



STATE OF WASHINGTON
Pharmacy Quality Assurance Commission

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Special Meeting – Amended Agenda

April 8, 2020

7:30 AM (Open Session)

Convene: Chair, Tim Lynch called the meeting to order April 8, 2020, 7:30 a.m.

Commission Members:

Teri Ferreira, RPh, Vice Chair
Jerrie Allard, Public Member
Steve Anderson, BSpHarm, RPh
Bonnie Bush, Public Member
Olgy Diaz, Public Member
Patrick Gallaher, BS, BPharm, MBA, MPH
Judy Guenther, Public Member
Ken Kenyon, PharmD, BCPS
Craig Ritchie, RPh, JD
Sepi Soleimanpour, RPh, MBA-HA
Uyen Thorstensen, CPhT
Kat Wolf Khatchatourin, PharmD, MBA

Staff Members:

Chris Gerard, AAG
Martin Pittioni, Director, Office of Health Professions
Lauren Lyles-Stolz, Executive Director, Pharmacy Commission
Doreen Beebe, Program Manager, Pharmacy Commission
Cori N. Tarzwell, staff member

1.1 MOTION: Craig Ritchie moved the meeting agenda be adopted. Patrick Gallaher, second. Motion carried, 13-0.

2.1 Update the Commission on Governor Proclamations related to COVID-19, including discussion of any waivers of specific Commission statutes or rules.

No new waivers.

2.2 Update the Commission on Governor Proclamations related to COVID-19, including discussion of any waivers of specific Commission statutes or rules.

2.2.1 Communication of CII prescriptions under COVID-19

On Friday, April 3, 2020, the Commission approved emergency rulemaking to clarify that the signed prescription requirements can be fulfilled upon the oral prescription in an ‘emergency’ by either mailing a hard-copy prescription, sending an electronic prescription, a faxed copy of the paper prescription, or a

photograph or scanned copy of the paper prescription within 15 days. Staff has taken the necessary next steps to begin the emergency rulemaking process at the Department of Health. The Commission will file a CR-103 with the Code Reviser once the internal emergency rulemaking process is complete and add summary information to Plan-19.

The average turn-around time for the code revisor's office is usually three weeks. However, we are trying to expedite this and have it back in about 10 days.

No further questions/comments from commission or stakeholders.

2.2.2 Therapeutic Substitution

On Friday, April 3, 2020, the Commission agreed that pharmacist should be allowed to engage in drug product substitution (other than brand/generic substitution) through a waiver a limited waiver of [RCW 69.41.110\(7\)](#), [RCW 69.41.120\(1\) and \(2\)](#), [RCW 69.41.150\(2\)](#), and [WAC 246-899-020\(c\)](#).

This removes “of the identical base or salt as the specific drug product prescribed” and “in the same dosage regimen,” the deletion of the word “generic,” and the deletion of the words “by its established name,” the deletion of the word “generic or trade” and “generic,” respectively.

Under present law, pharmacists can only engage in substitution of a prescribed brand name drug with a generic drug with minimal exceptions. This waiver would allow a pharmacist to engage in a broader range of drug product substitutions with prescriber authorization (*meaning the signing of the production selection permitted*). For example, it would allow a pharmacist to substitute a prescribed drug with another drug that is within the same therapeutic drug class, or the substitution of a prescribed drug with another drug that is outside the therapeutic drug class but will have the same efficacy and toxicity.

Staff (Lauren) has spoken with the prescribing community about “Therapeutic Substitution” as a necessary step in light of COVID-19 with the imminent drug shortages. There has been a general comment with pharmacist in the community substituting therapy, since the community pharmacist does not have the full patient profile, including patient history. There were also inquiries related to if the waiver could be narrow to COVID-19 therapy. (*WMC and NCQAC has not yet opined; only the Osteo Board*)

The PQAC team has submitted the proposed Governor's waiver to the Department's Incident Management Team waiver process. Staff plans to share updates in future Special Commission meetings.

Chris Gerard further clarified there are two issues here: #1) broadening what kind of drug substitution (brand vs. generic, etc.) can occur when the signing of the “substitution permitted” line and #2) the proposal of waiving the signing off of the “substitution permitted” line.

2.2.3 Waiver of MPJE

On Friday, April 3, 2020, the Commission approved emergency rulemaking related to the temporary practice permit (“TPP”) for pharmacists to practice in WA during this time of crisis. Specifically, it would take deletion of [WAC 246-863-035\(2\)\(d\)](#) that requires pharmacists to pass “the Washington state jurisprudence exam.” Staff has taken the necessary next steps to begin the emergency rulemaking process at the Department of Health. The Commission will file a CR-103 with the Code Reviser once the internal emergency rulemaking process is complete and add an FAQ to Plan-19.

Update on NABP Passport. The NABP passport is more of an avenue for individuals not wanting to be licensed in WA, but to do volunteer healthcare (see 70.15 waiver). Another aspect, individuals must have access to NABP e-connect to facilitate this passport. Further research is needed. This should be discussed in Friday’s upcoming meeting.

The TPP is for individuals wanting to be licensed in WA. TPP also allows for pharmacists licensed in other states to work in WA for 180 days. We are moving forward with the emergency rule utilizing our temporary permit language absent the MPJE language.

The language as it relates to the waiver of the MPJE was submitted to the policy office. It should be ready late next week (after the CII prescribing language).

2.3.2 Out-of-state pharmacy technicians working remotely.

A pharmacy technician employed by a pharmacy that holds an active non-resident Washington pharmacy license may be able to work remotely if this practice is permitted by the laws, rules, and regulations in the state where the pharmacy resides. However, if for example a pharmacy technician is work for a pharmacy located in Vancouver, Washington and is working remotely (at home) in Portland OR, the pharmacy technician must be licensed may work remotely with adequate supervision. (See Plan-19 page 12 regarding supervision.)

Due to technical difficulties, Chair asks stakeholders to email those to the commission’s email address: WSPQAC@doh.wa.gov .

I.e., a technician working in a pharmacy that is out of state and licensed in WA, the technician must abide by the laws of that state. Whether or not they *can* work remotely is dependent on laws in that state. However, if a pharmacy is physically licensed/located in WA with the technician working at home in Portland OR, the pharmacy technician must be licensed in WA and *can* work remotely based upon previous meetings. The key factors are: #1) if the pharmacy technician is employed by either a WA licensed/located pharmacy; and #2) if the pharmacy technician is working for a non-resident pharmacy.

2.4 Review FAQ, discuss, and then use your decision tree for actions. Staff is tracking questions from stakeholders to develop a frequently asked questions document to provide guidance to stakeholders.

Lauren notes all these FAQs here may not need commission action. Some are simply using these meetings as a platform to reinstate/reiterate things that have already happened. These are for licensees to know and continue to spread the word if they are not following up on Plan 19.

- **What is the meaning of the Governor’s Proclamation waiving or suspending “immediate” from the definition of supervision? And how does this apply to technician working remotely or performing sterile compounding?**

The governor waived language in the definition of pharmacy technician supervision to allow all pharmacy technicians to perform duties during the waiver period without *immediate* supervision by a licensed pharmacist. The definition of immediate supervision, in the rule, is by visual and/or physical proximity to a licensed pharmacist.

The waiver removes "immediate" from [WAC 246-901-020\(1\)](#) as it relates to pharmacy technicians performing nondiscretionary duties, and specialized functions consistent with their training in pharmacy practice under the supervision of a licensed pharmacist; and [WAC 246-901-040](#) as it relates to the “immediate” supervision of pharmacy technician trainees.

Take home point: The pharmacist still needs to be accessible to the pharmacy technician (located on page 12 of Plan-19).

As this relates to sterile compounding, a pharmacist must still be onsite when engaged in compounding in a pharmacy, according to [WAC 246-871-040\(1\)](#).

Commission members reiterated only the word “immediate” was removed. This does not mean “no supervision.” Electronic means (audio/video, etc.) is permitted. Also, [RCW 18.64A.080](#) states the pharmacist shall retain responsibility for any acts performed by a pharmacy technician or assistant.

Submit questions to email.

- **How can pharmacies limit patient contact, specifically as it relates to collecting the patient’s signature for the delivery to Medicaid beneficiaries, insurance reimbursements?**

According the Health Care Authority, Washington State has waived requiring a signature for prescriptions from pharmacies during this time period of a COVID-19 Public Health emergency.

MOTION: Kat Wolf Khatchatourin moved that Lauren Lyles and DOH staff work with the OIC in order to potentially engage in emergency rulemaking; or if not

emergency rulemaking, a proclamation that would waive patient signature requirements at pickup and require health plans to work with their PBM in order to implement and hold our stakeholders harmless. Craig Ritchie, second. Motion carried, 13-0.

- **How can pharmacies, shopkeepers or itinerant vendors selling a nonprescription drug containing ephedrine, pseudoephedrine, phenylpropanolamine, or their salts, isomers, or salts of isomers limit patient contact as it relates to collecting signatures of purchasers under federal requirements and state electronic tracking system (NPLEX – National Precursor Log Exchange)?**

This applies to restricted medications under the CMEA (the Combat Methamphetamine Act of 2005). Should a waiver be requested re: [RCW 69.43.105\(6\)](#) and [WAC 246-889-095\(1\)\(b\)\(v\)](#) which limits and requires the retailer to have the purchaser sign for the restricted products. [RCW 69.43.130 \(1\) and \(2\)](#)

Lauren Lyles will follow up with local DEA agent to see if they are considering waiving this requirement.

8:10 a.m.

3. Open Forum (10 minutes) (if time allows)

Due to technical difficulties, there was not an open forum. Doreen Beebe will print out any questions received during the meeting for Commission review. Other questions may be directed to the [Commission's email](#) or [Doreen Beebe](#).

4. Staff Reports *Information/Action*.

4.1 Executive Director – Lauren Lyles-Stolz

Hiring – extended an offer for the rules coordination position; finalizing the pharmacy supervisor position; hiring an administrative assistant.

Inspectors – stepped up managing the COVID19 inbox.

IMT – PQAC staff is providing additional support to the incident management team.

Thanks to the Commission and licensees for patience with our technical difficulties as we move through this unprecedented and strenuous time.

4.2 Assistant Attorney General – Christopher Gerard – nothing to report.

5. Summary of Meeting Action Items – Commissioner and staff will revisit action items identified during today's business meeting.

Add to Friday's agenda:

1. Self-inspection concerns – proposal to extend to May 31.

2. Residency – lack of testing available for graduating pharmacy students.
3. ASHP accreditation standards

Pharmacy Commission's COVID 19 inbox: COVID19.PQAC@doh.wa.gov

Meeting Recording: April 8:

<https://attendee.gotowebinar.com/recording/6038752461829702152>

There being no further business, the Commission meeting adjourned at 8:22 a.m.

*Respectfully Submitted by:
Amy Robertson, Administrative Assistant*

A handwritten signature in black ink, appearing to read "Tim Lynch". The signature is written in a cursive, flowing style.

*Approval August 28, 2020
Tim Lynch, Chair
Washington State Pharmacy Quality Assurance Commission*