking Update** –Staff will file the combined CR-101 related to both pharmacy assistant scope of practice and pharmacy technician final product verification rulemaking.
- **7.2 Emergency Rule Refile Request on Naloxone** – staff will refile the CR-103E.
- **7.3 Rules Workshop – OTP mobile units** – staff will send out the draft rule for public feedback again and put this on the August business meeting agenda.

- **7.4 Rules Petition – Classify Kratom as Schedule I CS** – staff will send petition approval letter and file a CR-101 to consider scheduling Kratom as a Schedule I Controlled substance.
- **8.2 Commission Recurring Dates Calendar** – staff will finalize and post the recurring dates calendar to Box.com.
- **9 Leadership Elections** – staff will update the website to reflect the new leadership.
- **10 Open Forum** – staff will post the updated MPJE study guide when its complete.
- **11.3 Open Commission Discussion** – staff will engage with L&I as directed.

**4:17 pm** Business Meeting Adjourned