STATE OF WASHINGTON
Pharmacy Quality Assurance Commission
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Pharmacy Quality Assurance Commission Meeting
July 15, 2022 - Minutes

Convene: Chair, Teri Ferreira called the meeting to order July 15, 2022, 9:01 a.m.

Commission Members:
Teri Ferreira, RPh, Chair
Jerrie Allard, Public Member, Vice Chair
Bonnie Bush, Public Member
Uyen Thorstensen, CPhT
Hawkins DeFrance, Nuclear Pharmacist
Patrick Gallaher, BS, BPharm, MBA, MPH
Judy Guenther, Public Member
William Hayes, PharmD, CCHP
Helen H. Jung, PharmD, MBA
Tim Lynch, PharmD, MS, FABC, FASHP
Craig Ritchie, RPh, JD
Matthew Ray, PharmD
Ann Wolken, PharmD, RPh
Ken Kenyon, PharmD, BCPS

Staff:
Marlee O'Neill, Executive Director
Lindsay Trant, Deputy Director
Christopher Gerard, AAG
Hope Kilbourne, Policy Analyst
Joshua Munroe, Legislative and Rules Consultant
Taifa "Nomi" Peaks, Pharmacist Consultant
Joanne Miller, Program Manager, Pharmacy
Amy L Robertson, Communications Coordinator and Program Support

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

   1.1 Meeting Agenda Approval – July 15, 2022

   MOTION: Craig Ritchie moved to approve the meeting agenda for July 15, 2022. Hawkins DeFrance, second. Motion carries, 13:0.

2. **Rules and Legislative Updates** – Joshua Munroe, Legislative and Rules Consultant briefed the commission on the following items:

   2.1 Rulemaking on Accessible Labeling – Listening Session

   Joshua Munroe informed the commission that staff are designing a survey for licensees to assess current capabilities surrounding both visual accessibility and the translation of prescription information.

   Commissioners Tim Lynch, William Hayes, and Ann Wolken concur the commission needs to ensure access is not compromised for smaller, independent, or rural pharmacies that may not have the capability to fulfill this type of requirement to ensure patient safety, and that the rulemaking process should not be rushed.

Various stakeholders addressed the commission in support of this effort to have prescription labels accessible to all. All thanked the commission, relayed personal experiences as patients and/or pharmacists. Many reiterated Radio Frequency Identification (RFID) readers, large print, braille, and multiple language options are integral to patient safety and care.

- Jenny Arnold – Washington State Pharmacy Association
- Judy Brown – Washington Council of the Blind, co-chair Advocacy Committee, RN
- Zandra Brown – President, Capital City Council of the Blind (Olympia)
- Holly Chisa – Northwest Grocery Association
- Doreen Cornwell – Co-chair Washington Council of the Blind Advocacy Committee
- Hart Edmonson – medical student
- Jim Hedrick – Walgreens
- Matthew Hines – Vancouver, consumer
- Lis Houchen – retired, National Association of Chain Drug Stores
- Corey Grandstaff – President, National Federation of the Blind (Clark County chapter) and administrator Washington State School for the Blind.
- Domeg Moore – medical student, member of Health Equity Circle Language Access Team
- Luis Perez Velasquez – Senior Biologist, Spokane County medical interpreter
- Sheri Richardson – chair, Washington Council of the Blind Government Affairs Committee

2.2 FDA Proposed Rule: National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers

On February 4, 2022, the FDA released proposed regulation, *National Standards for the Licensure of Wholesale Drug Distributors and Third Party Logistics Providers*. The proposed regulation will entirely replace the current set of federal regulations applicable to wholesale distributors. The FDA is currently seeking public and stakeholder comment on the proposed regulation. The comment period was originally set to close on May 24, 2022, however, the FDA extended the comment period, which now closes on September 6, 2022.

The Commission was provided an overview of the proposed regulation. The Commission was also informed that if the FDA adopts this regulation it may require the Commission to engage in legislative and rulemaking work because of FDA's interpretation of the preemption provision in the DSCSA.

Commissioner DeFrance raised concerns about the scope of the proposed rulemaking and whether it would apply to 503B outsourcing facilities, or nuclear pharmacy.

MOTION: Hawkins DeFrance moved to task staff to send comments to the FDA for clarification about the FDA licensed facilities and for additional clarification regarding the draft rule related to inspections. Judy Guenther, second. Motion carries, 13:0.

2.3 Manufacturers and Wholesalers of Dialysate (SHB 1675) Policy Statement

Joshua Munroe briefed the commission that the purpose of this policy statement is to establish the commission's position on expected practices surrounding dialysate provided

directly to home dialysis patients by wholesalers and manufacturers while standard rulemaking is ongoing. The statement sets an expectation that identified entities – wholesalers and manufacturers – must comply with WACs 246-945-090 through -093.

MOTION: Craig Ritchie moved to approve the proposed policy statement as written and for staff to distribute via GovDelivery and the commission website. Hawkins DeFrance, second. Motion carries, 13:0.

2.4 Rulemaking Authority Expansion on WAC 246-945-060 (Mobile OTP Units)

Joshua Munroe and Lindsay Trant briefed the commission on the history of this rulemaking project related to OTP mobile units. Inspections of OTP mobile units conducted jointly with the DEA revealed deficiencies that would apply to other licensed locations but are not covered in rule for mobile OTP units. WAC 246-945-060 would need to be amended to add additional requirements and adding a new WAC may also be needed.

Staff requests the commission consider expanding the scope of the previously authorized rulemaking project on WAC 246-945-060 and consider adding a new WAC to explore regulatory requirements for mobile OTP units.

MOTION: Craig Ritchie moved to expand scope of the previously authorized rulemaking project on WAC 246-945-060 and consider adding a new WAC to consider adding regulatory requirements for mobile OTP units. Hawkins DeFrance, second. Motion carries, 13:0.

2.5 Amended WAC Language for the AIDS Education Requirement Repeal (ESHB 1551)

Joshua Munroe presented on the history of this issue for newer commission members and an explanation of recent actions taken to advance the expedited rulemaking package. Staff requests the commission consider approving the amended language on WACs 246-945-162, -200, and -205. If approved, staff will proceed with filing the CR-105 for expedited rulemaking.

MOTION: Craig Ritchie moved to approve the amended language on WACs 246-945-162, -200, and -205 and authorize staff to proceed with filing the CR-105 for expedited rulemaking. William Hayes, second. Motion carries, 13:0.

2.6 Emergency Rule Refile Request: Retired Active Pharmacist License Status

Joshua Munroe provided an assessment of the emergency rule and a progress report on the same issue. The Proposal Phase rule packet (CR-102) is currently under division pre-review. In the meantime, emergency rules are still needed to allow pharmacists with retired active pharmacist licensure to practice during declared states of emergency. The current emergency rule is set to expire on September 24, 2022. Staff requests the commission approve the re-filing of the retired pharmacist emergency rule.

MOTION: Craig Ritchie moved to direct staff refile the emergency rule. Ken Kenyon, second. Motion carries, 13:0.

3. **Panel Review Study Plan** (Helen Jung, Patrick Gallaher, Judy Guenther)

MOTION: Craig Ritchie moved to delegate the authority to approve study plans in the cases listed in 3.1 and 3.2. to Commissioners Jung, Gallaher, and Guenther. Hawkins, second. Motion carries, 13:0.

3.1 PHRM.PH.60874656

MOTION: Patrick Gallaher moved to approve allowing candidate to take the exam a fourth time. Helen Jung, second. Motion carries, 3:0.

3.2 PHRM.PH.61230173

MOTION: Patrick Gallaher moved to approve allowing candidate to take the exam a fourth time. Judy Gallaher, second. Motion carries, 3:0.

4. **Open Forum**

5. **Commission Member Reports**

5.1 NABP Report – Teri Ferreira and Jerrie Allard attended the May NABP annual meeting. Hearing our peers' issues and challenges was very informative. One of the biggest challenges is workforce. Other states have gone into rulemaking to address some of that. DSCSA was another popular topic. Discussion on what individual pharmacies' responsibilities will be and how to prepare.

5.2 Pharmacy Practice Subcommittee – Craig Ritchie – the subcommittee will be working on the AUP form to ensure it is easy to complete the form and have it approved.

5.3 Legislative Subcommittee – William Hayes – the subcommittee met in June where the Uniform Facilities Enforcement Framework was presented. We started opening up listening sessions to prepare for the 2024 legislative sessions. The meeting in August has been cancelled in lieu of the special meeting

5.4 Compounding Subcommittee – Hawkins DeFrance – the compounding subcommittee met Tuesday, July 12. Stakeholders contributed to a very robust conversation.

The practices known as white, brown, and clear bagging were discussed. Stakeholders were largely concerned with patient safety. The staff was asked to research the various forms and the extent to which they fit within the commission's regulatory framework.

The second topic was the non-resident pharmacy directive of approved inspection programs from other states. Nomi Peaks presented an analysis on NABP law assessments. Four states stood out as having non-equivalent requirements compared to Washington State. Stakeholder discussion centered on "what does sufficiently equivalent mean?" Consensus of stakeholders came down to, "it should not be harder to be a compounding pharmacy in Washington doing business than it is for an out-of-state pharmacy not held to the same standards." Suggestions were to look closer at USP requirements 795, 797, and 800.

Staff was asked to send out GovDelivery to solicit feedback from stakeholders that know more about laws in specific states related to compounding.. Staff will report to commission in the future.

5.5 Budget Subcommittee – Patrick Gallaher reviewed the 2021-23 Budget & Fund Balance Overview. The fund balance is strong. Recently paid for the HELMS project – a modernized electronic licensing system.

Marlee O'Neill informed the commission we received permission from the department to hire nine additional staff – four inspectors, pharmacist consultant, and a few program team staff. We will need to do a decision package for the 2024 legislative session so the allotment can be reallocated elsewhere. This allotment will not require a fee increase. Marlee O'Neill and Lindsay Trant also clarified the rubric used to determine how many staff and where they will be used.

Miceal Carnahan advised the commission that in general moving to the two-year renewal cycle for the profession side, there will be a net-neutral effect. Also, this spring, there will be facility-type renewals, and this will contribute to the spike in March 2023. Also, the revenue seen now is a combination of fee change as well as increases in licensure.

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

Craig Ritchie mentioned the prescription label translation issues. The commission should make sure we reach out to the communities that need translations to gain insight on the actual needs.

Hawkins DeFrance regarding unintentional gap in veterinary medicine for emergency prescriptions. What can PQAC do to help? Chris Gerard confirmed there would need to be legislative change. PQAC staff will reach out to the Veterinary Board of Governors.

Jenny Arnold, Washington State Pharmacy Association – welcomed Marlee O'Neill as Executive Director. Encouraged all to support Marlee in this time as she learns the pharmacy profession and rebuilds the staff in this new post-COVID landscape.

6. Staff Reports *Information/Action.*

6.1 Interim Executive Director – Marlee O'Neill

- Paxlovid EUA Update – pharmacists can now prescribe Paxlovid if they have a CDTA with a prescriber that authorizes the pharmacist to prescribe Paxlovid or following the 9th amendment to the declaration under the Public Readiness and Emergency Preparedness Act (PREP) for medical countermeasures against COVID-19. With this revision there are still challenges in the department; and the commission and association are in discussion about those challenges.

6.2 Deputy Director – Lindsay Trant – staffing updates:

- Sasha DeLeon – formerly acting office director for Office of Health Professions (OHP) is now the Assistant Secretary for the division.

- Shawna Fox – is now the new permanent director for OHP. Shawna has been invited to meet the commission at the September meeting.
- Haleigh Mauldin, Program Consultant (HSC4) – non-permanent, one-year position to assist with the backlog of work, including but not limited to: rules work, non-routine applications, preparing for all meetings, etc.
- Amy Robertson – is now our Communications Coordinator and Program Support. She will assist with "all things technology." We will be posting the position of AA3 in the near future.

6.3 Assistant Attorney General – Christopher Gerard – will attend a webinar for attorneys in October via NABP for attorneys advising pharmacy boards/commissions.

7. **Summary of Meeting Action Items –** Commissioner and staff will revisit action items identified during today's business meeting.

- 2.1 – Survey on prescription label accessibility rulemaking to licensees
- 2.2 – Draft FDA comments to include asking for clarification on what is included as an FDA licensed facility; clarify inspection requirements for those seeking licensure for those seeking licensure from out of state.
- 2.3 – File policy on SHB 1675 with code revisor and distribute to licensees.
- 2.4 – Begin rulemaking to consider regulatory requirements for mobile OTP units and other controlled substance registrants.
- 2.5 – File CR-105 to continue expedited rulemaking on implementation of ESHB 1551 appealing aids education and training requirements.
- 2.6 – Refile emergency rules on the retired active pharmacists license status.
- 3.1 and 3.2 – Communicate with Office of Customer Service and the applicant(s) of a study plan as submitted
- 5 – Research ways to provide outreach and related materials on accessible label rulemaking in different languages.
- Correspond with veterinary board regarding emergency office use for short supplies for animals.

Business Meeting Adjourned. 4:04 p.m.