



STATE OF WASHINGTON
Pharmacy Quality Assurance Commission
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Pharmacy Quality Assurance Commission Meeting
April 23, 2021 – Minutes

Convene: Chair, Tim Lynch, called the meeting to order April 23, 2021, 9:05 a.m.

Commission Members:

Tim Lynch, PharmD, Chair
Teri Ferreira, RPh, Vice Chair
Bonnie Bush, Public Member
Jerrie Allard, Public Member
Hawkins DeFrance, Nuclear Pharmacist
Patrick Gallaher, BS, BPharm, MBA, MPH
Ken Kenyon, PharmD, BCPS
Craig Ritchie, RPh, JD
Uyen Thorstensen, CPhT
Judy Guenther, Public Member

Commission Member(s) Absent:

William Hayes, PharmD, CCHP
Note: Jerrie Allard absent 10:45-12:50

Staff Members:

Lauren Lyles-Stolz, PharmD, Executive
Director, Pharmacy Commission
Christie Strouse, Deputy Director, Pharmacy
Commission
Christopher Gerard, AAG
Marlee O'Neill, Deputy Director, OILS
Hope Kilbourne, staff member
Lindsay Trant, Rules and Legislative
Coordinator
Daniel Lari, Pharmacy Inspector
Joanne Miller, Program Manager, Pharmacy
Amy L Robertson, Pharmacy Admin

1. **Call to Order**

1.1. **Meeting Agenda Approval**

MOTION: Craig Ritchie moves to approve the April 23, 2021 meeting agenda; Ken Kenyon, second. Motion carries, 10:0.

1.2. **Meeting Minutes Approval – March 4, 2021**

MOTION: Craig Ritchie moves to approve the March 4, 2021 minutes; Bonnie Bush, second. Motion carries, 10:0.

1.3. **Meeting Minutes Approval – March 5, 2021**

MOTION: Craig Ritchie moves to approve the March 5, 2021 minutes with the correction that Bonnie Bush was absent; Ken Kenyon, second. Motion carries, 10:0.

2. **Executive Session**

The Commission convened in executive session between 9:05 am and 10:15 am to discuss with legal counsel representing the Commission matters relating to Commission enforcement actions, or to discuss with legal counsel representing the Commission litigation or potential litigation to which the Commission is, or is likely to become, a party, when public knowledge regarding the discussion is likely to result in an adverse legal or financial consequence to the Commission pursuant to RCW 42.30.110(1)(i).

Commission reconvened at 10:15 a.m. Called roll, remained unchanged.

3. **Consent Agenda**

- 3.3. **Ancillary Utilization Plans Approval** – Tim Lynch, chair, recuses himself from 3.3.5; Teri Ferreira requests to review 3.3.5; Patrick Gallaher, requests to review 3.3.1, 3.3.3, .3.3.6.

3.1 National Precursor Log Exchange Monthly Dashboard-March

3.2 Pharmaceutical Firms Application Report

- February 12th thru March 30, 2021– new and closed firms

3.3 Ancillary Utilization Plans Approval –

- 3.3.2 Bonney Lake Pharmacy
- 3.3.4 Evergreen Hospital Medical Center Pharmacy
- 3.3.5 Mary Bridge Children’s Hospital
- 3.3.7 Providence Sacred Heart-Providence
- 3.3.8 St. Joseph Medical Center Pharmacy
- 3.3.9 Virginia Mason Hospital Pharmacy
- 3.3.10 Washington Center for Bleeding Disorders

3.4 Pharmacy Technician Training Program Approval

- 3.4.1 Bartell Drugs
- 3.4.2 Chastains-Own Pharmacy
- 3.4.3 Fred Meyer
- 3.4.4 Purdy Cost Less
- 3.4.5 Saars Supermarket
- 3.4.6 The Owl Tri State

MOTION: Craig Ritchie move to approve the consent agenda with the exception of the items pulled from 3.3; Uyen Thorstensen. Motion carries, 10:0.

3b. **Regular Agenda/Items Pulled from 3.3**

- 3.3.1 Alto Pharmacy
- 3.3.3 Cascade Park
- 3.3.6 Pharm-A-Save Granite Falls

Patrick Gallaher noted all three have the same issue – the pharmacy assistant duties state “calls from physicians’ offices authorizing refills, providing no change in the prescriptions are involved.” Suggests these duties should be assigned to a technician or above. This also brings up the need to review the sample AUP on our website.

Notices will be distributed to all licensees that we will be reviewing the sample AUP posted on PQAC website as well as asking for public comments. Licensees will also be notified, pending the review of the sample AUP, there may be subsequent changes to the sample AUP.

MOTION: Teri Ferreira motions to approve 3.3.1, 3.3.3, and 3.3.6; Ken Kenyon, second. Motion carries, 9:1 (Patrick Gallaher).

3.3.5 Mary Bridge Children's Hospital

MOTION: Ken Kenyon motions to approve 3.3.5 and notify to licensee specialized functions no longer exist in the Commission's new rules, Craig Ritchie, second. Motion carries, 9:0 (Tim Lynch recused).

4. Old Business

4.1. Re-approval and re-authorization of SSB 6086 Rule Language

MOTION: Ken Kenyon moves to approve the new section of the draft rule language on SSB 6086 with the modifications and authorize staff to refile CR-102. Craig Ritchie, second. Motion carries, 10:0.

Jerrie Allard, absent 10:45-12:50

4.2. Virtual Inspections Presentation

MOTION: Ken Kenyon moves to adopt option 1 for the inspectors. Hawkins DeFrance, seconds. Motion carries, 9:0.

Option 1: Continue conducting virtual inspections as an option during times of public health emergencies, poor road conditions, natural disasters, inclement weather, limited in-scope inspections (e.g., remodels/modifications, change of ownership) and at the discretion of the inspector and professional judgement of the PQAC leadership team.

4.3. Re-authorization of Retired Pharmacist Status Emergency Rules.

MOTION: Craig Ritchie moves to authorize staff to file a CR-103E to extend the emergency rules for an additional 120 days; Ken Kenyon, second; Motion carries, 9:0.

4.4. WAC 246-945-585 Zero Reports/ Suspicious Order Process Update – Information only.

Christie Strouse, Deputy Director, notified the commission the questionnaire is completed. The GovDelivery communication is being fine-tuned for distribution to stakeholders at a later date.

5. New Business

5.1. Wholesaler Third Party Inspection Program Request: National Coalition for Drug Quality & Security (NCDQS).

Denise Frank, Director of Accreditation and Inspections for NCDQS provided information about how NCDQS can help pharmacies with third-party inspections.

MOTION: Craig Ritchie moves PQAC recognizes NCDQS as a third-party wholesaler inspection program pursuant to WAC 246-945-246(3)(a); Teri Ferreira, second. Motion carries, 9:0.

5.2. **Clarification of Tetrahydrocannabinol (THC) Compounds other than Delta-9 under Chapter 69.50 RCW.**

Liquor and Cannabis Board (LCB) reached out to PQAC for clarification of [RCW 69.50.204\(c\)\(30\)\(i\)](#) which includes tetrahydrocannabinols (THC) as a schedule I controlled substance. Specifically, LCB requested: does the Pharmacy Commission interpret the definition to broadly extend to all extracts, synthetic substances, derivatives, and isomers of the plant genera Cannabis?

Stakeholders Justin Nordhorn (LCB), Jenny Arnold, Vicki Christopherson, Chrystal Oliver, Kevin Oliver, Steve Sarich, Micah Sherman, and John Worthington addressed the commission on this matter.

MOTION: Tim Lynch motioned that the commission endorse the plain language reading of the statute and respond in the affirmative to the LCB's inquiry. Patrick Gallaher, second; motion carries, 9:0.

5.3. **Rules Petition requesting repeal WAC(s) 246-945-040, -051, -053, -054, -055, and -056**

The Commission considered a rules petition from John Worthington requesting repeal of WAC 246-945-040, -051, -053, -054, -055, and -056. Christopher Gerard, AAG, provided the Commission with an overview of the rules petition process, information related to the legal arguments made in the rules petition, and answered questions posed by Commission members.

The petitioner, John Worthington, presented his petition and responded to questions and issues raised by Commission members.

Stakeholder Steve Sarich also addressed the commission on the petitioner's behalf.

MOTION: Craig Ritchie moves the commission deny the rules petition requesting repeal of WAC(s) 246-945-040, -051, -053, -054, -055, and -056. The commission does not agree with the petitioner that the Commission has incorporated the drug schedules by reference unlawfully, nor has the commission unlawfully delegated its legislative authority to the Uniform Law Commission or to the federal government when it adopted the drug schedule rules. In addition, repeal of the rules listed in the rules petition would have a catastrophic impact on public health and safety. Second, Judy Guenther. Motion carries, 9:0.

Break – 15 minutes

Meeting resumed at 1:30 – Roll Call: Teri Ferreira, Vice Chair, took over for Tim Lynch, Chair. Roll Call: Ferreira, Bush, Ritchie, DeFrance, Allard, Guenther, Kenyon, Gallaher, Thorstensen. Lynch, absent.

6. **Rules and Legislative Session Updates.** (Information only; no action needed.)

Lindsay Trant, Rules and Legislative Coordinator, provided the commission with legislation and rules updates for the 2021 Regular Session of the Washington State Legislature.

7. **Requests for Review by Commission Panel.** Commission Panel A: Teri Ferreira, Patrick Gallaher, Hawkins DeFrance. Loann Bell (applicant) presented her plan of study. The commission approved to accept the 300 hours of internship after the MPJE is complete.

8. **Open Forum.**

- a. **Self-Inspection forms/Compounding** – Stakeholder Erika Anderson – Will the commission consider extending discretion on the self-inspection forms due to the new definition of compounding? Per Lauren Lyles-Stolz, PQAC staff will bring this back to the commission meeting in June.
- b. **OTC Wholesalers** – Lauren Lyles-Stolz brought to the commission’s attention that not all OTC wholesalers across the United States have inspection or licensure requirements therefore many are unable to comply with our new **WAC 246-945-246(3)(a)-(b) for out-of-state wholesalers**. Lauren requested the commission to consider in the interim accepting proof of license or evidence that the resident state does not require a license or inspections from the state board(s).

MOTION: Craig Ritchie motions the commission accept from OTC wholesalers a proof of license or evidence of a state that doesn’t require a license nor inspection and that we defer inspections of OTC wholesalers both in state and out-of-state until a method can be established for them both to be inspected. Patrick Gallaher, second. Motion carries, 9:0.

This issue will be brought back to the June 2021 meeting for further review/information.

9.1. **Commission member open discussion.**

- a. **Ken Kenyon** – Noted GoToWebinar seems to have significant technical challenges that other platforms do not exhibit. Commissioner asked if we/DOH are contractually obligated to use GoToWebinar? Lauren Lyles-Stolz confirmed research is ongoing to consider other platforms for in improved meeting experience.
- b. **Patrick Gallaher** – has there been further discussion or updates on an approach for gathering misfill and error data. Lauren Lyles-Stolz stated additional outreach/stakeholdering with L&I is needed before we bring this issue back to the commission. This will be our next step.
- c. **Teri Ferreira – face-to-face meeting updates** – is DOH working on that? Lauren Lyles-Stolz informed the commission the agency is hoping to transition back to in person meetings closer to the August/September timeframe.
- d. **FDA/MOU letter** – Lauren Lyles-Stolz also informed the commission that FDA responded to the commission’s FDA MOU letter. This information will be included at the June meeting.

10. **Staff Reports.**

10.1. **Executive Director – Lauren Lyles-Stolz.**

NABP is seeking volunteers to join some of their committees (NABP model act committee). If you are interested, email Lauren (and copy Tim and Teri).

Staffing – we have many applications for the pharmacist supervisor and pharmacist consultant positions. Also, we are working on filling the four commission vacant seats.

Sample Ancillary Utilization Plan Public Commenting Period – staff requested to prioritize the AUP discussion to the July or a later meeting due to competing priorities e.g., public commenting period for the HCE self-inspection worksheet. Commissioners concur.

11. **Summary of Meeting Action Items.**

- a. **March minutes correction** – ensure Bonnie Bush is marked “absent.”
- b. Commission will review/discuss of the **AUP template** regarding potential issues with the model template for the AUP applications and plan to request for public comments in the future. Staff will also notify stakeholders when this process has started.
- c. Staff will communicate via GovDelivery with stakeholders that the commission will be reviewing the sample **AUP** at a future meeting.
- d. **Specialized Functions Forms** – via GovDelivery staff will inform stakeholders this is no longer required under the new rules.
- e. **Re-approval and re-authorization of SSB 6086 Rule Language** – staff will file the CR102
- f. **Re-authorization of Retired Pharmacist Status Emergency Rules** – staff will file the CR103.
- g. **Medication Assistance Emergency and Permanent Rulemaking** – staff will work with stakeholders to establish permanent rulemaking
- h. Notify applicant and credentialing the 300 internship hours is approved after the MPJE is complete. Staff will send MPJE Study Guide link to applicant.
- i. **Inform the petitioner** to repeal WAC(s) 246-945-040, -051, -053, -054, -055, and -056 has been denied.
- j. Communication to **OTC Wholesalers** that PQAC accept license or evidence that state does not require licenses or inspections in lieu of inspection report.
- k. **NABP Committee** – notify Lauren, Tim, & Teri if any commissioner is interested in volunteering.

Business Meeting Adjourned: 2:25 p.m.

Next scheduled business meeting:

June 3-4, 2021

Business Meetings

9:00 a.m.

Virtual – by Webinar

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