



STATE OF WASHINGTON
Pharmacy Quality Assurance Commission
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Meeting Minutes
April 24, 2020
Webinar

CONVENE

Chair, Tim Lynch called the meeting to order April 24, 2020 at 9:01 a.m.

Commission Members:

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

Staff:

Lauren Lyles-Stolz, Executive Director
Chris Gerard, AAG
Lindsay Trant, Legislative Analyst, Rules
Coordinator
Caitlin Gates, Rules Consultant
Cori Tarzwell, Policy Analyst
Martin Pittioni, Director, Office of Health
Professions
Davis Hylkema, Program Support
Dan Frank, Management Analyst

1. Call to Order

1.1. Meeting Agenda Approval – April 24, 2020

Lauren Lyles-Stolz noted that, since the April 23, 2020 rules hearing had completed its business, Item 2, continuance of the public rules hearing can be removed from today's agenda.

MOTION: Craig Ritchie moved to approve the April 24, 2020 meeting agenda as amended with removal of Item 2. Steve Anderson second. **MOTION CARRIED.** 12-0

1.2. Meeting Minutes Approval – March 6, 2020

MOTION: Ken Kenyon moved to approve the March 6, 2020 meeting minutes. Bonnie Bush seconded. **MOTION CARRIED.** 12-0

2. Public Rules Hearing Chapter 246-945 WAC – Continuance

The public rules hearing was completed on April 23, 2020. This item is removed from the agenda (see 1.1 above).

3. Old Business

3.1. MPJE Emergency Rules and NABP Passport Program Re-evaluation

The MPJE Emergency Rule is the waiver of WAC 246-863-035(2)(d) that is currently in the Secretary's office. The need predicted for this waiver in response to the COVID-19 outbreak did not materialize. Similarly, the need for the NABP Passport Program did not materialize.

MOTION: Steve Anderson moved to remove the waiver for the MPJE Emergency Rules. Craig Richie second. **Motion carried.** 12-0

MOTION: Steve Anderson moved not to pursue participation in the NABP Passport Program. Second by Judy Guenther. **Motion carried.** 12-0

3.2. Therapeutic Substitution Re-evaluation

Based on previous stakeholder comments the commission considered the need for a Therapeutic Substitution waiver. The intricacies of this waiver were discussed. It was noted that the Medical Commission is also working on the issue and more dialog with them will be necessary.

MOTION: Teri Ferreira moved not to move the Therapeutic Substitution waiver forward. Sepi Soleimanpour second. **Motion carried.** 12-0

4. New Business

4.1. Discussion regarding pharmacists ability to independently order COVID-19 tests

On April 8, 2020, the United States Department of Health and Human Services (HHS), issued new guidance under the Public Readiness and Emergency Preparedness Act authorizing licensed pharmacists to order and administer COVID-19 tests that the U.S. Food and Drug Administration has authorized.

MOTION: Craig Richie moved to adopt the HHS declaration and to exercise prosecutorial discretion for pharmacists who engage in COVID-19 testing. Patrick Gallaher second. **Motion carried.** 11 approve, 1 abstention by Jerrie Allard.

4.2. Common Carriers Delivery of Medications in light of COVID-19

Chris Gerard, AAG, reported that common carriers and contract carriers fall under the jurisdiction of the Utilities and Transportation Commission (UTC). State law requires these carriers to be permitted by the UTC. Permitted carriers can deliver controlled substances. A permit secured by a company can cover carriers, or carriers can be permitted independently.

It is the pharmacy's responsibility to verify that a carrier is permitted by the UTC. It is required that controlled substances be packaged so contents cannot be identified. Moreover, there must be a process in place to account for failed delivery.

It was suggested that the Pharmacy Commission publish an FAQ on the subject.

4.3. Non-Resident Pharmacy Renewals

Non-resident pharmacies are required to pass an inspection by their home state within two years of license renewal. All renewals are due May 31. During the COVID-19 pandemic, some states are not performing inspections. The commission discussed options to address the situation.

MOTION: Teri Ferreira moved, for non-resident pharmacies renewing their licenses within the 2020 renewal cycle, the commission would accept a letter from their elected approved inspection agency explaining that the non-resident pharmacy was not able to obtain an inspection within the required two years due to the COVID-19 pandemic. Second by Bonnie Bush.

AMENDED MOTION: Teri Ferreira amended her motion to read, The commission will allow a non-resident pharmacy, in lieu of a required inspection, to submit a letter from an approved inspection agency, explaining that they were unable to get an inspection due to COVID-19. This only applies to license renewals within the 2020 renewal cycle. Further, this does not apply to new applicants. Seconded by Sepi Soleimanpour. **Motion carried.** 12-0

4.4. Provisional Pharmacist License

WSU and UW requests temporary licensure status of 2019 winter and 2020 spring graduating pharmacy students during the COVID-19 crisis.

DEFERRED: The commission determined to take no action at this time, and to evaluate the need for provisional pharmacist license at its next meeting.

4.5. Sterile Compounding Self Inspection form in Community Pharmacies

Community pharmacies who administer vaccines that require reconstitution to administration required to complete the Sterile Compounding Self Inspection form. Due to the WAC definition of compounding, reconstitution is considered compounding and given the route and form of an injection, this would technically require these community pharmacies to complete this inspection form.

MOTION: Ken Kenyon moved that any retail pharmacy under ____ is not required to fill out a USP 797 Self-Inspection form if it is for application of low risk products for immediate use in a retail setting. Teri Ferreira second. **Motion carried.** 12-0

4.6. Emergency Rules for Therapeutic Substitution

In response to the commission's pursuit of a Governor's Waiver for Therapeutic Substitution, the commission considered if it should develop emergency rules mirroring the language in the reporting to the prescriber of a biologic substitution for all drugs therapeutically substituted.

The commission identified that a response to Emergency Rules for Therapeutic Substitution was no longer required.

5. Rules, Legislation, Program and Department Updates

5.1. Petition to De-schedule Epidiolex

MOTION: Ken Kenyon moved that the commission move forward with rulemaking to de-schedule Epidiolex. Second by Craig Richie. Motion carried. Approved 11; Abstained 1, Kat Wolf-Khachatourian.

6. Open Forum

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.

No public comments were given. Kat Wolf-Khachatourian, for reasons of immediate economic impact and workforce need, encouraged revisiting Item 4.4 Provisional Pharmacist License in this current meeting. After discussion, the commission mutually agreed to address it at its next meeting.

7. Staff Reports

7.1. Executive Director – Lauren Lyles-Stolz

Lauren Lyles-Stolz acknowledged newly hired rules coordinator, Lindsay Trant, and Caitlin Gates' move to another position within the department. The hiring process is actively looking to fill the administrative support, the deputy director, and the pharmacist supervisor positions.

Ms. Lyles-Stolz noted priorities currently being worked on. Included is the PQAC Technical Enhancement Packet allowing the commission to 1) delegate action authority to a panel of three or more commission members, and 2) allow the commission to delegate a health law judge to conduct hearings on all licensing cases. Based on legislation passed in 2020-6086 setting minimum standards for registering remote dispensing sites for OUD medication, the commission will be working on rule language. Also on the list of priorities is modifying the definition of compounding to exclude reconstitution, and the omnibus bill to enhance the commission's compensation to class five of \$250 per day.

Finally, Ms. Lyles-Stolz announced that program manager, Doreen Beebe's daughter just had a baby and is the reason Ms. Beebe is not attending today's meeting.

7.2. Assistant Attorney General – Christopher Gerard

Chris Gerard reported his continuing monitoring of the governor's COVID-19 proclamations as it affects the profession and as the near their expiration.

8. Summary of Meeting Action Items

Items requiring follow up include:

- Dialog with the Medical Commission regarding therapeutic substitution (Item 3.2)
- Evaluate need for Provisional Pharmacist License (Item 4.4)

9. Adjournment

There were words of recognition and appreciation for the involvement of stakeholders, and the work of the commission members and staff through all of the rulemaking efforts. Thank you and “Great work”!

There being no further business, the commission meeting adjourned at 12:42 p.m.

Respectfully submitted by:

Approval May 29, 2020



Tim Lynch, Chair

Washington State Pharmacy Quality Assurance Commission