STATE OF WASHINGTON
Pharmacy Quality Assurance Commission
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Pharmacy Quality Assurance Commission Meeting
January 28, 2022 - Minutes

Convene: Chair, Teri Ferreira called the meeting to order January 28, 2022, 9:20 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

Staff:
Marlee O'Neill, Interim Executive Director, Pharmacy Commission
Lindsay Trant, Interim Deputy Director, Pharmacy Commission
Sasha De Leon, Acting Director, OHP
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, Administrative Assistant, Pharmacy

Commission Member Absent:
Ken Kenyon, PharmD, BCPS

Guest:
Ashley Bell, Behavioral Health Programs Coordinator, Office of the Assistant Secretary

1. Call to Order Teri Ferreira, Chair.

1.1 Meeting Agenda Approval – January 28, 2022

MOTION: Craig Ritchie moved to approve the meeting agenda for January 28, 2022. Jerrie Allard, second. Motion carries, 14:0.

1.2 Meeting Minutes Approval – December 17, 2021

MOTION: Craig Ritchie moved to approve the meeting agenda for December 17, 2021. Jerrie Allard, second. Motion carries, 14:0.

2. Consent Agenda

2.1 National Precursor Log Exchange Monthly Dashboard-November

2.2 Pharmaceutical Firms Application Report

- December 02, 2021 thru January 4, 2022 – new and closed firms (None to report)

2.3 Ancillary Utilization Plans Approval

2.3.1 Northwest Medication Management Services
2.3.2 Multicare Capital Medical Center
2.3.3 Olympic Pharmacy and Healthcare Services
2.3.4 Omak Pharmacy
2.3.5 Optum Infusion Services
2.3.6 Snoqualmie Valley Hospital

MOTION: Craig Ritchie moved to approve the consent agenda removing 2.3.2 and 2.3.5. Hawkins DeFrance, second. Motion carries, 14:0.

2.4 Pharmacy Technician Training Program Approval – None

2.5 Regular Agenda/Items Pulled from 2.3. The commission will discuss items removed from the consent agenda and placed on the regular agenda for separate discussion.

2.3.2 Multicare Capital Medical Center – Tim Lynch recused.

MOTION: Craig Ritchie moved to approve 2.3.2. Hawkins DeFrance, second. Motion carries, 13:0.

2.3.5 Optum Infusion Services - Ann Wolken recused.

MOTION: Craig Ritchie moved to approve 2.3.5. Hawkins DeFrance, second. Motion carries, 13:0.

3. Old Business – The commission will discuss, for clarification or decision, ongoing topics, and issues from previous meetings.

3.1 USP 800 & 825 self-inspection worksheets.

Shelley Feldner-Schuerman led the commission through the public comments.

MOTION: Craig Ritchie moved to approve the USP 800 and 825 self-inspection worksheets with the staff edits and the agreed changes made by the commission. Hawkins DeFrance, second. Motion carries, 14:0.

3.2 Research on White Bagging Regulations in Other States.

Nomi Peaks, PQAC Pharmacist Consultant, updated the commission how other states are addressing this issue from a legislative standpoint. The consensus is patient safety, quality assurance, and a focus to reduce the cost burden on patients. Recognition of the importance of medication pedigree, certification and adherence to the Drug Supply Chain Security Act which has updates that are set to become effective in 2023.

Massachusetts and New York have specifically expressed a requirement for medication pedigree to be certified so there is not a conflict when it comes down to being able to verify where the drug originated. In some cases of white bagging there is not always a second pharmacy involved.

Tim Lynch, commissioner, expressed concern that while these are important things to consider, this issue is outside the scope of this commission.

After significant discussion, the compounding committee has been assigned to review this issue and report to the commission to consider policy or rulemaking.

3.3 Suspicious Orders Requirement in WAC 246-945-585

MOTION: William Hayes motioned that the commission task the facility subcommittee (Commissioners: Kenyon, Ferreira, Hayes, Jung, and Lynch) with reviewing this rule and its implementation and preparing options and recommendations for the best way to proceed and presenting this at a future commission meeting. Craig Ritchie, second; Motion carries, 14:0.

3.4 ESSB 5229 Health Equity Continuing Education Implementation Update

Ashley Bell informed the commission of the importance of health equity, "when all people can reach their full health potential." ESSB 5229 establishes the requirement for health care professionals to take continuing education on health equity. This is a multi-phase project with a deadline of January 1, 2023 for the secretary of professions to develop these minimum standards continuing education. The deadline for boards and commissions is January 1, 2024.

To achieve these requirements prior to the rulemaking process, there will be multiple listening sessions with individuals who experience health inequity or racism. Once the listening sessions are complete, rulemaking workshops will commence where the comments gathered will be transformed into draft language for final the rulemaking process (CR-102, public comments, etc.)

4. **New Business --** The Commission will review items of interest related to pharmacy practice for discussion, clarification, information or action by or on behalf of the commission. ***Information/Action***.

4.1 FAQ on Labeling Requirement for Pre-drawn Syringes of COVID-19 Vaccine

MOTION: Tim Lynch moved to approve only FAQ #1 as presented/written by Taifa "Nomi" Peaks below; Judy Guenther, second. Motion carries, 14:0.

Q: Should a label be affixed to a pre-drawn COVID-19 vaccine syringe? If so, what information should the label include?

A: It is important to appropriately label any pre-drawn syringe to minimize the risk of administration errors and vaccine mix-ups. This includes pre-drawn syringes of the COVID-19 vaccine. A label should be affixed to a syringe so that the markings on the barrel of the syringe are not obscured and pertinent label information is easily visible and legible. In keeping with WAC 246-945-018 and per guidance from the Centers for Disease Control and Prevention (CDC) and the United States Pharmacopeia (USP), best practices for pertinent label information include:

- *The vaccine name and amount*
- *The expiration date and exact beyond-use date and time*
- *Lot number*
- *Initials of preparer(s)*

At a minimum, the label should include the information specified in WAC 246-945-018. Other rules may be applicable under certain conditions.

While the CDC notes that the safest practice is to draw up a dose of COVID-19 vaccine immediately before administration, the WA Department of Health recognizes that there are circumstances in which the use of a pre-drawn syringe is necessary. Please consult the CDC website for current beyond-use dating for COVID-19 vaccines, and for further guidance related to storing and handling pre-drawn COVID-19 vaccine syringes.

4.2 List and label request

MOTION: Tim Lynch moved staff evaluate the commission's ability to approve this request. Patrick Gallaher, second. Motion carries, 14:0.

5. Rules and Legislative Updates

5.1 2022 Legislation Update – Bill Report

Joshua Munroe, Legislative and Rules coordinator, reported on the status of the 2022 legislative session regarding legislation under the commission's jurisdiction in Washington State.

- HB 1852 / SB 5840 – Language requirements for prescription drug labels. There is quite a bit of momentum on this bill. PQAC supports the goals of the bill but expresses concerns due to the aggressive start date of January 2023.

- SB 5507 / SHB 1675 – Dialysate and dialysis devices – amends a few RCWs to include additional entities related to dialysis programs and treatment. The substitute bill changed verbiage to grant the commission rulemaking authority, addressing an expressed concern that oversight authority might be removed in the original version of the bill manufacturers and wholesalers are still required to have manufacturer or wholesaler licenses.

- SSB 5546 – Insulin affordability. This amends RCW 70.14.160 reducing the 30-day insurance copay cap for insulin from $100 to $35. This has been moved on to Ways and Means.

- HB 1728 – Insulin affordability – Workgroup funding and report deadline. Focus on the workgroup and extend deadline to provide preliminary reports. Due to COVID the workgroup was unable to meet.

- SB 5547 / HB 1668 – Expanding regulatory authority over cannabinoids This bill adjusts the regulatory oversight on certain cannabinoid substances. The substitute bill adds distinctions on artificial and synthetic cannabinoids.

- SB 5767 – Regulating hemp-derived cannabinoids. No significant movement made on this bill as focus is more on SB 1668.

- SSB 5753 – Enhancing the capacity of health profession boards, commissions.

- SB 5660 – Establishment of psilocybin board for behavioral wellness.

- SB 5743 – Designating kratom as a controlled substance; not much momentum.

- SB 5941 – The Washington Kratom Consumer Protection Act – establishes a board similar to the psilocybin board to create a regulatory structure. There are a number of concerns regarding the stated effect of the bill.

- HB 1863 – Authorizing prescriptive authority of psychologist – no follow up discussion or hearings.

5.2 Medication Assistance Emergency rules reauthorize

MOTION: Craig Ritchie moved to reauthorize the medication assistance emergency rules. Tim Lynch, second. Motion carries, 14:0.

5.3 Rules Petition on Translated Directions of Rx Labels

WSPA petitioned PQAC to adopt a new rule to make translations of prescription medication directions on the label available to ambulatory or community-based patients. Also, "to reduce medication errors and increase adherence in patients with limited English proficiency in a safe and implementable way" WSPA requests to amend WAC 246-945-417 to include a new section stating, "pharmacy outpatient dispensing systems must have the ability to translate prescription medication directions by July 1, 2025." Response must be delivered no later than March 14, 2022.

Jenny Arnold, WSPA, addressed the commission: We felt this is probably where we need to go as a pharmacy profession to better serve patients. However, if the legislation is overly detailed, it is difficult to implement in a meaningful way in pharmacies. WSPA believes PQAC is integral in implementing this safely.

MOTION: Craig Ritchie moved to approve the WSPA petition filed on January 13, 2022 for rules related to translation prescription descriptions. William Hayes, second. Motion carries, 14:0.

6. **Open Forum** (10 minutes)

Non-resident compounding pharmacies doing business in Washington State

Erika Anderson, Virginia Mason Franciscan Health, addressed the commission with a question regarding the directive for non-resident pharmacies and a list of inspection programs. In the latest revised directive under "approved inspection programs for non-resident pharmacies which do not engage in compounding" (four states), how do individuals verify if a pharmacy within one of these four states has either attested they do not compound or if they submitted an inspection report to the commission by an approved inspection program which would then allow them to send compounded products into our state? Is there an indicator on the non-resident pharmacy license that says "attested they do not engage compounding" or if they are one of these four states, they have submitted an inspection report from a commission approved inspection program? How do we find that out?

Commission response:

The commission/staff responded: There is no indicator on a non-resident pharmacy license to indicate if they are licensed to ship compounded drugs into Washington State. If an individual wanted to verify if a nonresident pharmacy could ship compounded drugs into Washington State they could make a public records request. If an individual believes a nonresident pharmacy is inappropriately shipping compounded drugs into Washington State then they could make a complaint.

The commission directed staff to investigate whether there is a way to operationalize (i.e., a list or website) or a way to make it easier for licensees to obtain the information and bring this back to the next meeting.

Routine Inspections / License/credentialling waiting period

Jenny Arnold, pharmacist, addressed the recent PQAC announcement / reminder about appropriate staffing. Pharmacies are in crisis right now, especially (but not only) community pharmacies. They are trying to staff but with COVID, it's tough to just keep medications flowing. In addition, our community pharmacies have given 42% of the COVID vaccinees in our state to date.

Due to the inundated pharmacies/pharmacists, she suggested pausing inspections again, because the pharmacies just do not have the time to go into an appropriate inspection or give the time for a good inspection at this point. No one wants to be judged by their worst day; and we are in some challenging days right now.

Secondly, she asked the commission to do something about the long turn-around time on licensing.

Lastly, she gave a heartfelt thank you to the pharmacy professionals out there every day serving patients.

Commission response:

The discussion regarding pausing inspections centered around finding a middle-ground, including whether the inspector could contact the pharmacy within a week (or so) to schedule the inspection. The pharmacy/pharmacist would then have time to adequately staff for the inspection. However, this issue would be better served at a special meeting or the next business meeting so PQAC inspectors/staff could gather information.

MOTION: Tim Lynch made a motion to 1) allow for scheduling routine inspections within a two-week time frame of first contact by the inspector and 2) the commission engage in further conversation about what we need to do long-term by the next meeting or special meeting and to consider precise steps needed related to routine inspections. Judy Guenther, second. Yay: 13; Nay, 1.

7. Commission Member Reports.

7.1 Commissioner Reports

7.1.1 Recognition of Service

The commission recognized the following for their service. Both will continue to serve until the positions can be filled, but their official term is completed.

- Tim Lynch – has served eight years on the commission as a member and chair. Also, Teri thanked Tim for being a mentor as former chair. Jerrie thanked Tim for staying on during this transition. Hawkins also thanked Tim for the newer commissioners, he has been a great source of information, setting a high bar for the rest of us. Marlee, thanked Tim for his support and guidance and taking all the phone calls. Helen Jung thanked Tim and mentioned she see the big part he played in this group of leaders. Tim is great role model and example for all of us.

  Tim replied: thank you all. I have learned so much being a part of the commission and working with amazing people It has been an honor and privilege.

- Bonnie Bush – has served three years. Teri stated she really appreciated Bonnie's patient advocacy approach and that you asked important questions.

  Bonnie stated it had been a pleasure and she had enjoyed working with the commission and phenomenal people. My only regret is not able to do it in person. Tim responded: I really appreciate Bonni the lens she brought to the work that we do.

7.2 Commissioners' open discussion related to items or issues relevant to commission business/pharmacy practice.

Tim Lynch recognized that we have the recent passing of Tim Fuller. Tim was a long-time supporter of the commission. On behalf of the commission, we are saddened by his loss. He was an incredible part of the commission and part of the pharmacy profession. Express the commission's thoughts and prayers for his family.

8. Staff Reports

8.1 Interim Executive Director – Marlee O'Neill

8.1.1 DOH Staff Farewell and Recognition

- Kirby Putscher, the commission's case manager, is celebrating 45 years of state service.
- Luke Park, staff attorney, will not be returning to the department after completing paternity leave.
- Project Pharmacy Inspector positions – on-going interviews.
- Pharmacy Inspector Supervisor position – interviews commencing soon.
- Pharmacy Inspector Stan Moore is retiring in February. Stan has served as both investigator and inspector with the department for ten years. His colleagues note his kindness, generosity, and great stories. He has unfailing dedication to pharmacy in the state of Washington.

8.2 Interim Deputy Director – Lindsay Trant

8.2.1 PREP Act Authorization for Oral Anti-virals

- Secretary Shah signed PREP Act Authorization on January 4, permitting hospitals to distribute the full course of antiviral drug authorized for the treatment of COVID-19.

8.2.2 Clarification on CE Rule

- The two-year renewal cycle went into effect with the new CE rules on December 1, 2021. Implementation is on-going. The commission voted to repeal the old CE rules. While we will need to repeal the old CE rules, the effective date will be December 1, 2022. Both sets of CE rules will need to be in place for a short time.

- The commission repealed guidance documents no longer needed at the December 17, 2021 meeting. DOH 690-346 states that CE credits will be applied for attending commission meetings. Licensees will no longer be able to earn CE for attending commission meetings.

8.3 Interim OHP Office Director – Sasha De Leon

Reported the search for PQAC's executive director and deputy director is on-going. This is a priority for OHP to fill these positions with quality candidates as soon as possible.

8.4 Assistant Attorney General – Chris Gerard

The lawsuit John Worthington filed against the commission, as well as Governor Jay Inslee and the Washington State Department of Health (Case No. 21-2-01099-34), was dismissed without prejudice in Thurston County Superior Court in November 2021.

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

- 1. Meeting Minutes Approval – December 17, 2021 post approved minutes to website (also we need to archive past meetings).
- 2.3 Ancillary Utilization Plans Approved all -staff will notify credentialing.
- 3.1 Finalize revision of the worksheets and post to website and send GovDelivery with guidance from the commission in accordance with policy statement #65.2.
- 3.2 Schedule meeting with compounding subcommittee to craft language to report back to the commission.
- 3.3 Suspicious order rule- Option one Schedule meeting with the Facilities Subcommittee to discuss potential solutions and bring options back to the full commission.
- 4.1 Staff will post FAQ #1 and distribute though GovDelivery without revisions and FAQ submitted to web team.
- 4.2 Staff will gather information on alternate options for list and label request.
- 5.2 Staff to refile emergency rules Medication Assistance.
- 5.3 Approve rules petition. The commission staff will work on draft of official response will provide by March 14, 2022 (or sooner).
- 6. Have staff look into ways to confirm that a non-resident pharmacy is permitted to compound medications. Report back on options.
- 6. Gather information from inspectors to bring back to next meeting regarding routine inspections.

Business Meeting Adjourned. 4:40 p.m.