



STATE OF WASHINGTON
Pharmacy Quality Assurance Commission

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October 25, 2019

Business Meeting

Highline Community College

2400 S 240th St., Bldg 8, Mt Constance

Des Moines WA

CONVENE

Chair, Tim Lynch called the meeting to order at 9:06 a.m.

Commission Members:

Tim Lynch, PharmD, Chair

Teri Ferreira, RPh, Vice-Chair

Craig Ritchie, RPh

Jerrie Allard, Public Member

Judy Guenther, Public Member

Patrick Gallaher, RPh

Kat Wolf-Khachatourian, PharmD

Kenneth Kenyon, PharmD, BCPS

Matthew Ronayne, RPh

Michael Sieg, PharmD

Olgy Diaz, Public Member

Steve Anderson, RPh

Uyen Thorstensen, CPhT

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

Absent Commission Members:

Bonnie Bush, Public Member

Sepi Soleimanpour, RPh, MBA-HA

1. Called to Order:

October 25, 2019 Meeting Agenda Approval

MOTION: Steve Anderson moved to approve the October 25, 2019 meeting agenda with correction to draft meeting minute dates to September 12 and 13, 2019. Teri Ferreira seconded the motion. **MOTION CARRIES: 12-0.**

September 12, 2019 Meeting Minutes Approval

MOTION: Teri Ferreira moved to approve meeting minutes for September 12, 2019. Steve Anderson seconded the motion. **MOTION CARRIES: 12-0.**

September 13, 2019 Meeting Minutes Approval

MOTION: Craig Ritchie moved to approve meeting minutes for September 13, 2019. Steve Anderson seconded the motion. **MOTION CARRIES: 13-0.** (Commission Olgy

Diaz arrived)

2. Consent Agenda – Routine Approvals

- National Precursor Log Exchange – September 2019
- Pharmaceutical Firms Applications Closed and Open Reports 9/3/2019 thru 10/18/2019
- Fairway Drug AUP
- Ocean Shores Pharmacy AUP
- Peninsula Compounding Pharmacy AUP
- Pharm-A-Save Granit Falls AUP
- Village Pharmacy Services AUP
- Whitestone Pharmacy AUP
- WRX Pharmacy LLC AUP

MOTION: Craig Ritchie moved to approve consent agenda items 2.1 through 2.3g. Teri Ferreira seconded the motion. MOTION CARRIES: 13-0.

- Rainier Springs Pharmacy AUP – (added item)

MOTION: Steve Anderson moved to approve Rainier Springs Pharmacy AUP (2.3h). Teri Ferreira seconded the motion. MOTION CARRIES: 13-0.

3. Old Business

Washington Department of Fish and Wildlife, Chemical Capture Program -- The Commission is reviewing revisions to the policies and procedures submitted by the WDRW at the September meeting. The revised policies and procedures removed the collective bargaining language that was of concern and ensured all referenced drugs and activities were consistent with chapter 246-866 WAC and law.

MOTION: Steve Anderson moved to approve the Department of Fish and Wildlife chemical capture program policies and procedures as proposed. Teri Ferreira seconded the motion. MOTION CARRIES: 13-0.

4. New Business

Official USP Chapters - <795>, <797>, <825>, and <800> -- The Commission discussed recent notification regarding the delays in official effective dates for revised USP compounding chapters, and the adoption of USP <800> as an official chapter on December 1, 2019 as informational only. Because <800> is compendially related to <795> and <797>, it is not enforceable until the others are official.

Chris Gerard led the discussion on the applicability of the USP chapters as it relates to Washington licensed pharmacies and pharmacists. Chris expressed that the state statute requires compliance with the official US pharmacopeia as it applies to nonsterile and sterile products. He suggested that the revised USP chapters <795> and <797> may not be enforced until they are official. This also results in the Commission needing to reconsider its position on excluding certain types of reconstitution from the requirements in <795> and <797> and will need to clarify its definition of compounding.

The Commission may approve adoption of USP <800> standards since it is consider an official compendium if RCW 18.64.270 is interpreted as referring to official US pharmacopeia compendiums as well as chapters.

Options: Allow early adoption of USP <800>; or
Enforce USP<800> addressing conflicts with official chapters of USP

MOTION: Steve Anderson moved that the Commission continue to allow early adoption of USP <800> including a statement of conflicts with official chapters. Teri Ferreira second the motion. MOTION CARRIED 12-0.

Dispensing legend drugs by health care entities (RCW 18.65.450(3)). – Dr. Lucinda Grande, Medical Director of the Olympia Bupe Clinic provides access to buprenorphine for opioid use disorder with low barrier access, targeting homeless and patient with other challenges. Dr. Grande asked for the Commission’s support and concerns related to a legislative change to the health care entity (HCE) law to increase the dispensing limitations from a 72-hour to a two-week supply.

Tracy West reiterated that the Commission formalized its interpretation of the law by vote at a business meeting in May 2016 by stating that regardless of source dispensing in an HCE is limited to a 72-hour supply unless dispensed by an on-site pharmacist. The Commission had a very robust discussion on the issue. The Commission appreciates the efforts to find a solution to the access to treatment for opioid use disorder, but has concerns that changing the law would broadly apply the increase dispensing limits to clinics licensed as HCEs not just to low-barrier access buprenorphine clinics.

MOTION: Kat Khachatourian moved that Tracy West and staff continue to work with Dr. Grande on developing a plan around supporting workflow develop that does not involve opening the statute for revision. Motion not seconded.

AMENDED MOTION: Kat Khachatourian moved that the Commission does not support adding language to amend the HCE statute or the proposed language. Steve Anderson seconded the motion. MOTION CARRIED. 12-0.

Secure Collaborative Solutions for Access to Category 3 and 4 Confidential/restricted information. – The Commission heard an overview of the Secure Collaborative project and a request for volunteers to test the system. Due to the lack of clarity in the testing scheduled no members volunteered. No motion.

Correspondence

- NABP – ED Memo USP Postponement Impact on NABP Programs
- NABP – ED Memo Amicus Brief Update - Opportunity for Boards of Pharmacy to Join – 503B Outsourcing Facilities
- NABP – ED Memo Live Student and Health Care Professional Continuing Education Webinar FDA Drug Topics: FDA Oncology Center of Excellence’s Project Facilitate: An Overview of the Oncology Expanded Access Program
- Washington Recover Assistance Program for Pharmacy June – Aug 2019

5. Rules, Legislation, Program and Department Updates

(SSB 5380) Commission discussed authorizing a CR-101 Preproposal Statement of Inquiry to initiate rulemaking to implement Substitute Senate Bill 5380 (codified as RCW 69.50.312) -- the law that all controlled substance prescriptions on or after January 1, 2021, are electronically communicated unless the prescriber has received a waiver from the Department of Health. Since the Commission is the regulatory authority under the Controlled Substance Act (chapter 69.50 RCW) the rules implementing the waiver process is also under the authority of Commission. Conditions for granting a waiver may include economic or technological hardship and others if deemed necessary. The Commission will not be the approver of waiver requests. Pharmacist are not restricted from dispensing controlled substance prescriptions to electronic communication or confirm if a prescriber holds a waiver.

MOTION: Steve Anderson moved that the Commission authorize staff to file a CR-101 to initiate rulemaking to implement SSB5380 electronic prescription waiver process. Kat Khachatourian seconded the motion. **MOTION CARRIED. 12-0.**

(Fee rules – chapter 246-945 WAC) Commission discussed authorizing a CR-101 Preproposal Statement of Inquiry to initiate rulemaking to update the pharmacy fee chapter. Rulemaking will facilitate moving the fee rule into the approved chapter 246-945 WAC (part 3). This will also authorize the Secretary of Health in collaboration with the Commission to make additional updates such as two-year renewal cycles for pharmacist, interns, technicians, and assistants; and create two distinct researcher credentials - controlled substances and non-controlled substances.

MOTION: Kenneth Kenyon moved that the Commission authorize staff to file a CR-101 to initiate rulemaking to amend the fee rules to align with the proposed changes in approved rules. Kat Khachatourian seconded the motion. **MOTION CARRIED. 12-0.**

6. Open Forum – no one signed up to address the commission.

7. Sub-Committee and Commission Member Reports

Commissioner Reports

Tim Lynch/Tracy West – Attended the FDA and NABP district 6, 7, and 8 meeting. Both Tim and Tracy expressed a need to be more familiar with the resolution process. It is not just simply presenting an idea but expected to have it thoroughly vetted before the resolutions is consideration at the meeting. There is 45-days timeline to submit a resolution prior to the annual district meeting. We may need to include resolution developing as part of our regular meetings going forward. A significant theme was around states about moving to standard of care model. District 7, which includes, Alaska, Idaho, Oregon, Montana and Wyoming support this model. Other districts were somewhat more hesitant.

Discussion on compact states for pharmacist similar to the nursing, physical therapy, and medical. Requires a legislative change - more discussion to come.

A copy of the final FDA MOU should be available by the end of the year. A number of states will not be signing either because they are unable to due to regulatory or resource restraints.

Wholesalers and 3PLs – DSCSA – how different entities may be licensed and how states are preempted from licensing them as wholesalers. 3PLs includes reverse distributors/ reverse logistic provider– no license or regulation required for the collection of drugs for destruction.

Briefed on FDA insanitary conditions guidance documents and inspections of state facilities.

Kat Khatchatourian -- Attended DOH Leadership Forum – discussed onboarding of new members, training, PMP, technologies and other initiatives that represented by other programs.

October 15 presented to the UW pharmacy law class on the Commission and perspective of a commissioner.

Matt Ronayne – Attend a drug take-back event in Idaho. Next week rolling out a technician verification program. This will be his last report to the Commission.

8. Staff Reports

Tracy West -- attended the Tri-regulators symposium in September where by boards' of pharmacy, nursing and medical boards meet. Conversations concentrated on artificial intelligence (AI) and health care.

She reported on improved oversight, involvement and collaboration with the Office of Health System Oversight on inspections.

Tracy was asked by the department to attend the Citizens Advocacy Center conference, and asked for support by the Commission as well.

Christopher Gerard, AAG – Attended the regulatory law seminar, national meeting involved attorneys representing board and discussion on board liability. Met with his counterparts from other state boards and found we are struggling with similar issues.

9. Summary of Meeting Action Items

- Update on CBD document
- Follow-up on USP
- Cost to PQAC for Box.com – Secure Collaboration System

There being no further business, the meeting adjourned at 12:24 p.m.

*Respectfully Submitted by:
Doreen Beebe, Program Manager
Approval December 20, 2019*



Tim Lynch, Chair
Pharmacy Quality Assurance Commission