



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  
November 17th, 2022 - Minutes**

Convene: Chair, Teri Ferreira called the meeting to order November 17, 2022, 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  
Timothy Lynch, PharmD, MS, FABC, FASHP  
Matthew Ray, PharmD  
Ken Kenyon, PharmD, BCPS  
Ann Wolken, PharmD, RPh

***Staff:***

Shawna Fox, OHP Office Director  
Traci Orr, OHP Deputy Director  
Marlee O’Neill, Executive Director  
Lindsay Trant-Sinclair, Deputy Director  
Christopher Gerard, AAG  
Irina Tiginyanu, Pharmacy Technician Consultant  
Joshua Munroe, Legislative and Rules Consultant  
Taifa “Nomi” Peaks, Pharmacist Consultant  
Haleigh Mauldin, Program Consultant  
Amy L Robertson, Communications Coordinator  
and Program Support

***Commission Members Absent:***

William Hayes, PharmD CCHP  
Bonnie Bush, Public Member

**1. Call to Order Terri Ferreira, Chair.**

**1.1 Meeting Agenda Approval – November 17, 2022.**

**MOTION:** Craig Ritchie moved to approve the business meeting agenda for November 17, 2022. Jerrie Allard, second. Motion carries, 11-0.

**1.2 OHP Office Director and Deputy Office Director Introductions.**

Shawna Fox stepped in as the Office Director of OHP in July 2022. Traci Orr has been serving as Deputy Director since 2021 and has since taken on the role permanently.

**1.3 Meeting Minutes Approval – Special Meeting – August 5, 2022.**

**MOTION:** Ken Kenyon moved to approve the special meeting minutes for August 5, 2022. Ann Wolken, second. Motion carries, 11:0.

**1.4 Meeting Minutes Approval – Special Meeting – August 24, 2022.**

**MOTION:** Craig Ritchie moved to approve the meeting minutes for August 24, 2022. Ken Kenyon, second. Motion carries, 11:0.

### **1.5 Meeting Minutes Approval – September 22, 2022.**

**MOTION:** Craig Ritchie moved to approve the meeting minutes for September 22, 2022. Ken Kenyon, second. Motion carries, 11:0.

### **1.6 Meeting Minutes Approval – September 23, 2022.**

**MOTION:** Craig Ritchie moved to approve the meeting minutes for September 23, 2022. Ken Kenyon, second. Motion carries, 11:0.

## **2. Consent Agenda.**

### **2.1 Ancillary Utilization Plans Approval.**

- 2.1.1** Aberdeen Health Mart/Aberdeen Pharmacy
- 2.1.2** Costco Pharmacy
- 2.1.3** Davenport Good Neighbor Pharmacy
- 2.1.4** Edmonds Pharmacy
- 2.1.5** ICHS Bellevue Pharmacy
- 2.1.6** Island Health Pharmacy
- 2.1.7** Key Compounding Pharmacy
- 2.1.8** Lincoln Pharmacy
- 2.1.9** Makers Pharmacy
- 2.1.10** Yakima Valley Memorial Pharmacy (North Star Lodge)
- 2.1.11** RK LTC Pharmacy
- 2.1.12** Union Avenue Compounding Pharmacy
- 2.1.13** Valley View Health Center Pharmacy
- 2.1.14** Yakima Valley Memorial Hospital Pharmacy

### **2.2 Pharmacy Technician Training Program Approval.**

- 2.2.1** Centralia Pharmacy
- 2.2.2** Costco Pharmacy
- 2.2.3** Jefferson Healthcare
- 2.2.4** Kittitas Valley Healthcare
- 2.2.5** Makers Pharmacy
- 2.2.6** Optum Pharmacy
- 2.2.7** Saars Pharmacy

### **2.3 Regular Agenda/Items Pulled from 2.1 and 2.2.**

#### **Items pulled:**

- 2.1.2 Costco Pharmacy
- 2.1.3 Davenport Good Neighbor Pharmacy
- 2.1.5 ICHS Bellevue Pharmacy
- 2.1.10 Yakima Valley Memorial Hospital (North Star Lodge)
- 2.1.14 Yakima Valley Memorial Hospital
- 2.2.4 Kittitas Valley Healthcare
- 2.2.7 Saars Pharmacy

**Recusals:**

Ann Wolken: **2.2.5, 2.2.6**; Timothy Lynch: **2.1.10, 2.1.14**.

**MOTION:** Craig Ritchie moved to approve the agenda with the exception of 2.1.2, 2.1.3, 2.1.5, 2.1.10, 2.1.14, 2.2.4, 2.2.7. Patrick Gallaher, second. Motion carries, 11:0.

**MOTION:** Craig Ritchie moved to approve AUP 2.1.2 Costco Pharmacy. Hawkins DeFrance, second. Motion carries, 11:0.

**MOTION:** Teri Ferreira moved to approve 2.1.3 Davenport Good Neighbor Pharmacy and 2.1.5 ICHS Bellevue Pharmacy with the recommendation being contingent on the following changes: update old WAC references in 2.1.3 and 2.1.5; update licensure reference from one year to two years in 2.1.5; and add that self-inspection is required within 30 days of change in responsible pharmacy manager in 2.1.5. Craig Ritchie seconds. Motion carries, 11:0.

**MOTION:** Teri Ferreira moved to approve 2.1.10 and 2.1.14 with the recommendation being contingent on the following changes: to update RCW to tech utilization RCW and update reference to two-year license cycle. 2.1.14's approval is also contingent on updating RCW to tech training program reference in chapter 18.64A RCW. Craig Ritchie, second. Motion carries, 10:0. (Timothy Lynch recused)

**MOTION:** Ann Wolken moved to approve 2.2.4 and 2.2.7 contingent on approval to add specific policies and procedures. Craig Ritchie, second. Motion carries, 11:0.

NOTE: Consent Agenda matters were tabled due to Public Hearing and resumed after Public Hearings were officially closed.

**3. Rulemaking for Reuse and Donation of Unexpired Prescription Drugs (SSB 6526).**

**3.1 PUBLIC RULES HEARING.**

Teri Ferreira, Chair, opened the public rules hearing at 9:21 AM. The purpose of this hearing was to propose adding a new section in chapter 246-945 WAC for the implementation of Substitute Senate Bill (SSB) 6526 (Laws of 2020), an act relating to the reuse and donation of unexpired prescription drugs.

Joshua Munroe provided a brief overview to the commission on the specifics of the CR-102 rule proposal filed under WSR 22-20-100 which introduces rule language for two new proposed sections of rule, WACs 246-945-486 and 246-945-488. Following the briefing the commission opened the floor to comments from interested parties.

Public Comment: George Wang; (Co-Founder of Sirum), testified in support of rules generally, but also provided amendments.

The comment from George Wang was delivered as an oral public comment in addition to previously submitted written comments. These were the only comments received by the commission.

Teri Ferreira, Chair, closed the hearing on WAC 246-945-486 and WAC 246-945-488 at 9:27 AM.

### **3.2 Approval of Comment Responses and Authorization to File CR-103P (SSB 6526 Rulemaking).**

**MOTION:** Timothy Lynch moved to accept proposed responses as edited today. Craig Ritchie, second. Motion carries, 11:0.

**MOTION:** Craig Ritchie moved to approve rule language including substantive edit to WAC 246-945-488 on prescriber notification, file supplemental CR-102, schedule public hearing on amended provision. Motion carries, 11:0.

**NOTE:** Approval of Comment Responses was tabled due to Public Hearing timing and resumed after Public Hearings were officially closed.

## **4. Rulemaking for the Retired Active Pharmacist License Status.**

### **4.1 PUBLIC RULES HEARING.**

Teri Ferreira, Chair, opened the public rules hearing on WAC 246-945-171 at 10:30 AM. The purpose of this hearing was to propose adding a new section in chapter 246-945 WAC to allow retired pharmacists to apply for a retired active pharmacist license status and practice pharmacy in emergent situations or intermittently.

Joshua Munroe provided a brief overview and background information on the issue, noting the importance of the rule language that was approved by the commission and filed with the CR-102 included continuing education requirements.

One written comment was received from an anonymous attendee regarding clarification of the rule.

Teri Ferreria, Chair, closed the hearing on WAC 246-945-171 at 10:34 AM.

### **4.2 Approval of Comment Responses and Authorization to File CR-103P (Retired Active Pharmacist License Status Rulemaking).**

**MOTION:** Craig Ritchie moved to approve responses to received comments, adopt WAC 246-945-171 and to authorize staff to file CR 103P. Timothy Lynch, second. Motion passes, 11:0

## **5. Old Business.**

### **5.1 Designation of Presiding Officer for Brief Adjudicative Proceedings.**

**MOTION:** Craig Ritchie moved to approve. Hawkins De France, second. Motion carries, 11:0.

### **5.2 Revised USP 795 and 797 Update.**

Lindsay Trant-Sinclair provided an update stating that staff are aware that the revised USP chapters 795 and 797 are now available and that the new chapters are under review. The revised 795 and 797 will not be official until November 1, 2023. No action deemed necessary by the commission at this time, but the topic will be placed on a future agenda.

Comment from Erika Anderson: Suggested the commission consider a statement on whether early adoption is allowed.

### **5.3 FAQs from Plan-19 for Review.**

Nomi Peaks updated the commission that Plan-19 was removed from the website with the state of emergency coming to an end; however, several FAQs were presented to the commission from Plan-19 that could be posted to the website as they are still relevant without the state of emergency.

**MOTION:** Timothy Lynch moved to approve FAQs. Craig Ritchie, second. Motion carries, 11:0.

## **6. Executive Session – CLOSED to the Public.**

The commission convened an executive session to discuss with legal counsel representing the commission matters relating to litigation or potential litigation to which the commission is, or is likely to become, a party, when public knowledge regarding the discussion is likely to result in an adverse legal or financial consequence to the commission pursuant to RCW 42.30.110(1)(i).

## **7. New Business.**

### **7.1 Out-of- Country Wholesalers.**

**MOTION:** Timothy Lynch moved to reaffirm that the commission does not have authority to issue credentials to out-of-country wholesalers and out-of-country pharmacies. Craig Ritchie, second. Motion carries, 11:0.

### **7.2 NABP District 8 Resolution.**

NABP's District 8 has put forth a resolution for the Pharmacy Quality Assurance Commission to consider supporting.

**MOTION:** Timothy Lynch moved to decline offer to support. Craig Ritchie, second. Motion carries, 11:0.

### **7.3 List and Label Request.**

The commission has a list and label request to consider approving.

**MOTION:** Timothy Lynch moved to approve WSPA list and label request. Ken Kenyon, second. Motion carries, 11:0.

### **7.4 Proposed Changes to 2023 Meeting Dates.**

Due to scheduling conflicts, some schedule changes are needed to the 2023 meeting dates.

**MOTION:** Timothy Lynch moved to approve changes to 2023 meeting dates. Hawkins DeFrance, second, Motion carries, 11:0.

## **8. Rules and Legislative Updates.**

### **8.1 PQAC Representative(s) for Office of Health Professions 2023 Weekly Legislative Update Call and PQAC Weekly Legislative Calls.**

OHP will host its weekly Legislative Update Calls for board and commission members. They have asked for two representatives from each board and commission to attend.

**MOTION:** Timothy Lynch moved to appoint Craig Ritchie and William Hayes to be PQAC representatives on OHP calls. Jerrie Allard, second. Motion carries, 11:0.

### **8.2 Update on OTC – only Wholesaler Rulemaking.**

Lindsay Trant-Sinclair provided a brief update. This rulemaking has been on hold as other projects have taken precedence. As the FDA is working on rulemaking related to wholesaler requirements, this project will remain on hold until the FDA completes their rulemaking. The commission deemed no action necessary at this time.

### **8.3 Authorization to Refile Retired Pharmacist Emergency Rule.**

The commission has emergency rules on the retired active pharmacist license status under WSR 22-20-023 that will expire in January 2023.

**MOTION:** Craig Ritchie moved to refile emergency rule and withdraw when permanent rule is in effect. Ken Kenyon, second. Motion carries, 11:0.

### **8.4 Proposed Update to Incorporation of 21 CFR in WAC 246-945-040.**

WAC 246-945-040 not only incorporates 21 CFR, but it also excludes certain sections. Updates were needed to which sections the commission is both incorporating and not incorporating in WAC 246-945-040.

**MOTION:** Craig Ritchie moved to approve amended rule language with proposed attachment inserted and file CR-105. Patrick Gallaher, second. Motion carries, 11:0.

### **8.5 Accessible Labeling Rulemaking – Survey Data Review.**

In October 2022, staff completed and conducted a survey to determine current practices and identified barriers by licensees related to accessible prescription information services to patients.

Joshua Munroe presented an overview of the survey and the data collected, as well as a brief updated report on state-level actions related to providing visually accessible and translated prescription information services.

#### **Commission Comments:**

**Craig Ritchie:** Noted concern that there are a few respondents who reported that the reason they are not participating is that it is not required by law.

**Jerrie Allard:** Suggested assigning to Pharmacy Practice Subcommittee to assist staff.

**Teri Ferreira:** Would like further review of Nevada language.

**Staff Comments:**

**Lindsay Trant-Sinclair:** There is no specific action needed at this time, a good next step would be to narrow down a starting point for the draft rule language. Any guidance that could be provided to staff to start a rough outline of what the rule language might look like would be helpful. We would like to bring an outline back to full commission for review before assigning to Pharmacy Practice subcommittee.

**Stakeholder comments:**

**Doreen Cornwell:** Anecdotal experience with the blind is that folks are not aware that accommodations are an option. Issue when labels are provided separate from medications. Rule language is not going to be perfect at first, need to get information from vetted source.

**Marci Carpenter, President of the National Federation of the Blind:** In discussing the issue of non-visual access, found that majority of people do not ask because they are not aware it is possible to get accommodation.

**David Streeter, WSHA:** Raised a question on incomplete responses and why, and how many were of those respondents were from hospital settings. Streeter noted interest in helping to get a larger pool of respondents from hospital settings.

**Joana Ramos:** Results should be disaggregated by setting. Distinction between translation (written) and translator (verbal). DSHS offers some translation services, but only in six languages.

**En-Vision America:** Reported cost data is in a very large range because there are many different possibilities. Costs really depend on services provided.

**9. Panel Review – Study Plan.**

**MOTION:** Jerrie Allard moved to approve Patrick Gallaher, Judy Guenther, and Teri Ferreira as the panel reviewing and approving/denying the study plans. Craig Ritchie, second. Motion carries, 11:0.

**9.1 PHRM.PH.61278050.**

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

**9.2 PHRM.PH.61188090.**

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

**9.3 PHRM.PH.61176247.**

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

## 10. Open Forum.

Public Comment: Richard Molitor brought to attention that for the second year in a row, NAPLEX scoring has had issues resulting in applicants receiving a false failing score. He would like to encourage the commission to stay abreast of the matter so that it does not happen again and that NABP remain transparent.

Marlee O’Neill confirms that the commission is aware of the issue and is working with NABP.

## 11. Commission Member Reports.

### 11.1 Pharmacy Practice Subcommittee Report – Craig Ritchie, Subcommittee Chair.

The Pharmacy Practice Subcommittee was unable to meet on its scheduled date of November 8, 2022, due to inclement weather. Revisions to the Sample AUP document and the definition of stocking as it relates to the pharmacy assistant’s scope of practice were the two topics designated for discussion. The Pharmacy Practice Subcommittee meeting rescheduled date is still pending. The program staff will provide this information via GovDelivery and on the commission’s webpage once finalized.

### 11.2 Legislative Subcommittee Report Out – Craig Ritchie (for William Hayes, Subcommittee Chair).

The Legislative Subcommittee met on October 7, 2022, to discuss if any bill proposals should be considered for the 2024 legislative session. At the June 2022 subcommittee meeting, commission staff was tasked with looking into the practice of “white bagging.” The Facilities Subcommittee will take up the conversation around rulemaking on white bagging at their next scheduled meeting.

### 11.3 Compounding Subcommittees Report – Hawkins DeFrance, Subcommittee Chair.

The Compounding Subcommittee engaged stakeholders and interested parties in a lively discussion regarding the directive entitled *Nonresident Pharmacy: Approved List of Recognized States*. Stakeholder feedback was reviewed and discussed during the September meeting. The subcommittee members then conducted an additional analysis of the states. The results returned to the PQAC program staff for information gathering in preparation for the next subcommittee meeting in December.

### 11.4 Open discussion related to items or issues relevant to commission business/pharmacy practice.

Hawkins DeFrance attended the FDA IGA conference and noted one topic of concern. The FDA has raised an alarm about mobile IV clinics and that these clinics are compounding without following <797>. He suggests asking staff to work with WMC and NCQAC to come up with ways of enforcing <797>.

Ken Kenyon suggests considering an agenda item for the next business meeting regarding expectations of transfer prescriptions and time to fill new prescriptions.



## **12. Staff Reports.**

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

The State Office audit of the Prescription Monitoring Program was completed was completed and posted in early October. The commission will also be working on continuing education but at this time no further action is required.

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

Staff made changes to the Uniform Facilities Enforcement Framework (UFEF) after the September business meeting. The current draft of the proposed legislation is under review at the Governor’s office.

The AA3 position has been filled and the new employee will be joining on December 16, 2022.

In regard to commissioner recruitment, the packet for the pharmacist candidate is under review and should be with the Governor’s office soon.

### **12.3 Assistant Attorney General – Christopher Gerard.**

Nothing to report.

## **13. Summary of Meeting Action Items.**

- Follow up with contingent AUP and TTP approvals
- 3.2 – Staff will file a supplemental CR-102 on WAC 246-945-486 and -488, reuse and donation of unexpired prescription drugs
- 4.2 – Staff will file a CR-103 on WAC 246-945-171, retired active pharmacist license status
- 5.1 – Staff will make changes to the BAP designation of presiding officer
- 5.2 – Staff will review the revised 795 and 797 and bring that information back to the commission at a future meeting
- 5.3 – Staff will post the FAQs taken from Plan-19 that are still relevant
- 7.1 – Communicate the commission’s position on out-of-country wholesalers and out of country pharmacies to credentialing
- 7.2 – Report back to NABP on commission’s position on resolution 8
- 7.3 – Convey commission's decision on WSPA list and label request to public disclosure unit
- 7.4 – File new 2023 meeting dates with the code reviser’s office and adjust calendar holds for 2023
- 8.1 – Notify OHP that Craig Ritchie and William Hayes are PQAC’s representatives on the OHP weekly calls and send out calendar hold for PQAC’s Friday calls
- 8.3 – Refile retired active pharmacist license status emergency rule and withdraw it when the permanent rule becomes effective
- 8.4 – File the CR-105 to update the incorporation by reference on title 21 CFR with the amended language as shown today
- 8.5 – Put together outline of feedback today on accessible labeling rule language to inform initial draft of rule language
- 9 – Notify credentialing of approvals to reexam for applicants presented today

- 11.4 – Reach out to WMC and NCQAC to get more information on IV infusion clinics and add future agenda item for increased times for prescription transfer at pharmacies

Teri Ferreira thanked all of commissioners, staff, licensees, and stakeholders for their preparation and participation in PQAC business meetings.

**Business Meeting Adjourned**

Teri Ferreira, Chair, called the meeting adjourned at 3:23 PM.