



STATE OF WASHINGTON
Pharmacy Quality Assurance Commission

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Business Meeting – Minutes

August 28, 2020

9:00 AM (Open Session)

Convene: Chair, Tim Lynch called the meeting to order August 28, 2020 at 9:05 a.m.

Commission Members

Teri Ferreira, RPh, Vice Chair
Bonnie Bush, Public Member
Craig Ritchie, RPh, JD
Jerrie Allard, Public Member
Judy Guenther, Public Member
Kat Wolf-Khatchatourian, PharmD, MBA
Ken Kenyon, PharmD, BCPS
Olgy Diaz, Public Member
Sepi Soleimanpour, RPh, MBA-HA (joined late)
Uyen Thorstensen, CPhT

Absent Commission Members

Patrick Gallaher, BS, BPharm, MBA, MPH

Staff Members

Lauren Lyles-Stolz, Executive Director,
Pharmacy Commission
Christie Strouse, Deputy Director, Pharmacy
Commission
Chris Gerard, AAG
Lindsey Trant, Rules Program Manager
Cori Tarzwell, staff member
Marlee O'Neill
Martin Pittioni, Office of Health Professions
Doreen Beebe Program Manager, Pharmacy
Commission
Amy Robertson, Administrative Assistant,
Pharmacy Commission

- 1.1 **August 28, 2020 Meeting Agenda Approval – MOTION** – Craig Ritchie moved to approve the August 28, 2020 meeting agenda as written. Jerrie Allard, second. Motion carries, 10-0.
- 1.2 **July 17, 2020 Minutes Approval – MOTION** – Craig Ritchie moved to approve the July 17, 2020 minutes per the edit suggestions made by Chris Gerard, AAG. Ken Kenyon, second. Motion carries, 10-0.
- 1.3 **April 8, 2020 Minutes Approval – MOTION** – Craig Ritchie moved to approve the April 8, 2020 minutes per the edit suggestions made by Chris Gerard, AAG. Ken Kenyon, second. Motion carries, 10-0.
- 1.4 **April 1, 2020 Minutes Approval – MOTION** – Craig Ritchie moved to approve the April 1, 2020 minutes per the edit suggestions made by Chris Gerard, AAG. Ken Kenyon, second. Motion carries, 10-0.

2a. **Consent Agenda Approval – MOTION** – Craig Ritchie moved to approve the consent agenda as written, excluding 2.5 WRAPP reports to be updated at October 1 Commission meeting. Bonnie Bush, second. Motion carries, 10-0.

3.1 **Psych Review Workgroup / Sunrise Review update** – Lauren Lyles-Stoltz notified the Commission the sunrise review report is not ready, but will bring a completed report to the October 1 business meeting. The workgroup (Gallaher, Gerard, Lyles-Stoltz, Ritchie, Strouse) wanted to remind the Commission of the following overall points:

- The Commission does not maintain any list of other prescribers, so why would we do it for psychologists?
- The bill does not actually amend all the necessary RCWs to allow psychologists to have prescriptive authority.
- A sunrise review ([RCW 18.120](#)) can be requested by legislature to the DOH to see if a profession meets the requirements needed to expand scope of practice or establish a new profession.

3.2.a **Self-inspection worksheets, update – MOTION** – Ken Kenyon moves that the Commission approve the compounding sub-committee’s recommendations from that public hearing/review. Craig Ritchie, second. Motion carries. 10-0.

3.2.b **Self-inspection worksheets, review input by stakeholders** – Lauren Lyles-Stolz reviewed new items/public comments the subcommittee recommends adding to the self-inspection sheets.

#10 WAC 246-945-100 Compounding minimum standards / USP 825 – Lauren confirmed for Erika Anderson (stakeholder) that the Commission is currently “applying enforcement discretion” on USP 825. The compounding subcommittee will meet to decide what will happen after the December 1, 2020 when the USP goes into effect.

#26 WAC 246-945-415 Dispensing and delivery of prescription drugs (7) – Craig Pederson (stakeholder) questioned why this question was included. The Commission agreed #26 should be moved to a future HCE self-inspection sheet.

MOTION – Bonnie Bush moves to accept the recommendations by the compounding sub-committee as discussed. Kat Wolf-Khatchatourian, second. Motion carries, 10-0.

3.2.c **Self-inspection worksheets, finalize – MOTION** – Ken Kenyon moves that we approve the new WACs and questions for the self-inspection worksheets that were just reviewed. Sepi Soleimanpour, second. Motion carries, 11-0.

4.1 **Review Commission authorized policies, guidance, and interpretive statements for updates, re-approval, and rescind** led by Lauren Lyles-Stoltz.

4.1.1 **MOTION** – Craig Ritchie moved to approve the non-substantive changes. Bonnie Bush, second. Motion carries, 11-0.

- (1) PQAC 3_Accreditation of Colleges of Pharmacy
 - (3) PQAC 35_CE Credit for Attending Commission Mtg
 - (4) PQAC 38 Continuing Ed Req for New Graduates
 - (5) PQAC 53 Procedure Diversion Inv 2.2017
 - (6) PQAC 54 Pharmacy Intern Registration
 - (7) PQAC 57 Nonresident Pharmacy Discipline Guideline
 - (8) PQAC 43a_Verification of Age by Applicant
 - (9) Interpretive Statement - Emergency Medical Reasons
 - (10) 690-331 ESRD or Kidney Dialysis Center Guidance
 - (11) PQAC 56_Labeling of Outpatient Meds for Adminss V2
 - (12) MD2015-13TreatingPartnersOfPatientsWithSTDsGuideline
 - (13) PQAC 61 - USP 795 Nonsterile Compounding Information
 - (14) D001 Use of photos-videos by OII pharmacists
 - (15) 690330 Directive Nonresident recognized states
- Category 1 Non-Substantive Changes Keep

4.1.2 **MOTION** – Teri Ferreira moved to rescind the policy statements, as they are included in the current WACs as identified. Jerri Allard, second. Motion carries, 11-0.

- (1) PQAC 39_Closing a Pharmacy - Patient Notification
 - (2) PQAC 47_ HIV-AIDS Education for Initial Credentialing
 - (3) PQAC 43_Official Transcripts - Reciprocity Applicants
 - (4) PQAC 36_Postgraduate Intern Registration.doc
 - (5) PQAC 63 Licensing of Virtual Manufacturer and Virtual Wholesaler
 - (6) PQAC 49 Absence of a Pharmacist
 - (7) PQAC 50 - Closed Door Long-Term Pharm-Personnel v 3
 - (8) PQAC 34_Job shadowing
 - (9) Directive - Parenteral Product Non-Enforcement
 - (10) PQAC 28_Internship Experience in Federal Facilities
 - (11) PQAC 45_ Internship Hours
- Category 2 Rescind

4.1.3 Lauren Lyle-Stoltz and Christopher Gerard reviewed documents/policies for further direction from Commission. Commissioners agreed to all staff suggestions.

- (1) PQAC 44_ Exception Application Guidelines
- (2) PQAC 40_ Qualification for Re-exam NAPLEX
- (3) 690327InterimCDTAGuidanceBookletRev0
- (4) Hazardous Drugs USP 797 vs 800
- (5) PQAC 51 E Signature- Delegation Authority LTC
- (6) PQAC 59 Opioid Overdose Medication - ED PS

- (7) 690-329 Guideline OTP medications
 - (8) PQAC 52 Patient Counseling Procedure 3.2017 PS
 - (9) PQAC 62 PQAC Technology and Services Guidelines
 - (10) Transfer of Unfilled or On-hold Prescriptions
- Category 3 - Keep Commission Review

MOTION – Bonnie Bush moved to accept the recommendations as discussed in Category 3. Second, Jerrie Allard. Motion carries, 11-0.

- 4.2 **Review COVID-19 Technical Assistance Letter** – Lauren Lyles-Stoltz, Marlee O’Neill, and Christopher Gerard explained these COVID-19 Technical Assistance letters will provide healthcare providers assistance if reported for allegedly not following or violating Governor issued proclamations related to the COVID-19 state of emergency. The NPDB would not be notified in the case of these allegations, but the allegations would be public record.

MOTION – Craig Ritchie moved we adopt the use of the technical assistance letters process as deemed appropriate when no violation of law has occurred and no potential for patient harm; has occurred. Ken Kenyon, second. Motion carries, 11-0.

- 4.3 **Commission Delegations** – Delegation of Decision-Making document tabled until Doreen Beebe can meet with and edit documents for clarity. Review at the October meeting.

MOTION – Craig Ritchie moves to update the Signature Delegation. Teri Ferreira, second. Motion carries, 11-0.

5. **Open Forum** –

- Cindy Wilson, stakeholder: **Is there any information whether or not the Governor’s proclamation 2036.4 would be extended? Specifically, part that relates to license of location, it expires at the end of this month.**

Lauren Lyles-Stoltz informed Cindy we usually only find out about 24 hours prior to the extension. We will be communicating and updating the Plan 19 as soon as possible, but do not have an update at this time.

HCE follow-up question: Is an HCE by definition a pharmaceutical firm and how does that work? Request a clarification document defining these types of ‘locations’ and how do we ensure we apply the rules and applying them correctly.

Lauren Lyles-Stolz and staff will convene a subcommittee meeting to develop an HCE self-inspection will identify the rules that apply to HCEs. Also, incorporate this into the POC communication which also addresses periodic inspections and which facilities.

- Justin Yee, stakeholder: **In regards to the change of dosage form, if a provider writes for one form and it is the salt forms that are different, kinetically the two agents may be different but pharmacodynamically and clinically, they are used for the exact same indications. Does the pharmacist have the ability to interchange those salt forms in order to best serve the patient?**

After some discussion, this question will be tabled until the next meeting on October 1, 2020.

- Mike Li, stakeholder: **Some transactions are not appearing in the Prescription Monitoring Program database. Is the Commission aware? Also, request a communication be sent to stakeholders due to safety and quality risk.**

Lauren Lyles-Stoltz will connect with the PMP program for more information to be discussed at the next Commission meeting October 1, 2020.

- 6.1 **Pharmacist applicant study plan approval and reauthorization to take MPJE a fifth time – MOTION** – Ken Kenyon motioned we delegate 6.1 panel review to Ken Kenyon, Jerrie Allard, and Sepi Soleimanpour, and Uyen Thorstensen. Second, Uyen Thorstensen. Motion carries, 11-0.

The subcommittee has reviewed applicant’s study plan and have the following recommendations:

- Find a mentor to help guide applicant through study plan.
- Do not take as soon as possible as this is the last attempt. Take the time to ensure applicant knows material.
- Create a study routine every day.

Doreen Beebe will supply resource information to applicant.

MOTION – Ken Kenyon move we approve candidate to sit for his next examination at a time he feels most appropriate for him. Uyen Thorstensen, second. Motion carries, 4-0.

7.2 **Commissioner’s Open Discussion.**

- On behalf of Patrick Gallaher, Teri Ferreira presents:

Patrick Gallaher is requesting and offering to author infection control guidelines for vaccine administration in the COVID environment. The guidance would be used for licensees under our authority and not direct how a shot is administered, but provide direction for workplace steps to reduce the risk of transmission of COVID while administering vaccine.

Lauren Lyles-Stoltz will find more information regarding vaccine-coordinating group to bring back to the October 1, 2020 meeting.

There was some discussion on the possibility of liability on the Commission. Suggestions to create sources for our licensees rather than create a document/guideline that must be continually updated was made.

- Ken Kenyon would like to request that we have a subcommittee meeting in September to discuss HPACs so we may collate the remaining questions and concerns (i.e., DEA) to bring back information at the October meeting.

Commission agrees.

8.1 **Executive Director Update.**

1. **Strategic planning meeting** – requests use day 1 of our 2 day meeting In October to do deeper strategic planning. Sending survey to Commission members to define priorities better.

Commissioners concur this should happen and ensure differentiation between strategy, visionary, priority for Commission. Delineation between strategic plan and tactical plan.

Lauren Lyles-Stolz, Bonnie Bush, Jerrie Allard, and Christie Strouse will work on the Commission strategic plan.

2. **Lisa V. Hunt**, new pharmacist supervisor starting next week. Welcome!

8.3 **Christopher Gerard, AAG, update** – continually monitoring the governor issued declarations addressing issues related to the practice of pharmacy and in regular communication with Lauren on these pieces. Waiting on news related to extension.

9 **Summary of Action items:**

1. Lauren Lyles-Stolz
 - a. Reach out to the PMP regarding why information is not crossing over in the database.
 - b. Adaptation language
 - c. Work with the Department of Health and vaccination coordinators for guidance documents; as well as CDC and other recommendations for the October meeting.
 - d. Strategic planning
 - i. Develop survey with Tim Lynch and Teri Ferreira
 - ii. Work with Jerrie Allard and Bonnie Bush for planning session for October meeting.
2. HPAC sub-committee initiated by Ken Kenyon.

3. HCE Inspection tool to be created to clarify facility vs. pharmaceutical firm questions.
4. SOD/POC – staff continue work on these documents to update licensees on the inspections.

There being no further business, the Commission meeting adjourned at 12:38 p.m.

Respectfully Submitted by:
Amy Robertson, Administrative Assistant

A handwritten signature in black ink, appearing to read "Tim Lynch". The signature is fluid and cursive, with the first name "Tim" and the last name "Lynch" clearly distinguishable.

Approval March 6, 2020
Tim Lynch, Chair
Washington State Pharmacy Quality Assurance Commission