STATE OF WASHINGTON
Pharmacy Quality Assurance Commission
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Pharmacy Quality Assurance Commission Special Meeting
September 23, 2022 - Minutes

Convene: Chair, Teri Ferreira called the meeting to order September 23, 2022, 9:06 a.m.

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

Commission Members Absent:
Hawkins DeFrance, PharmD

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

Inspectors:
Scott Craig
Stephanie Martin
Crystal Phipps

1. **Call to Order**

1.1 Meeting Agenda Approval – September 23, 2022

MOTION: Craig Ritchie moved to approve amended business meeting agenda adding *2.8 Subcommittee assignments* (replace Kat Wolf-Khachatourian as representative on the Total Cost of Insulin Workgroup) for September 23, 2022. Tim Lynch, second. Motion carries, 12:0.

2. Old Business

2.1 Sample Ancillary Utilization Plan *(Follow up from Pharmacy Practice Subcommittee)*

Taifa "Nomi" Peaks, Pharmacist Consultant, presented a brief review of past comments/ suggestions, how these comments/suggestions were applied to the form(s), and asked for additional feedback/instructions.

The commission tasked the subcommittee to make these following edits and discuss the following as possible changes:

- Remove the column that says *Reviewed by Responsible Pharmacy Manager*.
- Other Pharmacy Functions: gather feedback related to the function of cassettes/canisters.
- Add spot for pharmacy name and license number whether on the form or by using an addendum.
- Prescription Intake: add "or drug name."

- Add to assistant: “Handles calls from prescriber’s office authorizing refills, provided no changes in the prescriptions are involved.”
- Remove: “Pharmacist initials on the prescription label.” (page 9)

2.2 Pharmacy Assistants Scope of Practice (*Follow up from Pharmacy Practice Subcommittee)*

Taifa “Nomi” Peaks, Pharmacist Consultant, reviewed highlights of the Pharmacy Practice Subcommittee meeting. Specifically, the subcommittee was tasked with examining the guidance document, DOH 690-356 (Access to Drugs Stored Outside of the Pharmacy), to determine if modifications to the document’s current language were needed in order to address the question, “May assistants stock an ADDD?” The subcommittee was also tasked with engaging in stakeholdering to consider the viewpoints of those in support of, and those opposed to, pharmacy assistants retrieving (also called “pulling”) medications from pharmacy shelves for filling prescriptions and for stocking outside of a pharmacy. The subcommittee did not recommend making changes to DOH 690-356 because the document refers to unlicensed employees of healthcare facilities, and pharmacy assistants are licensed pharmacy personnel. The comments offered by stakeholders during the subcommittee meeting were compiled and shared with the full commission in an SBAR. During the discussion, commissioners and stakeholders expressed concern over patient safety and proper training for assistants. The commission also asked the pharmacy practice subcommittee to review the following:

- If pulling drugs should be part of a pharmacy assistant’s scope of practice.
- Defining whether “stocking” for assistants means just shelves or includes other things such as stocking an ADDD, etc.
- Related to prescription processing, does the definition of “obtain” encompass medication retrieval?

2.3 Uniform Facility Enforcement Framework (UFEF) Z-draft

Marlee O’Neill, Executive Director, reviewed the minor changes from the August 24, 2022 version to the draft Z-draft. Both changes were requested by the Code Revisor’s office:

1. Section 34(1) (page 91, line 6) – the last sentence now states: “**The Commission** ~~and~~ may deny the petition or may order reinstatement **of the licensee’s license. The Commission may** ~~and~~ impose terms and conditions ~~issue an~~ **in the** order of reinstatement.”

2. Section 34 (page 97, line 22) – removed RCW reference and redirected to Section 31 and 33.

Christopher Gerard also presented some potential edits to the draft Z-draft for consideration by the Commission.

3. Page 85, line 6 and line 17 – remove “corrective”.

4. Page 85, line 14 – definition: (36) "License," "licensing," and "licensure" shall be deemed equivalent to the terms “approval”, “credential”, ~~“licensure,”~~ "certificate," "certification," “permit”, ~~and~~ "registration", **and an “exemption” issued under chapter 69.50 RCW.**

5. PAGE 85, line 21, (38) “Statement of deficiency” means a written statement of the deficiencies ~~completed~~ **prepared** by the commission, or its designee, identifying one or more

violations of law. The report clearly identifies the specific law or rule that has been violated along with a description of the reasons for noncompliance.

6. Page 86, starting at line 1 and page 87 starting at line 9, replacing the word "their" with "its".

7. PAGE 86-87, starting at line 39 – a (6) ~~If the commission issues a written notice of revocation, suspension, or modification of a license and the licensee timely files an appeal, t~~ **The commission may accept the surrender of the licensee's license. A licensee that surrenders its license may not petition for reinstatement of their surrendered license.**

8. PAGE 90-91, starting at line 39 (page 90) – The commission may ~~only~~ take action under subsection (1) of this section against a nonresident pharmacy for failure to comply with any requirement of RCW 18.64.350 through 18.64.400, unless the nonresident pharmacy's conduct cause psychological, physical, or financial injury to a resident of this state* ~~and~~ **or** the conduct resulted in adverse action against the nonresident pharmacy by **a federal agency or** the regulatory or licensing agency in the state in which the nonresident pharmacy is located.

The commission discussed potential third-party payor language and wanting to ensure it has authority to take enforcement action against non-resident pharmacies.

MOTION: Craig Ritchie moved to approve the proposed changes and proceed with third party payor language and give the commission as much authority as possible around non-resident pharmacies . Bonnie Bush, second. Motion carries, 12:0.

2.4 Review Enforcement Discretion on USP 800

Lindsay Trant-Sinclair, Deputy Director reviewed Policy #65.3 on the enforcement of USP 800 is set to expire on September 30. The commission can consider extending its enforcement discretion on USP 800 for a period of time to be determined by the commission. The current enforcement discretion on USP 800 expires after September 30, 2022.

MOTION: Craig Ritchie moved to approve extend enforcement discretion until it is withdrawn by the commission at an open public meeting and staff will keep the commission updated at least once every three months on the status of revised USP 795 and 797. Jerrie Allard, second. Motion carries, 12:0.

2.5 Regulatory Framework for White Bagging *(Follow up from Compounding Subcommittee)*

Taifa "Nomi" Peaks, Pharmacist Consultant, presented a brief review of the SBAR on White Bagging. The commission tasked the legislative subcommittee with discussing whether legislation on this issue is something the commission should pursue. The commission also tasked the facility subcommittee with reviewing current laws and rules to see how those impact white bagging and to consider possible rulemaking.

2.6 Guidance for Prescription Drug Pick-up Lockers

Taifa "Nomi" Peaks, Pharmacist Consultant, presented a brief review of this document which serves to detail the commission's position on the topic of prescription drug pick-up lockers, with a specific examination of how the delivery of filled prescriptions of non-controlled legend drugs

to pharmacy-owned lockers does not fall under the commission's rules on drug stored outside of a pharmacy in WAC 246-945-455.

MOTION: Craig Ritchie moved to approve the guidance document for Prescription Drug Pick-up Lockers. Bonnie Bush, second. Motion carries, 12:0.

2.7 Update on Accessible Label Rulemaking

Joshua Munroe, Rules and Legislative Coordinator, informed the commission that staff developed and distributed a survey to licensed pharmacy personnel for two purposes: 1) to discover whether and how pharmacies are currently providing accessible labeling options to patients, and 2) to determine what logistic and fiscal obstacles exist for pharmacies and other facilities licensed under the commission's jurisdiction in providing accessible labeling options. The survey is open until October 16. Feedback from the survey will be shared with the commission at the November business meeting.

2.8 Updates to Subcommittee Assignments

Committee	Commission Members
Recurring	
Budget Subcommittee • HELMS	**Chair**: Patrick Gallaher **Members**: Williams Hayes, Bonnie Bush, Matthew Ray **Staff lead**: PQAC Executive Director and Finance Officer
Legislative Subcommittee • White bagging	**Chair**: William Hayes **Members**: Hawkins DeFrance; Craig Ritchie; Chair -or- Vice Chair **Staff lead**: Rules and Legislative Consultant
Strategic Planning Subcommittee	**Chair**: Jerrie Allard **Members**: Ann Wolken; Hawkins DeFrance; Chair **Staff lead:** Program Manager, Executive Director, Deputy Director
Ad Hoc	
Compounding Subcommittee • FDA MOU • Self-inspection worksheets	**Chair**: Hawkins DeFrance **Members**: Ken Kenyon, Uyen Thorstensen **Staff lead**: Pharmacist Consultant
Facility Subcommittee • HPACs committee • Suspicious orders • Facility enforcement authority • White bagging	**Chair**: Ken Kenyon **Members**: Teri Ferreira, William Hayes, Uyen Thorstensen **Staff lead**: Pharmacist Consultant
Pharmacy Practice Subcommittee • Misfill and Pharmacy Work Condition Workgroup • Sunrise review • CDTA WMC Committee (Teri) • Sample AUP review	**Chair**: Craig Ritchie **Members**: Teri Ferreira, Patrick Gallaher, Ann Wolken **Staff lead**: Pharmacist Consultant

Approved 092322

MOTION: Craig Ritchie moved to approve all the members as listed to the various subcommittees and other revisions made. Judy Guenther, second. Motion carries, 12:0.

Amended Item – Appoint New Commissioner to the Total Cost of Insulin Workgroup

MOTION: Craig Ritchie moved to appoint Tim Lynch as representative for the Pharmacy Quality Assurance Commission to the Total Cost of Insulin Cost Workgroup. Jerrie Allard, second. Motion carries, 12:0.

2.9 Governor Inslee Rescinding all Remaining COVID-19 Proclamations and the State of Emergency in Washington by October 31, 2022

Marlee O'Neill, Executive Director, and Lindsay Trant-Sinclair, Deputy Director, reviewed various decisions the commission made throughout the pandemic and next steps given the ending of the state of emergency (SOE).

- Staff will remove Plan-19 from the website but will take information or FAQs from it that remain applicable independent of the SOE and put those on the commission's website.
- In August 2020, the commission approved the use of a technical assistance letter to provide healthcare providers assistance if reported for allegedly not following or violating Governor issued proclamations related to the COVID-19 state of emergency. The Secretary's mask order will remain in effect. Staff can update the technical assistance letter so that it can still be used, on a case-by-case basis, to provide technical assistance for reports of not complying with the Secretary's mask order while it is in effect.
- In October 2020, the commission approved the use of virtual inspections when: (i) the inspector and licensee agree to a virtual inspection, (ii) the inspector makes this request to the inspector supervisor or designee to conduct a virtual inspection due to unavoidable circumstances (COVID-19, PPE shortages), and (iii) the inspector supervisor or designee approves the virtual inspection. The inspectors are using this option very infrequently now. The motion was tied to "unavoidable circumstances" and not specifically to COVID or the state of emergency. We would like to continue to have this option available when there are "unavoidable circumstances."
- Yesterday, the commission reauthorized refiling emergency rules on dispensing emergency oral Schedule II prescription drugs during the COVID-19 pandemic. The emergency rule mirrors guidance in place by the DEA. This emergency rules is necessary until the federal state of emergency ends or a similar policy announcement is made by the DEA.
- In March 2021, the commission approved joint COVID-19 safety guidance with L&I. This guidance was based on proclamation 20-24.2 which will be rescinded, effective as of October 27th. We will remove this from the commission's website effective October 27th.
- In May 2022, the commission agreed to waive the inspection report requirement for non-resident pharmacy renewals if the non-resident pharmacy provided a letter from its home state stating that the home state cannot timely complete an inspection due to COVID. This was just for the 2022 renewal cycle, so no action is needed as all non-resident pharmacies' credentials expire on May 31 of each year.
- The recission of the state of emergency in Washington will not impact the validity of the U.S. Dept of Health and Human Services' PREP Act, which authorizes pharmacists to "order and administer COVID-19 tests, including serology tests, that the Food and Drug administration has authorized." This guidance preempts any state law requirements that are different or conflict. HHS has explained that because pharmacists are covered persons

under the declaration, they may order and administer COVID-19 tests even if state law would typically require a prescription.

The commission agreed with what staff outlined and determined a FAQ related to the PREP Act was not necessary.

3 New Business

3.1 Monitoring of Drug Therapy

Marlee O'Neill, Executive Director, reviewed the SBAR, which outlined that "the monitoring of drug therapy" is within the "practice of pharmacy." RCW 18.64.011(28). The commission has further defined the definition of the "monitoring of drug therapy" in WAC 246-945-355. This rules states that "a review of the drug therapy regimen of patients by a pharmacist for the purpose of evaluating or rendering advice to the prescribing practitioner or patient regarding the patients' drug therapy. Monitoring of drug therapy includes, but is not limited to, the evaluation of the patient through history taking, physical examination, ordering, administering, or reviewing laboratory tests, imaging, and social evaluation related to an existing diagnosis and drug therapies for optimization of drug therapy."

Taken in aggregate, the commission's statute and rule do not permit pharmacists independently engaging in POC testing and health screenings related to a condition an individual has not received a diagnosis for and has not been prescribed any medication to treat, unless the pharmacist is acting pursuant to the terms of a CDTA, or other standing order or protocol developed by an interdisciplinary team that includes a prescribing practitioner.

Commissioners and stakeholders engaged in discussion around the how the rule impacts pharmacy practice. Concerns were raised by both Commissioner and stakeholders that the applicable statute and rule may be too restrictive and not reflective of current pharmacy practice.

MOTION: Tim Lynch moved that the commission staff further evaluate the monitoring of drug therapy and consider rulemaking. Craig Ritchie, second. Motion carries, 12:0.

4 Open Forum

5 Commission Member Reports. *Information/Action*

5.1 NABP District Meeting Report Out – Teri Ferreira / Jerrie Allard / Ann Wolken – reported the meeting had two very powerful presentations: 1) the impact of the pharmacist on the opioid epidemic and 2) maintaining temperature control for medications that are mailed. While informative, there were no 'take away' tools, but still a good meeting overall.

5.2 Budget Subcommittee – Patrick Gallaher – As of June 30, there is a balance $6.6 million. We are on target for the biennial projection for our fund balance.

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

5.3.1 Jerrie Allard commended the staff on our first successful hybrid meeting.

5.3.2 Ken Kenyon commented on Jerrie's meeting report – One thing to not forget is that Washington State is one of a handful of states that is not an "any willing provider state." One of the things we can advocate for patients is to work on Washington State to become an "any willing provider state" giving patients the freedom of choice to choose a pharmacy and how to receive their pharmaceutical care.

5.3.3 Matthew Ray asked where the six-month inspection letters are sent. Marlee O'Neill stated that they are sent to the mailing address that the entity provides the department.

6 Staff Reports *Information/Action*

6.1 Executive Director – Marlee O'Neill - Marlee provided the following report.

- We are tentatively planning to have all of the inspectors attend the January business meeting. Patrick Gallaher appreciates the inspectors will be joining to have more of a "boots on the ground" perspective.
- At the commission's direction, staff provided comment to the FDA in response to the FDA's proposed rule for National Standards for the Licensure of Wholesale Drug Distributors (and 3PLs). The letter is included in your correspondence.
- The State Auditor's Office (SAO) is conducting an audit of the Prescription Monitoring Program (PMP). The final audit report is scheduled to be released on October 4th. There will be a virtual Joint Legislative Audit and Review Committee (JLARC) hearing at 10am on October 19, 2022 to consider the audit findings and receive public testimony.

6.2 Deputy Director – Lindsay Trant-Sinclair – Lindsay provided the following report.

- The department is shifting to a new system for reviewing rules packages. This new system will replace the outdated RMS system currently used, but the implementation has resulted in some short delays. We will hold two public hearings in November.
- We will be hiring for a new Administrative Assistant 3 in the coming weeks.
- The recruitment for a new pharmacist member is finished and we are putting forth a candidate to the Governor's Office. We will have a second opening with Helen's resignation. We are also currently conducting interviews to fill the vacant public member seat.

6.3 Assistant Attorney General – Christopher Gerard – none.

7 Summary of Meeting Action Items –

Commissioners and staff will revisit action items identified during today's business meeting.

- **2.1 – Sample Ancillary Utilization Plan** – bring sample AUP back to the pharmacy practice subcommittee to review items identified.
- **2.2 – Pharmacy Assistants Scope of Practice** – Bring questions regarding pharmacist scope of practice back to pharmacy practice subcommittee for recommendations.
- **2.3 – Uniform Facility Enforcement Framework** – Staff will make the revisions and keep the commission apprised on the status of the UFEF.
- **2.4 – Review Enforcement Discretion on USP 800 –** Staff will update the policy statement on its enforcement direction on USP 800, will update website, and will update the commission regularly on the status of this matter on 795 and 797.
- **2.5 – Regulatory Framework for White Bagging** – bring this topic to legislative and facilities committees.

- **2.6 – Guidance for Prescription Drug Pick-up Lockers** –Staff will publish the guidance document on prescription drug pick-up lockers and distribute GovDelivery.
- **2.7 – Update on Accessible Label Rulemaking –** Survey – bring back results in November.
- **2.8 – Updates to Subcommittee Assignments** – Staff will update the subcommittee table.
- **2.9 – Governor Inslee Rescinding all Remaining COVID-19 Proclamations and the State of Emergency in Washington by October 31, 2022 –** Staff will review Plan 19 and maintain FAQs that remain relevant once the state of emergency ends and bring this back in November.
- **3.1 – Monitoring of Drug Therapy** – Staff will further evaluate the monitoring of drug therapy and bring this topic back at a future meeting.

Business Meeting Adjourned 2:30 pm