STATE OF WASHINGTON
Pharmacy Quality Assurance Commission
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Pharmacy Quality Assurance Commission Meeting
June 15, 2023 - Minutes

Convene: Chair, Teri Ferreira called the meeting to order June 15, 2023, 12:10 PM.

Commission Members:
Teri Ferreira, RPh, Chair
Jerrie Allard, Public Member, Vice Chair
Uyen Thorstensen, CPhT (*Joined at 12:34 PM)*
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
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
Si Bui, Pharmacist Inspector Supervisor
Joanne Miller, Program Manager
Desire 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. ***12:10 PM***

1.1 Meeting Agenda Approval – June 15, 2023

MOTION: Craig Ritchie moved to approve the business meeting agenda for June 15, 2023. Ken Kenyon, second. Motion carried, 11:0.

1.2 Meeting Minutes Approval – May 4, 2023

MOTION: Craig Ritchie moved to approve the meeting minutes for May 4, 2023. Ken Kenyon, second. Motion carried, 11:0.

1.3 Meeting Minutes Approval – May 5, 2023

MOTION: Craig Ritchie moved to approve the meeting minutes for May 5, 2023. Ken Kenyon, second. Motion carried, 11:0.

2. Consent Agenda

2.1 National Precursor Log Exchange Monthly Dashboard – May 2023

2.2 Pharmaceutical Firms Application Report

2.3 Ancillary Utilization Plans Approval

2.3.1 CHAS
2.3.2 Bellegrove Pharmacy
2.3.3 Confluence Health
2.3.4 Infusion Solutions
2.3.5 Madison Park Pharmacy
2.3.6 Makers Compounding Pharmacy
2.3.7 Acts Pharmacy
2.3.8 Genoa Pharmacy – multiple locations

2.4 Pharmacy Technician Training Program Approval

2.4.1 Infusion Solutions
2.4.2 Maker's Compounding Pharmacy
2.4.3 Sid's Pharmacy
2.4.4 South Gate Pharmacy

2.5 Regular Agenda/Items Pulled from 2.1 and 2.2

Items pulled:

- 2.3.1 CHAS
- 2.4.4 South Gate Pharmacy

Recusals:

Ann Wolken: 2.3.8 Genoa Pharmacy – multiple locations

MOTION: Craig Ritchie moved to approve item 2.3.8 Genoa Pharmacy – multiple locations. Ken Kenyon, second. Motion carried, 10:0. (Ann Wolken – recused).

MOTION: Craig Ritchie moved to approve all remaining consent agenda items except for items 2.3.1 CHAS and 2.4.4 South Gate Pharmacy. Ken Kenyon, second. Motion carried, 11:0.

(*Uyen Thorstensen joins the meeting)*

MOTION: Craig Ritchie moved to approve 2.3.1 CHAS. Ken Kenyon, second. Motion carried: 12:0.

MOTION: Craig Ritchie moved to approve 2.4.4 South Gate Pharmacy contingent upon the addition of the language that records must be readily available upon 72 hours of request. William Hayes, second. Motion carried, 12:0.

3. Old Business

3.1 Enforcement Discretion – WAC 246-945-585 (1)(b) Zero Reports

The commission has utilized its enforcement discretion on the zero order reports requirement in WAC 246-945-585. Lindsay Trant-Sinclair provided a summary stating that at the July 14, 2022 business meeting, the commission voted "to extend enforcement discretion of the submission of zero reports for 12 months (until July 14, 2023) or until the rulemaking is complete, whichever

comes first." The rulemaking on this WAC is still ongoing. The facility subcommittee discussed the rule on March 30, 2023, and staff have since drafted the rule language.

Staff recommend that the commission continue utilizing its enforcement discretion on WAC 246-945-585(1)(b) until the rulemaking on WAC 246-945-585 is complete.

MOTION: Craig Ritchie moved to extend the enforcement discretion of WAC 246-945-585(1)(b) until the rulemaking on WAC 246-945-585 is complete. Ken Kenyon, second. Motion carried, 12:0.

3.2 Pharmacy Assistants Stocking

Taifa "Nomi" Peaks presented an SBAR and draft FAQ for the commission's consideration related to pharmacy assistants stocking.

MOTION: Timothy Lynch moved to have staff file a CR-101 to define "stocking" and the use of technology as it relates to pharmacy assistants and potentially amend WAC 249-945-001 and/or WAC 245-945-315, and to add a new section to Chapter 246-945 WAC. Hawkins DeFrance, second. Motion carried, 12:0.

4. New Business

4.1 HCE FAQ

In an effort to address broader questions related to Health Care Entities (HCEs), program staff created an FAQ page to be considered by the commission for approval. The questions are organized by subtopic and the answers include hyperlinks to pertinent rules references.

MOTION: Ken Kenyon moved to approve the HCE FAQ with the edits as discussed. Craig Ritchie, second. Motion carried, 12:0.

4.2. Review Joint Operating Agreement (JOA)

In accordance with Section 15 of the JOA, the commission is required to review the JOA prior to the end of each biennium. The JOA also states that "[t]he agreement may be revised when necessary upon the request and mutual agreement of the secretary and the commission."

MOTION: Ken Kenyon moved to open the JOA to make organizational updates needed to reflect the current state which includes the inspectors being a part of the Office of Health Professions. Judy Guenther, second. Motion carried, 12:0.

4.3 FDA Proposes Easy-to-Read Medication Guide

On May 30, 2023, the FDA announced it is proposing an easy-to-read medication guide for patients called "Patient Medication Information." This represents an opportunity for commission input on a topic related to some of their own rulemaking.

Joshua Munroe briefed the commission on the proposal and presented the commission with the option on whether to submit a written comment to the FDA regarding the easy-to-read medication guide proposal.

MOTION: William Hayes moved to have staff to assist the commission with providing written comments regarding translation for alternate languages and for ensuring those who are visually impaired are also able to access the medication guides. Ken Kenyon, second. Motion carried. 12:0.

4.4 Emergent Drug Shortages.

Lindsay Trant-Sinclair provided information on how the recent drug shortages relate to commission's regulatory framework and the aspects of the commission's rules that may alleviate some of the impact in Washington relating to the transfer of drug supply.

5. Panel Review – Study Plan [Panel B – Craig Ritchie, Hawkins DeFrance, Matthew Ray, Timothy Lynch, Bonnie Bush (absent)]

MOTION: Ken Kenyon moved to delegate the study plan to Panel B. Jerrie Allard, second. Motion carries, 12:0.

(The main body of the commission will reconvene c. 3:15 PM)

5.1 . PHRM.PH.61323767

MOTION: Hawkins DeFrance moved to approve the study plan. Craig Ritchie, second. Motion carried, 4:0.

5.2 PHRM.PH.61176247

MOTION: Hawkins DeFrance moved to approve the study plan. Craig Ritchie, second. Motion carried, 3:0. (Timothy Lynch, absent.)

5.3 PHRM.PH.61314820

MOTION: Hawkins DeFrance moved to approve the study plan. Craig Ritchie, second. Motion carried, 3:0. (Timothy Lynch, absent.)

5.4 PHRM.PH.61322712

Presenter did not attend meeting.

6. Rules and Legislative Updates

6.1 Rules Workshop: Suspicious Orders and Zero Reports

In June 2021 the commission authorized staff to file a CR-101 to amend WAC 246-945-585 regarding suspicious orders and zero reports. The CR-101 was filed in April 2023 and staff has begun drafting rule language for commission approval and comment.

Haleigh Mauldin presented the proposed rule language.

In summary, the draft language defines "suspicious order" and changes the procedure for zero order reporting. This draft focuses on submitting a suspicious order when the wholesaler refuses to ship controlled substances or drugs of concern after conducting due diligence. It includes a

separate provision on reporting to the commission when a wholesaler refuses to onboard a new customer. Staff will bring this back to the August meeting to allow stakeholders additional time to review the draft.

6.2 Rules Workshop: Remote Dispensing of OUD Medications (SSB 6086)

Commission staff presented a rule language draft on remote OUD dispensing sites for the commission's approval at the May 2023 business meeting. Though the commission accepted the proposed language, legislative actions since that time prompted commission staff to amend the draft language and present it again.

MOTION: Craig Ritchie moved to accept the proposed language changes for the remote OUD dispensing site rulemaking project and allow staff to proceed with the CR-102. Ken Kenyon, second. Motion carried, 12:0.

6.3 CR-101 Scope Expansion: Mobile Opioid Treatment Program Licensing

Item 6.3 was removed from the agenda.

MOTION: Jerrie Allard moved to address the June 16 agenda items 4 and 5 during today's agenda. William Hayes, second. Motion carried, 12:0.

Agenda item 4 became the June 15, 2023 agenda item 8 pertaining to commission member reports. Action item 8.1, formerly 4.1 on the June 16, 2023 agenda, includes a report delivered by the Compounding Subcommittee.

Agenda item 5 became the June 15, 2023 agenda item 9 for staff reports.

7. Open Forum

8. Commission Member Reports

8.1 Compounding Subcommittee – Hawkins DeFrance, Subcommittee Chair

Since the last business meeting in May, the compounding subcommittee has held several meetings to discuss revisions to the draft USP <795> and USP <797> self-inspection worksheets for nonsterile and sterile compounding, respectively. As a reminder, the commission tasked the subcommittee with reviewing the worksheets in preparation for November 1, 2023, when the revised USP General Chapters <795> and <797> are scheduled to become official. We appreciate the input from our stakeholders on this project and look forward to presenting the worksheets to the commission in August.

9. Staff Reports

9.1 Executive Director - Marlee O' Neill

Commission staff have inquired whether the HELMS project can configure provider credential search to allow people to see whether a nonresident pharmacy has attested that is does not compound. Marlee shared her experience at the NABP annual meeting. Inspector Lisa Roberts' last day with DOH was May 31. Marlee informed the commission that ESHB 1503 requires the

collection of demographic information. OHP will likely hold listening sessions as it plans for the implementation of this bill.

9.2 Deputy Director - Lindsay Trant-Sinclair

Staff extended an informal offer to a non-permanent HSC4, a 7-month appointment to help get caught up with rules and stay on top of non-routine applications. Staff received additional applications for pharmacist commission members and are continuing interviews. The budget subcommittee did not meet this month due to a schedule conflict but will resume in August.

9.3 Pharmacist Consultant -Taifa "Nomi" Peaks

Nothing to report.

9.4 Pharmacist Inspector Supervisor - Si Bui

Si Bui was introduced to the commission as the new pharmacy inspector supervisor. He briefly shared his public health background, previous pharmacy experiences, and motivations for joining the commission staff.

9.5 Assistant Attorney General - Christopher Gerard

Nothing to report.

10. Rules Workshop: Accessible Labeling

Joshua Munroe provided the commission with background information on the draft. Commission staff updated the accessible labeling rule language draft based on commission discussion from the May 2023 business meeting. Among the items discussed was a determination of what prescription label elements must be made accessible to visually impaired, print disabled, and Limited English Proficient (LEP) patients. That information is provided in a separate document with a visual of the prescription information elements provided to a patient by category: written translation, oral interpretation, print disability, and vision impairment.

Additional columns representing federal requirements for the same elements are present because understanding this rulemaking process at this stage requires an understanding of the existing federal requirements relating to entities – including pharmacies – providing accessibility services to patients. These federal requirements include, but are not necessarily limited to, Title VI of the Civil Rights Act of 1964, the Rehabilitation Act of 1973, and Title III of the Americans with Disabilities Act. Today's rule language draft was prepared with both the commission's input and these federal laws in mind.

Commissioners reviewed the draft, provided feedback, and listened to stakeholder feedback. The commission ran out of time to complete the rules workshop and elected to resume the workshop at the business meeting on June 16, 2023.

11. Summary of Meeting Action Items

- 2.3 and 2.4. Staff will follow up with approvals and contingent approvals for AUPs and technician training programs.

- 3.1 Staff will send out a GovDelivery to communicate that the commission extended its use of enforcement discretion on WAC 246-945-585(1)(b) until rulemaking is complete.

- 3.2 Staff will file a CR-101 to amend WAC 246-945-001, 246-945-315, and add new sections in Chapter 246-945 WAC related to the definition of stocking, the assistants' scope of practice, and the use of technology. Pharmacy practice subcommittee will work on drafting rule language after CR-101 is filed.

- 4.1 Staff will post the HCE FAQs as edited here today to the commission's website and distribute them through GovDelivery.

- 4.2 Make edits to JOA to update and correct terms and begin negotiation process with Department. Staff will also bring aspects of the JOA that have been put aside, back to the commission for awareness and review.

- Staff will draft comments to submit to the FDA on their rulemaking requesting that the FDA requires manufacturers to translate medication guides in languages other than English as well as make accommodations to those who are vision impaired. Staff will bring the draft comment back at a future meeting for the commission to review.

- 5. Staff will communicate study plan approvals to credentialing.

- 6.1 Staff will bring back the draft language on suspicious orders back at a future meeting.

- 6.2 Staff will proceed with filing the CR-102 with the amended language for the remote dispensing sites for opioid use disorder medications and schedule the public hearing.

- Commissioner open discussion: Staff will send out updated guidance on administering and ordering the COVID vaccine under the extension of the PREP Act via GovDelivery when complete.

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 4:23 PM.