



STATE OF WASHINGTON

Pharmacy Quality Assurance Commission

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September 13, 2019

Meeting Minutes

Department of Health

Point Plaza East (PPE) 310 Israel Road SE

Tumwater, Washington 98501

CONVENE

Chair, Tim Lynch called the meeting to order at 9:18 a.m.

Commission Members:

Kenneth Kenyon, PharmD, BCPS

Steve Anderson, RPh

Michael Sieg, PharmD

Teri Ferreira, RPh, Vice-Chair

Bonnie Bush, Public Member

Matthew Ronayne

Craig Ritchie

Jerrie Allard, Public Member

Judy Guenther, Public Member

Patrick Gallaher, RPh

Tim Lynch, PharmD, Chair

Staff:

Tracy West, Interim Executive
Director

Chris Gerard, AAG

Caitlin Gates, Rules Consultant

Doreen Beebe, Program Manager

Bonita Campo, Office Manager

Marlee O'Neill, Director of Office

Inspection and Legal Services

Martin Pittioni, Office Director, Health
Professions

Absent Commission Members:

Uyen Thorstensen, Pharmacy Technician

Sepi Soleimanpour, RPh, MBA-HA

Olgy Diaz, Public Member

Kat Wolf-Khachatourian, PharmD

1. Call to Order

1.1 Amended Meeting Agenda – September 13, 2019

MOTION: Jerrie Allard moved that the Commission approve the Amended September 13, 2019 Meeting Agenda. Teri Ferreira seconded. **MOTION CARRIED: 11-0.**

1.1 Meeting Minutes – August 1, 2019 Approval

MOTION: Michael Sieg moved that the Commission approve the August 1, 2019 Meeting Minutes. Teri Ferreira seconded. **MOTION CARRIED: 11-0.**

1.2 Meeting Minutes – August 2, 2019 Approval

MOTION: Steve Anderson moved that the minutes be corrected to reflect absent members. Teri Ferreira seconded. **MOTION CARRIED: 11-0.**

MOTION: Craig Ritchie moved that the Commission approve August 2, 2019 Meeting Minutes. Steve Anderson seconded. **MOTION CARRIED: 11-0.**

4.1 Executive Director - Confirmation Vote

Tim Lynch reviewed the hiring process for the Executive Director position. A total of 11 applicants applied. 4 candidates moved forward and the hiring panel narrowed the pool down to 2 applicants. The final applicant Dr. Lauren F Lyles was selected and interviewed by the Commission at the September 12, 2019 meeting.

MOTION: Teri Ferreira moved to confirm Dr. Lauren Lyles as the new Executive Director of the Washington State Pharmacy Quality Assurance Commission and directed the Department of Health to move forward with the hiring process. Jerrie Allard seconded. **MOTION CARRIED: 11-0.**

2a. Consent Agenda

- 2.1** National Precursor Log Exchange Monthly report –August 2019
- 2.2** Pharmaceutical Firms Application Report Approval
 - a. Closed - July 19, 2019 thru September 3, 2019
 - b. New/Open – July 19, 2019 thru September 3, 2019
- 2.3** Ancillary Utilization Plans Approval (may include Specialized Functions)
 - a. Credena Health
 - b. Family Health Centers
 - c. Olympic Memorial Hospital Pharmacy
 - d. Rosauers Supermarket
 - e. Washington Centers for Bleeding Disorders
- 2.4** Pharmacy Technician Training Program Approval
 - a. Lakeside Pharmacy
 - b. Peninsula Pharmacy
 - c. Renton Technical College
 - d. Tri City Community Health

MOTION: Steve Anderson moved that the Commission approve consent agenda items 2.1, 2.2 (a-b), 2.3 (b-m), and 2.4 (a-d). Craig Ritchie seconded. **MOTION CARRIED: 11-0.**

2b. Regular Agenda/Items Pulled from 2a.

2.3 (a) Credena Health – Staff will draft a communication to stakeholders informing them that they are still bound by the AUP they submitted and need to come back to the Commission with an amended AUP for approval to adjust their technician ratio.

MOTION: Matthew Ronayne moved that the Commission approve agenda item 2.3 (a). Teri Ferreira seconded. **MOTION CARRIED: 11-0.**

3. Old Business

3.1 Reaffirm Policy #3

The Commission reviews its accreditation of the ACPE annually based on the requirement in RCW 18.64 010 (1)(c). The ACPE standards have not changed since 2016. Doreen Beebe proposed changes to reflect whether the Commission can reaffirm accreditation annually or defer until ACPE has any substantive changes to their standards.

MOTION: Ken Kenyon moved that the Commission approve ACPE as the accreditation standard. Steve Anderson seconded. **MOTION CARRIED: 11-0.**

MOTION: Kenneth Kenyon moved that the Commission will review its accreditation of the ACPE any time there are changes to the ACPE accreditation standards. Steve Anderson seconded. **MOTION CARRIED: 11-0.**

3.2 Finalize USP 800 Policy Statement on Separate Storage of Hazardous Drugs for adoptions.

Tracy West, Interim Executive Director, explained that staff were bringing back a interpretive statement that will be filed with the Office of the Code Reviser reflecting that the USP <800> as currently written does not require a separate storage room for hazardous drugs for final approval by the Commission. Minor grammatical changes were made to the document prior to bringing to the Commission for approval.

MOTION: Steve Anderson moved that the Commission adopt the interpretive statement as amended and directed staff to file with the code reviser. Craig Ritchie seconded. **MOTION CARRIED: 11-0.**

3.3 Guidance related to USP <800> specifically where the standards are applicable.

Christopher Gerard, AAG, explained that USP 800 is not simply a compounding chapter, it is about the handling of drugs. The Commission has made prior interpretations that when USP <800> becomes effective it will be the standard that is applied when licensees engage in sterile, non-sterile compounding of hazardous drugs. USP <800> is not a compounding chapter but is being incorporated by reference in various parts of the new USP <795> and <797>. USP would consider USP <800> enforceable in context where it is incorporated into USP <795> and <797>. In addition USP <800> deals with the handling of hazardous drugs, the argument is much broader than simply compounding and can be anytime anyone is handling hazardous drugs. The legal requirement in statute requires that the portions of USP <800> that are incorporated into USP <795> and <797> is the context in which it would apply. Mr. Gerard asked for clarification of the Commission's position on the

application of USP <800>. Tim Lynch, Chair, asked Mr. Gerard to develop a written interpretation to bring to the October meeting. **No action was taken on this item.**

4 Update on Communication and Resolution Program (CRP) – Statement of Understanding.

Christopher Gerard, AAG, notified the Commission that work continues on the Statement of Understanding, all but two provisions are ready. He will bring the SOU for approval at the October meeting.

4. New Business.

4.1 Executive Director Vote – moved to beginning of agenda

4.2 Discuss the inspection of clinics (HPACs) that close and/or removed from a Hospital Pharmacy license.

Tracy West, Interim Executive Director, explained that HPACs are clinics that are listed under a parent hospital pharmacy license so they can supply drugs to clinic that are commonly owned, operated, or controlled by the health system. The current state under the emergency rules allows a hospital or health system to remove or add HPAC's at any time to their hospital pharmacy license. DOH conducts closing inspections as part of the current standards includes inventory, disposition of patient records, removing signage, etc. What should be done when closing an HPAC? HPAC's don't have an individual license, they operate under a hospital license that is extended to the clinic. The license would not be closed causing operational issues. There are no standards for clinic closure, does the Commission want to conduct a physical closing inspection? There is attestation language in the closing procedures. The Commission decided the current language is acceptable.

MOTION: Steve Anderson moved that an informal attestation be written regarding how inspectors verify a sample of closed HPAC's on routine inspections. Judy Guenther seconded. **MOTION CARRIED: 11-0.**

The Commission adjourned for a break at 10:20 a.m.

The Commission reconvened from break at 10:31 a.m.

4.3 Review for approval updated policies and procedures submitted for the Washington State Department of Fish and Wildlife chemical capture program

Doreen Beebe, Program Manager, and Dr. Mansfield addressed the statute and rule requirements for WDFW's Chemical Capture Program's policies and procedures with the Commission. WDFW submitted a request to add legend drug substances to their approved list. WDFW submitted updated policies and procedures for the Commission to review. The submission has been reviewed by two inspectors and Dr. Mansfield and the changes were accepted. Only veterinarians will have access to Schedule II drugs. Tim Lynch, Chair, commented that the policy could be amended by bargaining unit rules. Any changes would have to come back to the Commission. The bargaining unit agreement supersedes the agreement and would be put in place immediately. Dr. Mansfield explained that bargaining unit agreement language is boilerplate language that is in all of WDFW policies and could not see where it would come into play. Tracy West, Interim Executive Director,

explained that all state agencies have bargaining unit language in their policies. Tim Lynch, Chair, expressed concern that the policy states that if there is a bargaining unit change, then that is the policy. The Commission would like a chance to review any changes.

MOTION: Ken Kenyon moved to return the policy to WDFW to amend the statement to reflect that the Commission has purview over any changes to the policy. Michael Sieg seconded.
MOTION CARRIED: 11-0.

4.4 Discuss guidance or expectations for authorization for Child Resistant Containers – WAC 246-869-230.

Christopher Gerard, AAG, commented that there is strong federal language that states that child resistant containers are not required in skilled nursing facilities, but the language is not as clear for other long-term care facilities. Assisted living facilities have both self-medication administration and assisted medication administration which makes it hard to determine. Mr. Gerard pointed out that historically the rule has been applied to every setting but a hospital. Could reference the CPSC guidelines referring to special packaging in a policy document.

MOTION: Tim Lynch moved that the Commission approves not using child safety caps in areas where licensed caregivers are administering medication. The Commission wishes to have a policy statement drafted to provide guidance. Judy Guenther seconded. **MOTION CARRIED: 11-0.**

4.5 Delegate Commissioner and/or staff member to attend the Annual NABP/AACP District 6, 7, 8 Meeting, October 6-8, 2019 in Boise, Idaho.

The Commission agreed that Tim Lynch, Chair, would attend as a voting member and Tracy West, Interim Executive Director, would attend as the alternate.

MOTION: Jerrie Allard moved that Tim Lynch would attend as a voting member and Tracy West would attend as the alternate. Craig Ritchie seconded. **MOTION CARRIED: 11-0.**

4.6 Review for approval suggested updates to Policy #58 Inspection Process – WAC 246-869-190 – Implemented March 1, 2018.

Tracy West, Interim Executive Director, recommended changes to update the policy due to changes in reporting structure for inspectors, and general changes in office names at DOH, and to extend the timeline for the Commission to respond to a dispute deficiency or rejected plan of correction to 45 days.

MOTION: Ken Kenyon moved that the Commission accepts the updates to Policy #58 Inspection Process with the change of 45 days as suggested. Craig Ritchie seconded. **MOTION CARRIED: 11-0.**

4.7 Correspondence – There was no discussion

5. Legislation, Program and Department Updates - Information/Action.

5.1 Strategic Plan for Future Legislative Proposals.

Tracy West, Interim Executive Director, shared that DOH is supportive of the

Commission's legislative plan moving forward and now that the new Executive Director is onboard she will work closely with her to map out the process. Ms. West has requested agency request process deadlines from the DOH policy and legislative office. Commissioner Jerrie Allard requested adequate time to do legislative stakeholding as there is now limited time.

5.2 Discuss potential updates to the Non-resident pharmacy inspection – approved list of recognized states e.g. non-compounding pharmacies, etc.

Caitlin Gates, Rules and Legislative Consultant, reviewed the changes made to the document at the last Commission meeting. Pennsylvania did adopt USP as their compounding standards, the Commission directive clarifies that inspections from PA will be accepted after June 22. Comments were received asking if the Commission will accept states not on the approved list that don't engage in compounding. Tracy West, Interim Executive Director, suggested an attestation be added to the non-resident pharmacy application that and applicant would have to sign to indicate they do not engage in compounding so reports can be accepted by states not on the approved list. A decision was made to accept non-compounding reports from FL, IL, and SC. We would not accept AK, WI, and HI. There is a chart available for the website indicating the non-compounding state we accept. Ms. Gates and Doreen Beebe, Program Manager, will work with credentialing to create the attestation on the application.

Next steps: Caitlin will keep the list as it is with minor modifications, post the compounding document, update the credentialing application with attestation, and send to the Commission when updated.

MOTION: Bonnie Bush move to accept document with minor amendments stated by Caitlin. Steve Anderson seconded. **MOTION CARRIED: 11-0.**

5.3 Discuss and consider potential position or guidance regarding CBD (hemp) products in pharmacies.

Tracy West, Interim Executive Director, shared that pharmacies have been inquiring about whether CBD products can be sold in Washington State pharmacies. Products that meet the definition of cannabis health and beauty aids (CHABA) can be sold in locations that are not licensed by the Liquor and Cannabis Board (LCB). The LCB has authority over all marijuana products. CBD can also be derived from hemp. Hemp was removed from the federal schedules in by the signing of the 2018 FARM bill, however the DEA has not updated their schedules in the Code of Federal Regulations (CFR). WA state legislature also legalized hemp in the 2019 legislative session. There is no test to determine what plant CBD is derived from. LCB is the authority over marijuana products and the Washington State Department of Agriculture has authority over hemp and industrial hemp products. Department of Agriculture has announced that adding hemp derived CBD to food or ingestible products is prohibited. The Department of Agriculture will enforce this standard on entities that sell marketed hemp derived CBD products. Marijuana derived hemp products that contain over .3% THC must be sold in an LCB licensed retail store. The Commission discussed their position regarding pharmacies possessing CBD and the regulation of dietary supplements. Christopher Gerard, AAG is hesitant about the Commission taking a position either way, they do not want to be in conflict with the FDA, and they cannot enforce anything. Mr. Gerard suggested that the Commission can advise on

the position of the state law and should identify that other regulators might not be in agreement. Discussion ensued surrounding possession and where products are stored after hours.

Mr. Gerard will do further research and bring additional information back to the Commission.

MOTION: Ken Kenyon moved to accept the draft policy statement that pharmacies cannot possess CBD products as amended in the meeting. Judy Guenther seconded. **MOTION CARRIED: 11-0.**

The Commission adjourned for lunch at 12:10 p.m.

The Commission reconvened from lunch at 12:24 p.m.

6. Open Forum

Jackson Leon, Pharmacy Corporation of America asked if the people in their pharmacy technician program have to reapply if they are changing trainers. Tracy West, Interim Executive Director, informed him they need to notify the Commission. He also commended Stephanie Martin, Pharmacist Inspector, for her professional and thoughtful approach to their inspection.

7. Commissioner Reports - Information/Action.

7.1 Commissioner Reports

Commissioner Ken Kenyon: Stakeholder meeting that was held to discuss HPAC that was very successful.

7.2 Commissioners' open discussion related to items or issues relevant to Commission business/pharmacy practice.

There were no comments

8. Staff Reports Information/Action.

8.1 Interim Executive Director – Tracy West

- The HPAC meeting was helpful to understand challenges under the HPAC structure.
- Working on OTP's concerns around dispensing under the HCE license and approaching the Commission to consider changing the statute surrounding limitations to dispensing amounts.
- Received information from USP that there have been appeals to their draft language. We are monitoring for impact to WA State.
- Actively recruiting for a supervisor and an inspector, as well as office staff
- Extended her thanks to all who have helped her keep everything on track.

8.2 Assistant Attorney General – Christopher Gerard

- He was heavily involved in statewide standing order for Naloxone.
- Meeting with AAG from Government Enforcement and Compliance Division communicating directives to the prosecuting AAG's. He is fostering better communication with them about what the Commission's expectations

- are
- Reviewing rule language with AAG's

9. Summary of Meeting Action Items –

Commissioners and staff revisited action items identified during today's business meeting.

There being no further business, the Commission adjourned at 12:40 p.m.

*Respectfully Submitted by:
Bonita Campo, Office Manager
Approval October, 25, 2019*



*Tim Lynch, Chair
Pharmacy Quality Assurance Commission*