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Pharmacy Quality Assurance Commission August 22, 2024 - Minutes

Convene: Hawkins DeFrance, Chair, called the meeting to order August 22, 2024, 9:04 a.m.

Commission Members:

Hawkins DeFrance, Chair
Ann Wolken, Vice Chair
Jerrie Allard
Stephanie Bardin
Bonnie Bush
Teri Ferreira
Patrick Gallaher
Judy Guenther
William Hayes
Matthew Ray
Craig Ritchie
Uyen Thorstensen

Commission Members

Absent:
Kenneth Kenyon
Huey Yu

Staff:

Marlee O'Neill, Executive Director
Lindsay Trant-Sinclair, Deputy
Director
Si Bui, Inspector Supervisor
Christopher Gerard, AAG
Rachel Sahi
Taifa "Nomi" Peaks
Joshua Munroe
Haleigh Mauldin
Julia Katz
Irina Tiginyanu
Amy Robertson
Scott Craig
Tina Lacey
Danielle Lee
Crystal Phipps
Justin Sisney
Jonathan Chamrad

1. Call to Order Hawkins DeFrance, Chair

1.1. Meeting Agenda Approval – August 22, 2024

MOTION: Craig Ritchie moved to approve the amended business meeting agenda removing agenda item 2.2.2 for August 22, 2024. Teri Ferreira, seconded. Motion carried, 12:0.

1.2. Meeting Minutes Approval – June 27, 2024

MOTION: Craig Ritchie moved to approve the business meeting minutes for June 27, 2024. Jerrie Allard, seconded. Motion carried, 12:0.

2. Consent Agenda

2.1. Correspondence

- 2.1.1. National Precursor Log Exchange Monthly Dashboard – June and July
- 2.1.2. Pharmaceutical Firms Application Report

2.2. Ancillary Utilization Plans Approval

- 2.2.1. Bob Johnsons Pharmacy
- 2.2.2. Item was removed as part of agenda item 1.1
- 2.2.3. Factoria Pharmacy
- 2.2.4. Jefferson Healthcare Port Ludlow Pharmacy
- 2.2.5. Neil’s Pharmacy
- 2.2.6. Providence Swedish Rehabilitation Hospital
- 2.2.7. Odessa Drugs
- 2.2.8. Quincy Valley Pharmacy
- 2.2.9. Valley Drug Co.
- 2.2.10. Wenatchee Valley Pharmacy, LLC
- 2.2.11. Skagit Regional Health Pharmacy
- 2.2.12. Madison Park Pharmacy & Wellness Center
- 2.2.13. Ostroms Drug and Gift
- 2.2.14. Jefferson Healthcare Pharmacy

2.3. Pharmacy Technician Training Program Approval

- 2.3.1. Evergreen Pharmacy
- 2.3.2. Harbor Health, LLC
- 2.3.3. Jims Pharmacy and Home Health

MOTION: Craig Ritchie moved to approve the consent agenda with the exception of items 2.2.1, Bob Johnsons Pharmacy, 2.2.3 Factoria Pharmacy, 2.2.4, Jefferson Healthcare Port Ludlow Pharmacy, 2.2.5, Neil’s Pharmacy, Inc., 2.2.7, Odessa Drugs, 2.2.14, Jefferson Healthcare Pharmacy, and 2.3.1, Evergreen Pharmaceutical, LLC. William Hayes, seconded. Motion carried, 12:0.

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

2.2.1 Bob Johnsons Pharmacy

MOTION: William Hayes moved to approve item 2.2.1 Bob Johnsons Pharmacy contingent on striking “assists the pharmacist in providing pharmacist care by transcribing pharmacist generated patient specific notes into the patient’s record, to be checked for accuracy by the

pharmacist” from the pharmacy assistant AUP. Stephanie Bardin, seconded. Motion carried, 11:1.

2.2.3 Factoria Pharmacy

MOTION: William Hayes moved to approve item 2.2.3 Factoria Pharmacy contingent on removing “providing guidance and assistance to patients regarding medication administration techniques and proper storage conditions” from the pharmacy technician AUP. Patrick Gallaher, seconded. Motion carried, 12:0.

2.2.4 Jefferson Healthcare Port Ludlow Pharmacy

MOTION: Craig Ritchie moved to approve item 2.2.4 Jefferson Healthcare Port Ludlow Pharmacy contingent on referencing the Commission’s Ancillary Utilization Plans and the Administration of Drugs and Devices guidance document. William Hayes, seconded. Motion carried, 12:0.

2.2.5 Neil’s Pharmacy, Inc.

MOTION: William Hayes moved to approve item 2.2.5 Neils Pharmacy Inc. contingent on removing “have been checked/verified by pharmacist” from T9 in the pharmacy technician AUP which stated, "Reconstitute medications that have been checked/verified by pharmacist." Patrick Gallaher, seconded. Motion carried, 12:0.

2.2.7 Odessa Drugs

MOTION: William Hayes moved to approve item 2.2.7 Odessa Drugs contingent on changing “Pharmacy technicians at Odessa Drug will be supervised ...” to “Pharmacy assistants at Odessa Drug ...” in the pharmacy assistant AUP. Stephanie Bardin, seconded. Motion carried, 12:0.

2.2.14 Jefferson Healthcare Pharmacy

MOTION: Patrick Gallaher moved to approve item 2.2.14 Jefferson Healthcare Pharmacy contingent on removing assistants from number 20 which stated “maintains automated dispensing equipment, including processing updating user, patient, and medication records” and removing number 11 which stated “performs other duties as assigned by the Director of Pharmacy or designee, within the scope of role.” Uyen Thorstensen, seconded. Motion carried, 12:0.

2.3.1 Evergreen Pharmaceutical, LLC

MOTION: Teri Ferreira moved to approve item 2.3.1 Evergreen Pharmaceutical, LLC contingent on striking number 6 which stated “enters prescription data into the computer under the supervision and control of a

licensed pharmacist per WA ST 18.64A.030” from the pharmacy assistant AUP and contingent on clarifying what registration enrollees need to obtain before beginning the training program. Patrick Gallaher, seconded. Motion carried, 12:0.

3. Rulemaking for the Dialysate and Dialysis Devices Manufacturers and Wholesalers

- 3.1. PUBLIC HEARING** The commission held a public rule hearing on the rulemaking to propose amending WAC 246-945-090, 246-945-091, 246-945-092, and 246-945-093 to include manufacturers and wholesalers of dialysis devices and approved legend drugs, including dialysate, in home dialysis program rules under the commission’s jurisdiction in response to statutory changes made by Substitute House Bill (SHB) 1675 (chapter 23, Laws of 2022).

The public rule hearing began at 9:30am and was closed at 9:37am. The commission received one written comment during the public comment period. This commentor also presented oral testimony during the public hearing.

- 3.2. Approval of Comment Responses and Authorization to File CR-103 (Dialysate and Dialysis Device Manufacturers and Wholesalers)**

The commission discussed the comments received both in writing and orally and approved responses to those comments.

MOTION: Teri Ferreira moved to approve the draft responses to the comments received, to accept the restoration of the word “may” to WAC 246-945-090, to add a list of approved dialysis devices to WAC 246-945-090, and to direct staff to file a supplemental CR-102 for the addition of “may” and the list of approved dialysis devices. Patrick Gallaher, seconded. Motion carried, 12:0.

4. Presentations

- 4.1. Department of Health Rules Team on Best Practices in Rulemaking**

Cori Tarzwell, Legislative Affairs Manager for the Health Systems Quality Assurance (HSQA) division, Stephanie Vaughn, HSQA’s Rules Manager, and Alonso Munizaga Cortes, HSQA’s Community Engagement Initiatives Coordinator presented on best practices in rulemaking.

- 4.2. Guiding Principles When Writing Rules**

MOTION: Stephanie Bardin moved to have staff add a section to the guiding principles on diversity, equity, and inclusion working with the presenters from agenda item 4.1 and bring the revised draft to a future business meeting. Jerrie Allard seconded. Motion carried, 12:0.

- 4.3. Healthcare Enforcement and Licensing Management System (HELMS) Update**

Ratna Craig, HELMS Project Director, and Elizabeth Geisler, HELMS Business Deputy Project Director, provided an update on the HELMS project.

5. Panel Review – Study Plan (Panel C)

MOTION: Teri Ferreira moved to delegate study plans to Panel C: Jerrie Allard, William Hayes, Ann Wolken, and Uyen Thorstensen. Stephanie Bardin, seconded. Motion carried, 12:0.

5.1. PHRM.PH.61446691

MOTION: Uyen Thorstensen moved to approve the study plan. William Hayes, seconded. Motion carried, 3:0.

5.2. PHRM.PH.61382757

MOTION: Uyen Thorstensen moved to approve the study plan. Ann Wolken, seconded. Motion carried, 3:0.

5.3. PHRM.PH.61452661

MOTION: Uyen Thorstensen moved to approve the study plan. Jerrie Allard, seconded. Motion carried, 3:0.

5.4. PHRM.PH.61471906

MOTION: Uyen Thorstensen moved to approve the study plan. William Hayes, seconded. Motion carried, 3:0.

6. New Business

6.1. Draft Statement on Compounding of Semaglutide

MOTION: Teri Ferreira moved to approve the draft with the edits discussed at the meeting and directed staff to send the statement out via GovDelivery and publish it on the commission's What's New webpage. Jerrie Allard, seconded. Motion carried, 12:0.

7. Old Business

7.1. Delegation Agreements

MOTION: Craig Ritchie moved to approve the delegation agreements for 2024-2025 as presented. Patrick Gallaher, seconded. Motion carried, 12:0.

7.2. Nonresident Pharmacy: List of Approved Inspection Programs

MOTION: Craig Ritchie moved to approve the Nonresident Pharmacy: List of Approved Inspection Programs directive as presented and to make the effective date October 1, 2024. Ann Wolken, seconded. Motion carried, 12:0.

7.3. Drug Supply Chain Security Act (DSCSA) Follow-up Research

MOTION: Jerrie Allard moved to incorporate the DSCSA into the commission's rules and directed staff to develop enforcement policies that include priority areas for inspectors to focus on, while allowing discretion to the inspectors while they are on site so that inspectors can focus on other things within the DSCSA as the need arises. Staff will bring the enforcement policies to a future business meeting. Patrick Gallaher, seconded. Motion carried, 12:0.

8. Rules Update

8.1. Rules Tracker Spreadsheet

Joshua Munroe presented the rules tracker spreadsheet.

8.2. CR-103P Authorization: Incorporation by Reference

MOTION: Craig Ritchie moved to authorize the filing of the CR-103P for Incorporations by Reference. Patrick Gallaher, second. Motion carries, 12:0.

8.3. Emergency Rule Refile Request: Medication Assistance

MOTION: Craig Ritchie moved to authorize the re-filing of the CR-103E on medication assistance because there is an emergent need for this rule to be extended for the health and safety of the public. Stephanie Bardin, second. Motion carries, 12:0.

8.4. Rules Workshop: Permanent Facility Closure Reporting Requirements

MOTION: Teri Ferreira moved to approve the draft language with the edits discussed and tasked staff with filing the CR-102. Jerrie Allard, second. Motion carries, 12:0.

8.5. Rules Workshop: Mobile Opioid Treatment Program Units

MOTION: Teri Ferreira moved to approve the draft rule language as presented and to file the CR-102. Uyen Thorstensen, second. Motion carries, 12:0.

8.6. Rules Workshop: Fining Severity Matrix for Uniform Facilities Enforcement Framework

The commission discussed the draft fining severity matrix and what metric to use for operation size. Staff will continue to refine the matrix based on the discussion and will reach out to the Health Care Authority (HCA) to get more information on the data HCA collects on number of prescriptions dispensed.

9. Strategic Plan Update

Marlee O'Neill updated the commission on the strategic plan implementation.

10. Open Forum

No public comments

11. Commission Member Reports

11.1. Alternate Distribution Model Task Force Report Out

Ann Wolken reported that the task force met on June 13, 2024. Since that time, staff have continued to draft rule language, and the task force will meet again in the coming months to review that draft.

11.2. New Commissioner Orientation Task Force Report Out

Hawkins reported that the task force directed staff to develop a draft handbook for new commissioners based on feedback received from commissioners over the years. The draft handbook will be reviewed at the task force meeting on August 30.

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

Patrick Gallaher suggested that the commission have a biennial team building event for staff and commissioners.

MOTION: Patrick Gallaher moved to have staff look into holding a biennial team building event for staff and commissioners. Uyen Thorstensen, seconded. Motion carries, 12:0.

Patrick Gallaher suggested the commission consider amending the definition of a wholesaler to include a minimal use exemption. This is a proposal that staff will have the legislative task force consider.

William Hayes shared that he is participating in NABP's task force to review institutional pharmacy and compounding model rules. The task force meets at the end of September.

12. Staff Reports

12.1. Executive Director – Marlee O’Neill

- Attending NABP Executive Officer forum Illinois in September.

12.2. Deputy Director – Lindsay Trant-Sinclair

- Pharmacy Profession Credentialing staff transition is going well, and they are working hard to stay on top of incoming applications.
- Staffing
 - The AA3 position has been filled. Start date is September 3, 2024.
 - Posted a position for non-permanent credentialing specialist, HSC1.

12.3. Pharmacist Supervisor – Si Bui

- Inspector Daniel Lari’s last day was Thursday, August 15, 2024. He moved on to his new role as a Pharmacist Investigator.
- With Daniel’s departure and inspector Stephanie Martin’s departure in May, there are two inspector positions we are working to fill.

12.4. Pharmacist Consultant – Taifa “Nomi” Peaks

- Taifa “Nomi” Peaks shared an update about her participation on the Aesthetics Interagency Taskforce.

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.
- **3.2 Rulemaking for the Dialysate and Dialysis Devices Manufacturers and Wholesalers** – Staff will revise the rule language in response to the comments received and bring it back to the commission for consideration before filing the Supplemental CR-102.
- **4.1 Best Practices and Rulemaking Presentation** – Staff will seek continual feedback to make the rule workshops more accessible.
- **4.2 The Guiding Principles** – Staff will amend to include a subsection on diversity, equity, and inclusion and bring it back to the commission at a future meeting.
- **4.3 Healthcare Enforcement and Licensing Management System (HELMS)** – Staff will invite the HELMS team to return and provide a demo of HELMS.
- **5. Panel Reviews** – Staff will convey the decisions to the credentialing team.

- **6.1 Draft Statement of Semaglutide** – Staff will make the edits discussed and publish the statement on the commission’s What’s New website and distribute it via GovDelivery as well as share it with the partner commissions.
- **7.1 Delegation Agreements** –Staff will finalize and share them with the impacted staff at DOH.
- **7.2 Non-resident Pharmacy Directive** – Staff will publish that with the effective date of October 1, 2024 on the commission’s website and distribute it via GovDelivery as well as share it with the impacted staff at DOH.
- **7.3 Supply Chain Security Act (DSCSA)** – Staff will bring information on the option of incorporating DSCSA and developing enforcement priorities for inspectors while allowing discretion to a future business meeting.
- **8.2 Incorporations by Reference** – Staff will file a CR-103P.
- **8.3 Emergency Medical Assistance** – Staff will file a CR-103E.
- **8.4 Permanent Facility Closure Reporting** – Staff will revise the rule language and file a CR-102 and schedule a public rules hearing.
- **8.5 Mobile OTP Units** –Staff will file a CR-102.
- **8.6 Fining Severity Matrix** – Staff will connect with the HCA and continue to develop ideas for how to determine operation size.
- **10 Open Forum** – Staff will look into the possibility of having a biennial teambuilding event for the commission and staff and add potentially amending the definition of “wholesaler” in statute to the Legislative Task Force.

4:23 pm Business Meeting Adjourned