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STATE OF WASHINGTON
Pharmacy Quality Assurance Commission
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Business Meeting – Minutes
COVID-19, Rulemaking and Chapter 246-945 Review
December 4, 2020
9:00 AM (Open Session)

Convene: Chair, Tim Lynch called the meeting to order December 4, 2020, 9:08 a.m.

Commission Members:

Tim Lynch, PharmD, MS, FABC, FASHP,
Chair
Teri Ferreira, RPh, Vice Chair
Jerrie Allard, Public Member
Hawkins DeFrance, Nuclear Pharmacist
Olgy Diaz, Public Member
Patrick Gallaher, BS, BPharm, MBA, MPH
Judy Guenther, Public Member
William Hayes, PharmD, CCHP
Ken Kenyon, PharmD, BCPS
Kat Wolf Khachatourian, PharmD, MBA
Craig Ritchie, RPh, JD
Uyen Thorstensen, CPhT
Bonnie Bush, Public member

Staff Members:

Lauren Lyles-Stolz, Executive Director,
Pharmacy Commission
Christie Strouse, Deputy Director, Pharmacy
Commission
Christopher Gerard, AAG
Marlee O'Neill, Deputy Director, OILS
Adam Wood, Supervising Investigator
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: December 4, 2020 Meeting Agenda Approval** – Craig Ritchie moved to approve draft meeting agenda; Judy Guenther, second. Motion carried (13-0).
- 1.2 **MOTION: October 1, 2020 Meeting Minutes** – Craig Ritchie moved to approve meeting minutes as amended; Jerrie Allard, second. Motion carried (12-0).
- 2.3 **MOTION:** Ken Kenyon move to approve consent agenda except for 2.3b, 2.3c, 2.3j; Patrick Gallaher, second. Motion carried (12-0).
- 2b Items removed for discussion from 2.3 consent agenda.
 - 2.3b **Cherry Hill Pharmacy** – missing/conflicting information has been corrected or is acceptable.

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MOTION: William Hayes move to approve the technician and assistant AUP for Cherry Hill Pharmacy; Craig Ritchie, second. Motion carried (12-0).

- 2.3c **Doctors Pharmacy** – missing information (key individual license number, signature) was updated in ILRS.

MOTION: Patrick Gallaher moves to approve 2.3c AUP for Doctors Pharmacy; Craig Ritchie, second. Motion carried (12-0).

- 2.3j **The Medicine Shoppe** – Pharmacy AUP form missing. Shelly Feldner-Schuerman updated the Commission on the specific aspects of this case.

MOTION: Patrick Gallaher moves to approve 2.3j The Medicine Shoppe AUP; Kat Khachatourian, second. Motion carried (12-0).

- 3.1 **Update Commission on Medical Commission’s rule making regarding prescribers’ engagement in collaborative drug therapy agreements. (CR101).** Lauren Lyles-Stolz confirmed no action at this time. The CR102 seems to be out until January 20, 2022. The Medical Commission website has an option for public commenting on the CDTA/rulemaking.
- 3.2 **Suspicious Orders Exemption Application. MOTION:** Bonnie Bush moves to approve this form with the stated modifications of PQAC staff; Jeri Allard, second. Motion carried (12-0).
- 3.3 **Suspicious Order Letter of Cooperation (LOC). MOTION:** Craig Ritchie moves to approve the Suspicious LOC as modified; Bonnie Bush, second. Motion carried (12-0).
- 3.4 **Commission Delegation Forms. MOTION:** Craig Ritchie moves to approve the delegation form as edited; Patrick Gallaher, second. Motion carried (12-0).
- 3.5 **Guidance Document – Intern Registration.** PQAC will not enforce WAC 246-945-155(3), which states that an intern registration can only be renewed twice, until the 2-year license renewal cycle is implemented.
- MOTION:** Ken Kenyon moves to approve the Guidance Document as written; Craig Ritchie, second. Motion carried (12-0).
- 4.1 **Discuss NABP’s memo regarding change in processing requests for ADA testing accommodations and if the Commission requests an exemption.** PQAC staff will supply the Commission with further information at the next meeting (opt out/in criteria; percentages of accommodation requests).
- 4.2 **Review, for approval, a draft of self-inspection worksheet for Health Care Entities.** PQAC staff will supply the Commission with further information after collecting public comments from licensees/stakeholders.

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- 4.3 **Discuss the Food and Drug Administration's MOU addressing inordinate amounts of distributions of compounded human drug products interstate.** PQAC staff will supply the Commission with further information at the next meeting after determining impact on staff workload.
- 4.4 **Identify Commissioner(s) who will participation in the Office of Health Profession's legislation review calls.** Tim Lynch, Patrick Gallaher, Craig Ritchie, Hawkins DeFrance, and William Hayes volunteered to participate (Wednesdays, 8:30-9a).
- 4.5 **Pharmacy Changes of Ownership.** Commission recommended PQAC staff gather additional information/historical content for further evaluation. In addition, stakeholder Richard Molitor asked about if the Commission has a 'rapid response' plan for immediate change of ownership (i.e., by court order).
- 6 **Panel Review (Panel B). MOTION:** Ken Kenyon moves to delegate himself, Craig Ritchie, Hawkins DeFrance, Kat Khachatourian, Tim Lynch, and Bonnie Bush for Panel Review (Panel B); Jeri Allard, second. Motion carried (12-0).
- 6.1 **Pharmacist applicant requests Commission approval of her study plan for reauthorization to take the MPJE. MOTION:** Ken Kenyon moves to delegate himself, Craig Ritchie, Hawkins DeFrance, Kat Khachatourian, Tim Lynch, and Bonnie Bush for Panel Review (Panel B); Jeri Allard, second. Motion carried (12-0).
- MOTION:** Kat Khachatourian moves to allow applicant to take a fifth (and final) attempt to pass the MPJE; Craig Ritchie, second. Motion carried (6-0).
- 6.2 **Pharmacist applicant requests Commission approval of her study plan for reauthorization to take the NAPLEX.**
- MOTION:** Craig Ritchie moves to authorize applicant to attempt the NAPLEX a final time; Hawkins DeFrance, second. Motion carried (6-0).
- 7.1 **Update from HPAC Subcommittee.** Further research is needed for defining what does a hospital license actually entail as far as those outpatient clinics as well as when does one need an HPAC registration. An SBAR should be considered brought to the Commission in January to begin to refine the rules.
- 7.3 **Commissioners' open discussion related to items or issues relevant to Commission business/pharmacy practice.**
- January agenda: discussion related to entity licensees and complaints in terms of the conditions that exist when an investigation is authorized (information collected; what led to error/reporting; ensure inspectors adequately informed; when to use Notice of Correction rather than discipline; capturing error data voluntarily).

8.1 Staff Report: Executive Director, Lauren Lyles-Stolz

- Emailed the following correspondence to commissioners:
 - a) Slides from the FDA intergovernmental meeting on compounding.
 - b) FDA MOU from the American Pharmacy Association Alliance for Pharmacy Compounding, the National Alliance of State Pharmacy Association, and National Community Pharmacists Association have strong concerns related to the MOU.
- SSB 6061 – Telehealth services – beginning January 1, 2021 if a pharmacist/pharmacy intern are providing telehealth services, they are required to complete a telehealth training. UW telehealth collaborative is working on this training. WSPA as well. This bill passed in 2020 session. The department does recognize this may impact licensees and boards of commission. The department is evaluating strategies to respond to this new telehealth requirement.
- Vaccination legislation, Dentists – possible legislation in the 2021 session where dentists will be pursuing adding vaccinations in their scope of practice.
- Guidance document – Accessing drugs outside a pharmacy: changed “institutional” with “healthcare” facilities.

8.3 Staff Report: Christopher Gerard, Assistant Attorney General

- Governor proclamations that impact pharmacy were extended through December 7 (healthcare worker and facility licensing).
- Commission review: CREPP act declaration fourth amendment by HHS: authorizes healthcare personnel using telehealth to order/administer COVID countermeasures (diagnostic tests, etc.).
- Monitoring of Drug Therapy – in the scope of practice of pharmacists to screen in/out specific drug therapy for a patient upon a patient request that the patient is already being prescribed. (January agenda item.)

8.4 Staff Report: Lisa Hunt, Pharmacist Inspector Supervisor

- Draft self-inspection forms for hospital, HCEs, wholesalers, and manufacturers in the final stages. Nuclear, general and long-term care pharmaceutical facilities also updated. These all include updated citations to the new rules.
- Reviewed application forms provided update notes on those. Mapped the process workflows from start-to-finish and developed SOD letters and POC process for our licensing software.

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- All inspectors have been stepping up to help review documents, email influx, onboarding new staff, providing training, while doing the ‘normal’ job.
- Commission requested an overview of problematic trends in general areas.

9 Summary of Meeting Action Items.

- 1) 3.2 Suspicious Order Exemption Application to add an email address to application; then post.
- 2) Suspicious Letter of Cooperation – no action
- 3) Commission delegation form – adopted Bonnie’s recommendation to left side that.
- 4) NABP ADA testing accommodating – review any liability concerns; more information from NABP regarding basis of denial of ADA request.
- 5) Self-Inspection worksheets – HCEs, wholesalers, and manufacturers – release for public comment.
- 6) 4.3 FDA MOU – more research and finalize questions/concerns to the FDA (further modifications based on concerns identified today; estimate of resource impact to comply with MOU; implications of FDA MOU corporate vs small compounding pharmacy)
- 7) Legislative Update calls – send OHP the five commissioners volunteering to serve on these calls.
- 8) Change of Ownership rule – research implications of impact to corporations that may pursue mergers as well as transfer of stock.
- 9) Monitoring of Drug Therapy – additional research of where screening in/out drug therapy falls into the practice of pharmacy.
- 10) Research/discuss NOC feasibility for entities
- 11) Develop – list of questions for investigation team on assessing entities patterns/trends in mis-fills/errors.

Business meeting adjourned, 1:00 p.m.

The Commission will meet next on January 21-22, 2021.