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STATE OF WASHINGTON
Pharmacy Quality Assurance Commission
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Business Meeting - Minutes
October 1, 2020
9:00 AM (Open Session)

Convene: Chair, Tim Lynch called the meeting to order October 1, 2020, 9:01 a.m.

Commission Members:
Tim Lynch, PharmD, MS, FABC, FASHP, Chair
Teri Ferreira, RPh, Vice Chair
Jerrie Allard, Public Member
Bonnie Bush, Public Member (left at 1:00 PM)
Hawkins DeFrance, Nuclear Pharmacist
Olgy Diaz, Public Member (arrived at 9:30 AM)
Patrick Gallaher, BS, BPharm, MBA, MPH
Judy Guenther, Public Member
William Hayes, PharmD, CCHP
Ken Kenyon, PharmD, BCPS
Craig Ritchie, RPh, JD
Uyen Thorstensen, CPhT
Kat Wolf Khachatourian, PharmD, MBA

Staff Members:
Lauren Lyles-Stolz, Executive Director, Pharmacy Commission
Christie Strouse, Deputy Director, Pharmacy Commission
Chris Gerard, AAG
Marlee O'Neill, Deputy Director, OILS
Adam Wood, Supervising Investigator
Cori N. Tarzwell, staff member
Lindsay Trant, Rules Program Manager, Pharmacy
Lisa V. Hunt, Pharmacist Supervisor
Doreen Beebe, Program Manager, Pharmacy
Amy L Robertson, Administrative Assistant, Pharmacy

1.1 **MOTION: October 1, 2020 Meeting Agenda Approval** – Craig Ritchie moved to approve meeting agenda; Jerrie Allard, second. Motion carried (12-0).

1.2 **MOTION: August 27, 2020 Meeting Minutes Approval —** Craig Ritchie moved to approve meeting agenda; Judy Guenther, second. Motion carried (12-0).

1.3 **MOTION: August 28, 2020 Meeting Minutes Approval —** Craig Ritchie moved to approve meeting agenda; Uyen Thorstensen, second. Motion carried (12-0).

2a **Consent Agenda —** Craig Ritchie moved approve to Consent Agenda items 2.1, 2.2, 2.3d, 2.3e, 2.3g, 2.3h, and 2.4; and remove Consent Agenda items 2.3a, 2.3b, 2.3c, 2.3f for placement on the regular business agenda; William Hayes, second. Motion carried (12-0).

2b **2a Agenda Items removed for discussion.**

2.3a **MOTION:** Kat Khatchatourian moved to deny 2.3a Cherry Hill Pharmacy until clarifying information can be submitted; Ken Kenyon, second. Motion carried (12-0).

2.3b **MOTION:** Kat Khatchatourian moved to deny 2.3b Doctors Pharmacy until clarifying information on PIC and AUP can be submitted; Ken Kenyon, second. Motion carried (12-0).

2.3c **MOTION:** Kat Khatchatourian moved to approve 2.3c High School Pharmacy previously known as Furnesse Drug; Ken Kenyon, second. Motion carried (12-0).

2.3f **MOTION:** Kat Khatchatourian moved to approve 2.3f West Pasco Pharmacy; Ken Kenyon, second. Motion carried (12-0).

3.1 **Suspicious Orders Update**

Letters of Cooperation – Marlee O'Neill – Commission agreed the letters of cooperation needed further review and tabled the issue until December meeting. Concern was expressed about the length of time to report any potential diversion should be shortened.

Suspicious Order Reports - WAC 246-945-585 – DEA has not started rulemaking process for suspicious orders. This could be a 12-16-month process. Lauren Lyles-Stolz recommends our licensees submit their own report/format of diversion as long as it meets all requirements in WAC 246-945-585. Secondly, allow companies and licensees a defined amount of time (120-180 days) to reconfigure their systems.

Gary Cacciatore, Cardinal Health, stakeholder will submit information to Lyles-Stolz on how their process works as an example how each wholesaler has a slightly different system to assist in understanding of the process.

There has been some confusion among licensees regarding submitting ARCOS report. This is not required in our rules, simply to use it as a template to meet our rules.

MOTION: Craig Ritchie moved to exercise enforcement discretion and accept suspicious order reports in a format selected by wholesaler which includes all information required in WAC 246-945-585 for a period of 180 days; Patrick Gallaher, second. Motion carried (12-0).

MOTION: Exemption Reports – Craig Ritchie moved to exercise enforcement discretion of the new rules until PQAC team can develop an exemption application for wholesalers that do not distribute controlled substances or drugs of concern to be discussed at the December meeting; Patrick Gallaher, second. Motion carried (12-0).

Zero Reports – The monitoring and compliance of this issue needs more conversation due to the PQAC workload and time to develop this system properly. The DEA asks for licensees make the zero-report available, but not required to submit. PMP was approached about possibly incorporating their system, but it is not possible at this time. PQAC would need to create a new system.

MOTION: Kat Khatchatourian moved that the Commission exercise discretion authorization over zero reports for 180 days while working with staff to develop operational plan around receipt and monitoring of reports to be as efficient as possible and reduce the need on human workload and a preference toward automation when possible; Craig Ritchie, second. Motion carried (12-0).

*** Olgy Diaz, Public Member, arrived and introduced herself.

3.2 **Euthanasia Training Program Guidelines for Animal Control Agencies and Humane Societies Review**.

MOTION: Craig Ritchie moved to approve; Ken Kenyon, second. Motion carried (13-0).

4.1 **Strategic Planning Discussion** – Lauren Lyles-Stolz, Christie Strouse, Bonnie Bush, and Jerrie Allard presented a PowerPoint and reviewing history of Mission Vision, Innovative Goals, Current PQAC Climate, Top 3 Priorities and how to implement them, as well as the next steps in PQAC's strategic planning.

Jerrie Allard presented an interactive SWOT (strengths, weaknesses, opportunities, and threats) discussion.

- **Strengths**: Diverse membership, willingness for collaboration, support from department, strong leadership, stakeholder involvement, and availability of Commission.

- **Weaknesses**: Frequency of discretionary enforcement, lack of resources, availability and timing of commitments, difficulty of legislative packages moving forward, limits based on outdated RCWs, constraints in ability to have necessary and depth of conversation, technology issues, and diverse membership.

- **Opportunities**: Collaboration with other commissions, healthcare reform and looking at broader landscape of healthcare and value based payment and health equity, using innovative components from private sectors (opportunity or weakness?), applying better job equity lens, workplace behavior (production pressure and patient safety), and better leveraging our influence to address reimbursement issues.

- **Threats**: Legislative healthcare initiatives, large budget deficit and impact, production pressure, and lack of legislative engagement.

Some of the top priorities for the current program staff moving into 2020-2022 are implementing the new rules, working with the legislature, recruitment/training of new staff, and managing our current resources.

Results from a survey of the Commission show the priorities seem to be:

1. Compounding,
2. Facility enforcement authority,
3. Remote dispensing and drug ownership
4. Staffing and hiring
5. Population health and value-based care
6. Drug donation programs
7. HPACs
8. CBD
9. Tech-Check-Tech

Some of these things may be out of PQAC's control because the issue may require legislative action. Better use of PQAC's time may be to focus on things we can affect such as population health, HPACs, value-based care, etc. Another priority focus also should be how do we influence legislative activity. A better list might be: Must haves (but blocked), actionable daily operations, planning for our future.

One issue not captured today: PQAC being under the umbrella of DOH versus being independent. It is a strength and a weakness – that sometimes it has been an impediment to PQAC's ability to move forward on these goals.

Lauren Lyles-Stolz would like to add a strategic planning session to every other business meeting. Revisit the Mission Vision statement. Adopt the priorities discussed today. Also, consider a possible survey or special meeting of stakeholders and what they see as the priorities.

4.2 **Review Compounding Subcommittee's USP 800 and USP 825 Policy Statement Proposal and Policy #60 for re-approval.**

MOTION: Ken Kenyon moved to reapprove USP 800 policy #60 and approve the compounding subcommittee's policy statement proposal with the amendment to the presented document that the effective period of the policy be October 1, 2020 through March 30, 2021 for both USP 800 and USP 825; Patrick Gallaher, second. Motion carried (13-0).

Dawn Ipsen, stakeholder, asked clarification on USP 795, USP 797, and USP 800. Tim Lynch clarified this would be brought back to Commission prior to expiration dates and reevaluate. FAQs will also be available throughout this process. This issue will be a standing issue on the Commission's agenda and adjustments made as necessary.

4.3 **USP Applicability Clarification: Non-compounding pharmacies versus compounding pharmacies.**

Staff would like the Commission's endorsement to add to our new rule's implementation FAQ list. This FAQ will include the specific definition/clarification of compounding vs. reconstitution and handling hazardous drugs that specifically the WAC states "actively engaged in compounding" is what triggers the compliance with USP 800. In addition, ensure stakeholders understand, Julie Akers (stakeholder), added pharmacies must follow PQAC as well as L&I rules related to hazardous material handling (Policy #60).

4.4 **Monitoring of Drug Therapy: Pharmacists Conducting Health Screenings and Point-of-Care Testing**

After significant discussion, Commission agreed this SBAR communication will be tabled for further review/edits/clarifications (i.e., "and" vs. "or"; "but is not limited to", etc. as stated in the WAC) to be discussed at the December meeting (or earlier, when it is complete).

5.1 **Prescription Adaptation Clarification: Dosage Formulation WAC 246-945-335**

MOTION: Chair Tim Lynch moved that the Commission confirms that the assessment provided by PQAC staff related to intent and interpretation prescription adaptation WAC 246-945 regarding changing dosage forms is accepted; Patrick Gallaher, second. Motion carried (13-0).

Discussion clarified the difference between prescription adaptation and prescription drug product substitution. WAC 246-945-335 is regarding adaptation i.e., prescription is 10 mg oxycodone; dispensing may be 5 mg oxycodone to equal the dosage prescribed. This also involves notifying the prescriber/provider of any adaptation. The DEA specifies to notify the prescriber. An FAQ may be developed further to inform stakeholders.

*** Bonnie Bush excused herself and exited the meeting.

5.2 **Wholesaler Licenses for Out-of-State Manufacturers**

Lauren Lyles-Stolz led discussion regarding potential Commission approach on accepting FDA inspections for out-of-state manufacturers seeking a WA state wholesaler license as required by WAC 246-945-246(3).

MOTION: Chair Tim Lynch motioned that applicants may follow the current practice of submitting a copy of a State Board inspection reports from their resident state or NABP Drug Distributor Accreditation if completed within the previous 2 years or, in the absence of either the state inspection or NABP DDA accreditation, the Commission will utilize the current exception application process to review applications; Craig Ritchie, second. Motion carried (12-0).

5.3 **Internship Registration Renewal WAC 246-945-155(3)**

Lindsay Trant informed the Commission with the new rules in effect, there may be some confusion on the two-year license renewal cycle. The Commission may engage in rulemaking to change the language (could take up to 12 months for approval) or approve a policy statement/guidance document outlining enforcement discretion until the two-year renewal cycle is implemented.

MOTION: Kat Khatchatourian moves that a guidance document be drafted outlining the Commission's intent to exercise enforcement discretion until the full two-year renewal cycle is implemented; Craig Ritchie, second. Motion carried (12-0).

5.4 **WAC 246-945-430 vs -455 frequently asked questions**

Staff has developed an FAQ on these specific WACs to assist stakeholders as the new rules take effect. Lauren Lyles-Stoltz briefly discussed the FAQ:

- 430 does not include other facility types (i.e., HCE) and only deals with pharmacies operating (storing and dispensing drugs) without a pharmacist on site. 455 is about storing drugs outside a pharmacy.
- Remote supervision of ancillary personnel is acceptable as long as the conditions meet PQAC's definition of "immediate supervision" in WAC 246-945-001(44) .
- Remote dispensing sites for opioid use disorders policy statement and link to FDA application form on FAQ.
- HCE's must comply with WAC 246-945-455

MOTION: Ken Kenyon moves to approve the FAQ on WAC 246-945-430 vs -455 as discussed. Jerrie Allard, seconds. Motion carried (12-0).

6.1 **SSB 6086 Stakeholder Workshop –**Commission suggested the following edits to SSB 6086 rule language:

1. Clarify that remote dispensing sites registered under SSB 6086 are for dispensing FDA-approved medications indicated for opioid use disorder.
2. Add a subsection clarifying that remote dispensing sites registered under SSB 6086 must adhere to all applicable federal regulations in Title 21 C.F.R.

6.2 **Authorization to re-file Emergency Rules**.

MOTION: Craig Ritchie moved to refile emergency rules WAC 246-945-056 and -010 for an additional 120 days. Patrick Gallaher, second. Motion carried (12-0).

6.3 **Medical Commission files for CR-101**

Lauren Lyles-Stolz informed the Commission that physicians and physicians assistants have no rules for CDTAs at this time. The Medical Commission is considering adopting their own rules regulating the roles of physicians and physician assistants in CDTAs. This will be a standing agenda in the future.

9.1 **Executive Director, Lauren Lyles-Stolz**: will attend the NABP meeting on October 13. The recent NABP ED workshop topics included discussion regarding what is happening in other states. Significant topics: virtual inspections, regulating corporations, the FDA MOU, as well as future discussion regarding the HHS final rule of drug importation from Canada.

9.2 **Assistant Attorney General, Christopher Gerard:** recently met with DOH pharmacy staff/inspectors to provide an AAG perspective on pharmacy laws and rules. In addition, the four corners extended certain Commission related proclamations through November 9, 2020 (DOH Health Care Worker Licensing, 20-32; Health Care Facilities and Hand Sanitizer, 20-36; and Open Public Meetings Act and Public Records Act, 20-28).

9.3 Pharmacist Supervisor, Lisa Hunt

9.3.1 **Virtual Inspections –** While not a replacement for in-person inspections, virtual inspections have been tested and used successfully. With coordination of the pharmacy staff, the inspector can take a virtual tour and is able to direct the camera for close-ups to inspect items such as labels or the security of controlled substances. These virtual inspections are conducted only if there is an impediment to conducting an in-person inspection (i.e., COVID-19, wildfires, road conditions, etc.). If the inspector feels the virtual inspection did not suffice, a follow-up in-person inspection would be scheduled. Our inspectors are asking for more training and specifics to move forward with these inspections. The SBAR lists three options the Commission can consider. After discussion, the Commission agreed to adopt option 2. Also, A six-month report and update of virtual inspections to be presented with specifics on how the virtual inspections are going.

MOTION: Ken Kenyon moves to allow Pharmacist Inspectors to conduct virtual inspections when: (i) the Inspector and applicant/licensee agree to a virtual inspection, (ii) the Inspector makes a request to the Pharmacist Supervisor or designee to conduct a virtual inspection due to unavoidable circumstances e.g. COVID-19 or PPE shortages, and (iii) the Pharmacist Supervisor or designee approves the virtual inspection. In addition, after six months the DOH Pharmacy Team will report to the Commission on how the virtual inspection process; Patrick Gallaher, seconds. Motion carried (12-0).

10 Summary of Meeting Action Items

- 2.3a and 2.3b need further clarification
- Suspicious order update – exercised enforcement discretion for a period of 180 days, and wholesalers use their own format.Customer order reports – can now be enforced if there is diversion suspected.
- PQAC team will develop
    - an exception application for 585 for wholesalers not distributing controlled substances
    - a proposal to streamline Zero Order reporting using automated technology for Commission review
    - Guidance document on intern registration renewals WAC 246-945-155
- Letter of Cooperation – revise to a softer tone, rework/edit questions 2, 3, and 4; Commission will vote at a later date.
- Strategic Action Plan – will be a standing agenda item for future meetings.
- Seek out Stakeholder input on what they see as their priorities.
- USP 800 / 825 – discretion will be exercised October 1, 2020-March 30, 2021.
- Share updated USP 800/825 and Policy #60. Revisit and table monitoring of drug therapy.
- In absence of NABP or state report, the Commission will accept an alternative report (e.g., Form 483) from wholesaler. Each instance will go through the current application exception process.
- Update the definition of drug therapy monitoring.

- Update 6086 draft rule language to bring back to the commission for approval.
- Virtual Inspection process to begin and follow-up with a six-month report.

The Commission publicly acknowledged/commended the PQAC staff for excellent work during this difficult time of more work and less time due to furloughs all while working virtually

Meeting adjourned, 2:36 p.m.

The Commission will meet next on December 3 and 4, 2020 via webinar.