



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
January 12, 2023 - Minutes**

Convene: Chair, Teri Ferreira called the meeting to order January 12, 2023, 9:05 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
William Hayes, PharmD CCHP

Staff:

Marlee O’Neill, Executive Director
Lindsay Trant-Sinclair, Deputy Director
Sierra McWilliams, AAG
Christopher Gerard, AAG
Irina Tiginyanu, Pharmacy Technician Consultant
Hope Kilbourne, Policy Analyst
Joshua Munroe, Legislative and Rules Consultant
Taifa “Nomi” Peaks, Pharmacist Consultant
Haleigh Mauldin, Program Consultant
Amy L Robertson, Communications Coordinator
and Program Support
Desiré Gudmundson, Administrative Assistant

Commission Members Absent:

Bonnie Bush, Public Member

1. Call to Order Terri Ferreira, Chair.

1.1 Meeting Agenda Approval – January 12, 2023.

MOTION: Craig Ritchie moved to approve the business meeting agenda for January 12, 2023. Jerrie Allard, second. Motion carries, 12:0.

1.2 Meeting Minutes Approval – November 17, 2022.

MOTION: Craig Ritchie moved to approve the meeting minutes for November 17, 2022. Jerrie Allard, second. Motion carries, 12:0.

2. Consent Agenda.

2.1 Ancillary Utilization Plans Approval.

- 2.1.1** Albertson’s Central Fill
- 2.1.2** Biocompound LLC
- 2.1.3** Geneva Woods
- 2.1.4** Moses Lake Professional Pharmacy
- 2.1.5** Omnicare of Seattle

- 2.1.6 Peace Health Locations
- 2.1.7 UWMC NW OPMC

2.2 Pharmacy Technician Training Program Approval.

- 2.2.1 Arlington Pharmacy
- 2.2.2 Fred Meyer Pharmacy
- 2.2.3 Valley Pharmacy
- 2.2.4 West Pasco Pharmacy
- 2.2.5 Whidbey Health Medical Center
- 2.2.6 Yakima Valley Farmworker
- 2.2.7 Saars Pharmacy

MOTION: Hawkins DeFrance moved to approve 2.1 and 2.2 with the exception of 2.1.1, 2.1.3, 2.2.1, 2.2.4, 2.2.6. Craig Ritchie, second. Motion carries, 12:0.

2.3 Regular Agenda/Items Pulled from 2.1 and 2.2.

Items pulled:

- 2.1.1 Albertson's Central Fill
- 2.1.3 Geneva Woods
- 2.2.1 Arlington Pharmacy
- 2.2.4 West Pasco Pharmacy
- 2.2.6 Yakima Valley Farmworker

MOTION: William Hayes moved to approve AUP 2.1.1 Albertson's Central Fill contingent upon the cooperating adding appendix A and updating licensing to every two years. Hawkins DeFrance, second. Motion carries, 12:0.

MOTION: Teri Ferreira moved to approve AUP 2.1.3 Geneva Woods contingent upon updating language on administrative technician not included in ratio. Hawkins DeFrance, second. Motion carries, 12:0.

MOTION: William Hayes moved to approve 2.2.1 Arlington Pharmacy Technician Training Program contingent upon the pharmacy providing the requested information regarding trainee accreditation, program length requirements, exam score requirements, notification of changes to the program, and student record retention as outlined in the staff recommendation. The pharmacy must also ensure the technician immunization language is consistent with the commission's guidance document on technicians administering vaccinations. Craig Ritchie, second. Motion carries, 12:0.

MOTION: Hawkins DeFrance moved to approve 2.2.4. Technician Training Program contingent upon the pharmacy providing the requested information regarding trainee accreditation, exam score requirements, notification of changes to the program and student record retention as outlined in the staff recommendation.. Craig Ritchie, second. Motion carries, 12:0.

MOTION: Hawkins DeFrance moved to approve 2.2.6 Yakima Valley Farmworker Technician Training Program contingent upon the pharmacy providing the requested information regarding

trainee accreditation, notification of changes to the program and student record retention as outlined in the staff recommendation.. Craig Ritchie, second. Motion carries, 12:0.

3. Old Business.

3.1 2023 Self-Inspection Worksheets Review.

3.1.1 Pharmacy Self-Inspection Worksheet.

MOTION: Craig Ritchie moved to approve changes to general pharmacy self-inspection worksheet . Hawkins DeFrance, second. Motion carries, 12:0.

3.1.2 Hospital Self-Inspection Worksheet.

MOTION: Hawkins DeFrance moved to approve changes to the hospital self-inspection worksheet. Craig Ritchie, second. Motion carries, 12:0.

3.1.3 Health Care Entity Self-Inspection Worksheet.

MOTION: Hawkins DeFrance moved to approve changes to health care entity self-inspection worksheet. Craig Ritchie, second. Motion carries, 12:0.

3.1.4 Manufacturer Self-Inspection Worksheet.

MOTION: Hawkins DeFrance moved to approve changes to manufacturer self-inspection worksheet. Craig Ritchie, second. Motion carries, 12:0.

3.1.5 Wholesaler Self-Inspection Worksheet.

MOTION: Hawkins DeFrance moved to approve changes to wholesaler self-inspection worksheet. Craig Ritchie, second. Motion carries, 12:0.

3.1.6 Long-Term Care Self-Inspection Worksheet.

MOTION: Hawkins DeFrance moved to approve changes to long-term care self-inspection worksheet. Craig Ritchie, second. Motion carries, 12:0.

3.1.7 USP 795 Nonsterile Compounding Addendum.

MOTION: Hawkins DeFrance moved to approve USP 795 nonsterile compounding addendum with changes and to bring the commission's guidance document #61 (United States Pharmacopeia General Chapter <795> - Nonsertile Compounding – Information) to a future meeting for possible recision. Craig Ritchie, second. Motion carries, 12:0.

3.1.8 USP 797 Sterile Compounding Addendum.

MOTION: Hawkins DeFrance moved to approve USP 797 sterile compounding addendum with the changes addressed and retaining the 800 early adopter language. Craig Ritchie, second. Motion carries 12:0.

3.1.9 USP 825 Radiopharmaceuticals Self-Inspection Worksheet.

MOTION: Hawkins DeFrance moved to approve changes to USP 825 radiopharmaceuticals self-inspection worksheet. Craig Ritchie, second. Motion carries, 12:0.

3.1.10 USP 800 Hazardous Drugs Self-Inspection Worksheet.

MOTION: Hawkins DeFrance moved to approve changes to USP 800 hazardous drugs self-inspection worksheet. Craig Ritchie, second. Motion carries, 12:0.

4. New Business.

4.1 Health Care Entity (HCE) FAQ.

Marlee O'Neill: With the commission's rules re-write, one organization occupying multiple suites in one facility is deemed to be occupying one location requiring only one Health Care Entity (HCE) license as opposed to a separate HCE license for each suite under the old rules. As a result, the commission has received an increase in inquiries related to HCEs that program staff are working to address in an FAQ.

5. Panel Review- Study Plan (Panel B)

MOTION: Jerrie Allard moved to delegate item 5.1 Study Plan to Panel B – Hawkins DeFrance, Craig Ritchie, Timothy Lynch and Matthew Ray. Judy Guenther, second. Motion carries, 12:0.

5.1 PHRM.PH.61181493

MOTION: Hawkins DeFrance moved to approve Study Plan. Timothy Lynch, second. Motion carries, 4:0.

6. Rules and Legislative Updates.

6.1 Authorize CR-103P for HIV/AIDS Education Requirement Repeal (ESHB 1551).

MOTION: Craig Ritchie moved to adopt the rule language and approve filing the CR-103P to repeal the AIDS education and training requirement removed under ESHB 1551. Jerrie Allard, second. Motion carries, 12:0.

6.2 Authorize CR-105 for Incorporation by References Updates.

WAC sections in need of an update:

- WAC 246-945-010

- WAC 246-945-013
- WAC 246-945-030
- WAC 246-945-075
- WAC 246-945-550
- WAC 246-945-565

MOTION: Craig Ritchie moved to authorize staff to file the CR-105 to update the identified incorporations by reference. Hawkins DeFrance, second. Motion carries, 12:0.

6.3 Reauthorize CR-105 for Technical Edits in Chapter 246-945 WAC.

MOTION: Craig Ritchie moved to approve additional technical edits to the previously authorized CR-105 package for chapter 246-945 WAC. Jerrie Allard, second. Motion carries, 12:0.

MOTION: Craig Ritchie moved to direct staff, with legal assistance, to evaluate possible rulemaking pathways to amend WAC 246-945-355, including whether to amend “and” in the last sentence to “or needed” drug therapies. Matthew Ray second. Motion carries, 12:0.

6.4 Refile Request: CR-130E for Prescribing CII's During COVID.

MOTION: Craig Ritchie moved to authorize the re-filing of an emergency rule CR-103E on prescribing Schedule II (CII) medications during the COVID pandemic. Hawkins DeFrance, second. Motion carries, 12:0.

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

MOTION: Craig Ritchie moved to authorize the re-filing of CR-103 E and define that an emergency exists for public health. Hawkins DeFrance, second. Motion carries, 12:0.

6.6 Uniform Facility Enforcement Framework (UFEF) Update.

Marlee O’Neill provided the commission with an update on the UFEF.

6.7 Guiding Questions for Health Equity Continuing Education Rulemaking (ESSB 5229).

Commission staff filed a CR-101 statement of inquiry for health equity continuing education requirements on December 19, 2022. Health equity CE requirements were established in statute by ESSB 5229 in 2021 and the Department filed model rules in late 2022.

MOTION: Timothy Lynch moved to include a minimum of one hour health equity continuing education (CE) in the current required 30 hours by pharmacists and 20 hours by technicians that is due every two years. The CE can be ACPE accredited or approved by the Department of Health. Craig Ritchie, second. Motion carries, 12:0.

7. Summary of Meeting Action Items.

- **2.** Consent Agenda – Follow up with approvals and get information needed for contingent approvals.
- **3.1** Post all self-inspection worksheets with the edits reviewed today in both Word and PDF form.
 - Bring back policy statement 61 on USP 795 in March.
 - Bring back statement on early adoption of USP 800 on USP 797 self-inspection worksheet in March.
 - Bring USP 800 self-inspection worksheet to Compounding Subcommittee who will review if and how the commission regulates the administration of hazardous drugs.
 - Bring back technician administration guidelines to future commission meeting.
 - Send out GovDelivery directing folks how to submit questions to staff for the HCE FAQs.
- **5.1** Notify credentialing of approved study plan.
- **6.1** File CR-103P to repeal AIDS training and education requirements following ESHB 1551.
- **6.2** Bring back amendments to rules identified today in need of an update to incorporations by reference to the commission at a future meeting before filing the CR-105.
- **6.3** Bring amendments to WACs identified today in need of a technical fix for the commission to review before filing the CR-105. Staff will also conduct a legal analysis to determine which rulemaking options are available to address the various suggested changes to WAC 246-945-355 discussed. This will include an analysis of emergency, expedited, and standard rulemaking potential pathways.
- **6.4** Re-file emergency rules on prescribing schedule II drugs during the COVID pandemic.
- **6.5** Re-file the emergency rules on medication assistance in in-home and community-based care setting.
- **6.7** Begin drafting rule language on health equity CE with guidance from commission today to prepare for future rules workshop.

Business Meeting Adjourned

Teri Ferreira, Chair, called the meeting adjourned at 2:23 PM.