

STATE OF WASHINGTON Pharmacy Quality Assurance Commission PO Box 47852 – Olympia, Washington 98504-7852 Tel: 360-236-4030 – 711 Washington Relay Service

Pharmacy Quality Assurance Commission Meeting December 17, 2021 - Minutes

Convene: Chair, Teri Ferreira called the meeting to order December 17, 2021, 9:10 a.m.

Commission Members:

Teri Ferreira, RPh, Chair Jerrie Allard, Public Member, Vice Chair Ken Kenyon, PharmD, BCPS 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 Ann Wolken, PharmD, RPh

Commission Member Absent:

Bonnie Bush, Public Member

Staff Members:

Margaret C Holm, Interim Executive Director, Pharmacy Commission Lindsay Trant, Interim Deputy Director, Pharmacy Commission Heather Carter, AAG Hope Kilbourne, Policy Analyst Martin Pittioni, Director, OHP Marlee O'Neill, Deputy Director, OILS Joshua Munroe, Legislative and Rules Consultant Taifa "Nomi" Peaks, Pharmacy Consultant Irina Tiginyanu, Pharmacy Technician Consultant Joanne Miller, Program Manager, Pharmacy Amy L Robertson, Administrative Assistant, Pharmacy

- 1. Call to Order Teri Ferreira, Chair Action
 - 1.1 Meeting Agenda Approval December 17, 2021

MOTION: Craig Ritchie moved to approve the meeting agenda for December 17, 2021. Ken Kenyon, second. Motion carries, 12:0.

1.2 Meeting Minutes Approval – October 22, 2021

MOTION: Craig Ritchie moved to approve the minutes for September 2, 2021. Ken Kenyon, second. Motion carries, 12:0. Staff members will confirm commissioner attendance for voting count accuracy for the October 22, 2021 meeting.

2. Consent Agenda Items listed under the consent agenda are considered routine and necessary commission matters and will be approved by a single motion of the commission without separate discussion. If separate discussion is desired, that item will be removed from the consent agenda and placed on the regular business agenda. *Action item.*

- 2.1 National Precursor Log Exchange Monthly Dashboard-November
- **2.2** Pharmaceutical Firms Application Report October 05, 2021, thru December 1, 2021– new and closed firms
- **2.3** Ancillary Utilization Plans Approval
 - 2.3.1 Lake Chelan Community Hospital Pharmacy
 - 2.3.2 Olympia Pharmacy
 - 2.3.3 Seattle Childrens Forest
 - 2.3.4 Amerita

2.4 Pharmacy Technician Training Program Approval

- 2.4.1 Yokes Pharmacy
- 2.4.2 Duvall Family Drugs

MOTION: Craig Ritchie moved to remove 2.3.4 Amerita to 2.5 for discussion and to approve the remaining consent agenda. William Hayes, second. Motion carries, 12:0.

- **2.5 Regular Agenda/Items Pulled from 2a.** The commission will discuss items removed from the consent agenda and placed on the regular agenda for separate discussion.
 - 2.3.4 Amerita

MOTION: Tim Lynch moved to tentatively approve Amerita's AUP and task staff to clarify with Amerita the checklist they are referencing in the AUP ("Washington State Department of Health 797 Checklist"). Craig Ritchie, second. Motion carries, 12:0.

- **3.** Old Business The commission will discuss, for clarification or decision, ongoing topics and issues from previous meetings. *Information/Action.*
 - **3.1** Nonresident Pharmacy Directive: Approved list of recognized State inspections

Lindsay Trant informed the commission a few clarifying statements were added to this document (Illinois – approved while USP 800 is not enforced in Washington). Staff also reconfigured the categories of state inspection reports to help clarify the different state inspections that are approved based on whether the nonresident pharmacy applicant engages in compounding.

Additional discussion clarified that an inspection report conducted by the Florida Board of Pharmacy would be accepted if a nonresident pharmacy attests they do not engage in compounding. If the nonresident pharmacy does engage in compounding then they would need to submit an inspection report from another commission approved inspection program. **MOTION:** Craig Ritchie moved to approve the December 17, 2021 list of nonresident pharmacy approved state inspections. Ken Kenyon, second. Motion carries, 12:0.

- 4. New Business-- The commission will discuss, for clarification or decision, ongoing topics and issues from previous meetings. *Information/Action*.
 - **4.1** FAQ on Inventory Requirement for Controlled Substance Registrant

Lindsay Trant informed the commission that currently the rule requires registrants to conduct the inventory on the anniversary of the registration issuance date. However, it may be difficult for a registrant to meet that requirement on the same exact date. The FAQ as drafted mirrors the requirement for the DEA. If approved, staff will post the FAQ and distribute through GovDelivery.

MOTION: Tim Lynch motioned to approve the FAQ as written. Ken Kenyon, second. Motion carries, 12:0.

4.2 Feedback on DOH Interpretive Statement: Electronic Communication of Controlled Substance Prescriptions to Pharmacies Unable to Receive Electronic Prescriptions

Nomi Peaks reported to the commission that tribal pharmacies using the Indian Health Services' Resource and Patient Management System (RPMS) are having difficulty implementing the electronic prescription requirement for controlled substances in RCW 69.50.312. Commission instructed staff that further clarification is needed on this issue before taking any action. Staff will investigate the legislative intent of RCW 69.50.312(2).

4.3 List and label request

MOTION: Craig Ritchie moved to approve the list and label request. William Hayes, second. Motion carries, 11:0, one abstains.

5. Rules and Legislative Updates - Information/Action.

5.1 Reauthorize emergency rules deleting Epidiolex from Schedule V

MOTION: Ken Kenyon moved to approve refiling of the emergency rules deleting Epidiolex from Schedule V. Craig Ritchie, second. Motion carries, 12:0.

5.2 Reauthorize emergency rules on prescribing Schedule II's during COVID-19

MOTION: Craig Ritchie moved to approve refiling of the emergency rules on prescribing Schedule II's during COVID-19. Hawkins DeFrance, second. Motion carries, 11:0, one abstains.

5.3 Two-Year License Renewal Cycle Implementation

MOTION: Craig Ritchie moved to begin rulemaking on repealing CE rules 246-861 WAC and WAC 246.901-061. Ken Kenyon, second. Motion carries, 12:0.

MOTION: Craig Ritchie moved to rescind policy statement, "New WAC Supersedes Old WAC: Clarification of Rules Enforcement After July 1, 2020". Ken Kenyon, second. Motion carries, 12:0.

MOTION: Craig Ritchie moved to rescind guidance document, "Enforcement of Intern Registration Renewal Limit." Ann Wolken, second. Motion carries, 12:0.

MOTION: Craig Ritchie moved to instruct staff to prepare a guidance document stating we are not enforcing chapter 246-861 WAC and WAC 246-901-061 because we are in the process of repealing them. Ken Kenyon, second. Motion carries, 12:0.

5.4 DOH Request Regarding Pharmacist Licensure Requirement for Executive Director.

The commission is in agreement that the Executive Director position for pharmacy should be required to be a licensed pharmacist. Martin Pittioni will take PQAC's feedback to DOH leadership.

6. **Open Forum** (10 minutes) - *Information Only.* The purpose of the open forum is to provide the public an opportunity to address the commission on issues of significance to or affecting the practice of pharmacy. Discussion items may not relate to topics for which a hearing has or will be scheduled.

Immunization records:

Richard Molitor brought the following to the attention of the commission:

Immunization teams are encountering patients requesting COVID-19 booster shots. In the public sectors, but in particular for patients in adult family homes, patients do not have immunization records in the IIS system. We have been told contract pharmacies that vaccinated patients last January and February were not required to report these vaccinations or issue certificates of immunization. This has prompted questions by our staff of the CDTA protocol authorized by the medical director, booster shots should only be given to those who have received the initial series. However, with no online or written records, how do we confirm that we can administer boosters to these individuals? Additionally, I suspect this affects the statistical reporting of the vaccination status of state residents. When he contacted DOH for advice on how to proceed with this particular situation, he was told "contact your local county department of health" – and that's not been helpful either.

Jenny Arnold, WSPA, noted the nursing home administered shots though the federal long-term care program partnership were required to be reported to the registry. If you are seeing holes in that reporting data, they have realized misalignments between reporting and getting the information into the system. Please write to jenny@wsparx.org for further information or help. At this point, all we can do is take a person at their word and having a validated statement by the homes owners will help until this can be worked through.

Processing of new licenses: Cindy Wilson, pharmacist, MultiCare Health System, continues to experience delays with processing new licenses (facilities and people) as well as changes in licensures (facility address / name changes). What efforts are being made in credentialling to try to improve the turn-around time?

Martin Pittioni assured Cindy this issue has the attention of the entire division. There is a new interim director in place, additional staff is being hired, as well as developing a new action plan to correct this issue.

7. Commission Member Reports. Information/Action.

- 7.1 Commissioner Reports
 - Budget Subcommittee report Patrick Gallaher
 - \circ Pharmacy ended 2019-2021 biennium with \$1.4 million in the black.
 - Discussed keeping credentialing accountable
 - If a commissioner requests something that requires funding it begins with the executive director and final determination is at DOH level.
 - Two HELMS payments in June of 2022 and 2023. The budget projections show us still ahead at the next biennium.

Is there a plan for going back to neutral licensure rates? Martin Pittioni responded that this is reviewed on a regular basis.

- 7.2 Commissioners' open discussion related to items or issues relevant to commission business/pharmacy practice.
 - **MOTION:** Tim Lynch moved to approve developing an FAQ stating: "FAQ question: Can a pharmacy or pharmacist supply naloxone to a behavioral health clinic that is not licensed by the department of health or to an individual who is not credentialed by department of health for substance use disorder treatment. The pharmacy commission will not take action on a pharmacist or a pharmacy for suppling naloxone for substance use disorder in support of SB 5195. In addition to supply naloxone to persons or entities that are not licensed or credentialed by department of health in support of said bill. Craig Ritchie, second. Motion carries, 12:0.

Cite the actual RCW and cite examples.

- Ken Kenyon notes there have been significant increases in complaints and business operations in pharmacies, closures, long waits. Staff will develop a GovDelivery regarding safety of our patients using the points above.
- Tim, oral anti-viral therapeutics labeling. Lindsay will investigate further.

8. Staff Reports *Information/Action*.

8.1 Interim Executive Director – Margaret Holm - none

8.2 Interim Deputy Director – Lindsay Trant

- **8.2.1** 2022 Legislative Update Calls
 - Weekly Legislative Calls on Fridays through March 11.
 - Craig Ritchie and William Hayes volunteered to attend Martin Pittioni's legislative calls Wednesday mornings.
 - Potential draft legislation, still research to be done on this topic: would require pharmacies to provide translated directions for use and side effects on prescription labels in languages other than English when requested. Oregon and California have implemented similar requirements but taken very different approaches.

8.3 OILS Deputy Director – Marlee O'Neill

- Routine Inspections GovDelivery sent out
- Staffing
 - Pharmacy inspection supervisor job posting will be out soon
 - Pharmacy inspector positions recruiting opening. Funded by the federal grant. An informal offer has been made to one candidate.
 - Staff attorney OILS continuing to recruit for the vacant staff attorney positions.

8.4 Assistant Attorney General – Heather Carter – none

- **9.** Summary of Meeting Action Items Commissioner and staff will revisit action items identified during today's business meeting.
 - 1.2 October minutes Staff to confirm vote count vs number of panelists
 - 2.3.4 AUPs clarification needed on USP 797 check list reference
 - 3.1 Nonresident pharmacy directive post the updated directive on website and send via GovDelivery.
 - 4.1 FAQ on controlled substance registrants post the FAQ on website and send via GovDelivery.
 - 4.2 E-prescribing interpretive statement provided feedback to the department
 - 4.3 Approve the list and label request
 - 5.1 Refile Epidiolex emergency rules
 - 5.2 Refile Emergency rules on prescribing CIIs during the COVID pandemic

- 5.3 Implementing two-year renewal cycle initiate rulemaking to repeal old CE rules. Rescind the policy statement "new WAC supersedes old WAC"; resend the guidance document on the interim registration renewal limit and new guidance document that the old CE rules are not in effect while they are being repealed.
- 5.4 DOH request for pharmacist licensure requirement Martin Pittioni will relay feedback to the department
- 7.2 Commissioner reports publish FAQ on naloxone requirement and distribute via GovDelivery. Also send Gov Deliver on increased complaints we have received and sufficient staffing requirement under the new rules.
- 8 Staff Updates convey back to the department that Craig and William will be joining the Wednesday calls with Martin.

12:16 p.m. Business Meeting Adjourned.