



STATE OF WASHINGTON  
DEPARTMENT OF HEALTH  
*Olympia, Washington 98504*

WASHINGTON STATE PHARMACY QUALITY ASSURANCE COMMISSION  
DRAFT Meeting Minutes  
August 2, 2019  
Department of Health  
Highline Community College  
Des Moines, WA

**CONVENE**

Chair, Tim Lynch called the meeting to order August 2, 2019 at 9:12 am.

*Commission Members:*

Teri Ferreira, RPh, Vice-Chair  
Sepi Soleimanpour, RPh, MBA-HA  
Tim Lynch, PharmD, Chair  
Olgy Diaz, Public Member  
Judy Guenther, Public Member  
Steve Anderson, RPh  
Uyen Thorstensen, Pharmacy Technician  
Michael Sieg, PharmD  
Kat Wolf-Khachatourian, PharmD  
Jerrie Allard, Public Member  
Patrick Gallaher, RPh

*Staff:*

Tracy West, Deputy Director  
Steven Saxe, Executive Director  
Caitlin Gates, Rules Consultant  
Doreen Beebe, Program Manager  
Leann George, Secretary Senior  
Marlee O'Neill, Director of Office  
Inspection and Legal Services  
Martin Pittioni, Office Director of  
Health Professions

*Absent Commission Member:*

Bonnie Bush, Public Member  
Kenneth Kenyon, PharmD, BCPS

**Call to Order**

**1.1** Amended Meeting Agenda – August 2, 2019

**MOTION:** Steve Anderson moved that the Commission approve the Amended August 2, 2019 Meeting Agenda. Teri Ferreira seconded. **MOTION CARRIED: 9-0.**

**1.2** Meeting Minutes – June 20, 2019 Approval

**MOTION:** Steve Anderson moved that the Commission approve June 20, 2019 Meeting Minutes. Judy Guenther seconded. **MOTION CARRIED: 9-0.**

### 1.3 Meeting Minutes – June 21, 2019 Approval

**MOTION:** Steve Anderson moved that the Commission approve June 21, 2019 Meeting Minutes. Judy Guenther seconded. **MOTION CARRIED: 9-0.**

*\*\* Commissioner Sepi Soleimanpour arrived*

## 2. Consent Agenda

- 2.1 National Precursor Log Exchange Monthly report – June 2019
- 2.2 Pharmaceutical Firms Application Report Approval
  - a. Closed - June 12, 2019 thru July 19, 2019
  - b. New/Open – June 11, 2019 thru July 19, 2019
- 2.3 Ancillary Utilization Plans Approval (may include Specialized Functions)
  - a. Access Central Pharmacy
  - b. Credena Health Pharmacy Colville
  - c. Credena Health Pharmacy Monroe
  - d. Credena Health Pharmacy Sacred Heart
  - e. Elk Drug, Inc.
  - f. Family Health Centers
  - g. Ferndale Pharmacy
  - h. HealthPoint Specialty Pharmacy
  - i. Millenium Pharmacy
  - j. Onuri Pharmacy
  - k. South Sound Behavioral Hospital
  - l. Suncrest Pharmacy
  - m. Whidbey Health Medical Center
- 2.4 Pharmacy Technician Training Program Approval
  - a. Twin Harbor Drug
  - b. Wenatchee Valley College

**MOTION:** Steve Anderson moved that the Commission approve consent agenda items 2.1, 2.2 (a-b), 2.3 (a-m), and 2.4 (a-b). Sepi Soleimanpour seconded. **MOTION CARRIED: 10-0.**

## Old Business

- 3.1 Policy Revisions of SSB 5380 Opioid Use Disorder Treatment
  - a. Naloxone distribution from emergency department.

**MOTION:** Steve Anderson moved that the Commission approve the Opioid Overdose Medication - Distribution from Hospital Emergency Policy as amended. Judy Guenther seconded. **MOTION CARRIED: 10-0.**

- b. Partial fill of C-II prescriptions

During the 2019 Legislature, SSB 5380 passed, this bill adds a new section to Chapter 18.64 RCW to allow partial fills of C-II drugs if requested by the patient or prescriber. The Commission no longer needs the existing policy and it may be rescinded. Mr. Saxe

presented a Q & A that would provide guidance and requested it be posted to the FAQ's page.

**MOTION:** Steve Anderson moved that the Commission rescind Policy #55 Partial Fill of C-II Prescription and add Partial Fill Q & A to the FAQ page. Teri Ferreira seconded.  
**MOTION CARRIED: 10-0.**

**3.2 Statement of Understand Communication and Resolution program (CRP) Update**  
Executive Director, Steve Saxe provided an update to the Commissioners that staff has edited policies and a "Statement of Work" based on documents used by the medical commission and osteopathic physician and surgeon board. After legal review it will be shared with the Commission for approval and then sent through DOH Contracts office.

### **3.3 Mis-fill Investigation Guidance**

Executive Director, Steve Saxe provided a draft mis-fill guideline to establish appropriate guidelines for questions and information the panel will request the investigator to collect when investigating misfill cases. Each case presents unique facts and must be assessed based on the facts presented. However, there are several common pieces of information and evidence that the Commission would like to attempt to obtain in order to better assess each case. This procedure sets out those common pieces of information and evidence. These guidelines are not intended to be an exclusive list of information and evidence.

**MOTION:** Kat Wolf-Khachatourian moved that the Commission approve the Guidelines for Investigating Misfill Cases. Patrick Gallaher seconded. **MOTION CARRIED: 10-0.**

## **New Business**

### **4.1 Issues related to USP 795, 797, and 800**

Deputy Director, Tracy West led the discussion with the Commission requesting them to consider early adoption of the revised USP chapters that relate to compounding, and guidance around enforcement of the revised chapters as well as the current chapters.

- a. Definition analysis of USP 795 and 797

**MOTION:** Steve Anderson moved that the Commission adopt the position to read the RCW definition of compounding in tandem with the definitions of USP 795 and 797. Compounding in Washington means "the act of combining two or more ingredients in the preparation of a prescription". Licensees engaged in compounding would have to meet USP standards and the revised USP 795 standards excludes certain types of reconstitution. Information on this decision will be posted to the Commission's website. Judy Guenther seconded. **MOTION CARRIED: 10-0.**

- b. Commission's position related to early adopters of USP 795 and 797 standards.  
Tracy West, Deputy Director, requested the Commission allow for early adoption of the revised USP chapters 795 and 797. The request was made based on the upcoming effective date of December 1, 2019 and because the Commission allowed for early adoption of USP 800 in the spring of 2018.

**MOTION:** Steve Anderson moved that the Commission approve early adoption of revised USP chapters 795, 797, 800, and 825. Kat Wolf-Khachatourian seconded. **MOTION CARRIED: 10-0.**

- c. How will the Commission handle non-compliance and enforcement issues effective December 1, 2019. Tracy West, Deputy Director requested the Commission consider recommendations on how to inspect and enforce to USP standards for compounding while early adoption is allowed making two standards available for licensees to comply with. A lengthy discussion took place with Commissioners and stakeholders on what licensees can expect in terms of being cited for deficiencies and how licensees should handle submitting plans of corrections in the interim period while two standards can be met. Questions primarily revolved around compliance ON December 1, 2019. The Commission advised licensees that citations will still occur but plans of correction can include specific plans and timelines for coming into compliance. Sufficiency of plans of correction will still be considered on a case by case basis.

**MOTION:** Teri Ferreira moved that the Commission approved interim guidance for inspections and plan of correction sufficiency during the transition to include:

- Until December 1, 2019, if licensee is meeting currently enforceable USP standard **no citation** will be given.
- If licensee is meeting revised USP chapter standards that conflict with current enforceable USP standard **no citation** would be given.
- Until December 1, 2019, if licensee does not meet currently enforceable USP standard or revised standards **a citation** for violation of current USP chapters **will be issued**.
- Plan of Correction Sufficiency: Any citation to noncompliance of the current standard will require a corrective action to the currently enforceable USP chapters. However, a licensee can opt to have their corrective action to be compliance with the revised standards and the sufficiency will be determined on the revised chapter.

Michael Sieg seconded. **MOTION CARRIED: 10-0.**

- d. Guidance related to USP 800 specifically where the standards are applicable. Tracy West, Deputy Director led the discussion on where USP 800 regarding hazardous drug handling would apply in Washington. Ms. West indicated that similar to other USP chapters, USP 800 would only be applicable to licensees under the Commission's jurisdiction, but requested more time to consult with Christopher Gerard, AAG, and bring information back to the Commission at their September meeting.

#### **4.2 Exemption Request from the Washington Methamphetamine Precursor Electronic Retail Sales Tracking system (NPLeX).**

A licensed pharmacy submitted a request to the Commission to be exempt from the methamphetamine statewide electronic sales tracking system. The Commission was presented with the relevant statutes and rules on the requirement for pharmacies to register and report these transactions.

**MOTION:** Steve Anderson moved that the Commission deny the request for exemption from the Washington Methamphetamine Precursor Electronic Retail Sales Tracking system (NPLEx). This doesn't meet the requirements and the Commission would like more detail on the hardship. Judy Guenther seconded. **MOTION CARRIED: 10-0.**

#### 4.3 Renew Pharmacy Commission Delegation:

- a. Signature authority to designated staff (ED, Credentialing Manager, etc.) to sign on behalf of the Commission on specific routine tasks/approvals.
- b. Decision-making as it relates to select adjudicative services.

**MOTION:** Teri Ferreira moved that the Commission approve the updated delegation decision making documents. Kat Wolf-Khachatourian seconded. **MOTION CARRIED: 10-0.**

#### 4.4 Correspondence

The Commission discussed and reviewed correspondence received or distributed on behalf of the Commission.

- Wildfire Smoke Information for Pharmacist
- American Council for Pharmacy Education (ACPE) Names New Executive Director Washington Recovery Help Line
- American Council for Pharmacy Education (ACPE)
- Some Medicines and Driving Don't Mix Notice

### Legislation, Program and Department Update

#### 5.1 Strategic plan for future legislative proposals.

Tracy West, Deputy Director informed the Commission that the strategic plan originally requested by the Commission to be made available at the August meeting was not completed prior to the meeting due to several assignment conflicts and understaffing. Ms. West will be bringing the strategic plan to the September meeting.

#### 5.2 Update on 2019 Legislative bill implementation

Commission staff received several questions on the list of approved states for nonresident pharmacy inspection reports. One question that came in asked whether a nonresident pharmacy located in a state that is not on the approved list could submit an inspection report from a state that was (i.e. Hawaii pharmacy being inspected by the California Board of Pharmacy could submit the California inspection report and meet the requirements of HB 1412.

**MOTION:** Steve Anderson moved that the Commission accept non-resident Inspections from a Board of Pharmacy on the approved list that is done in a different state. Teri Ferreira seconded. **MOTION CARRIED: 10-0.**

#### 5.3 Update on recruitment process for Executive Director (ED) and discuss appointment of acting ED.

Martin Pittioni, Office Director of the Office of Health Professions at the Department of Health provided an update to the Commission on the hiring process, and informed the Commission that second round interviews would be held in tandem with the September meeting.

### **Open Forum**

*Ericka Anderson*, asked the Commission to consider changing the format of the Compounding Self-Inspection Worksheets to only be the requirements in USP and not in question format. Ms. Anderson's review of the forms seemed to show that the questions sometimes missed the importance of the USP language or misstated it.

*Jenny Arnold*, with WSPA asked the Commission staff to look into the delay in licensing Pharmacy Technicians.

### **Requests for Review by Commission Panel**

#### **7.1 Multi-state Pharmacist Jurisprudence Examination (MPJE)**

Commissioners, Steve Anderson, Olgy Diaz, Michael Sieg, Teri Ferreira and Judy Guenther: **Panel A** were asked to review and approve study plan submitted by applicants to retake the Multi-state Pharmacist Jurisprudence Examination (MPJE) for Applicant.

**MOTION:** Steve Anderson moved that the Commission approve the study plan and authorize Applicant A to re-take the MPJE. Michael Sieg seconded. **MOTION CARRIED: 5-0.**

### **Rules and Sub-Committee Reports**

#### **8.1 Discuss chapter 246-870 WAC Electronic Transmission of Prescription Information and enforcement as it relates to implementation of SSB 5380 (Chapter 214, Laws of 2019).**

Tracy West, Deputy Director, discussed whether chapter 246-870 WAC which sets the requirements for electronic prescribing systems needs to remain in effect since the underlying statute had changed and the Commission is no longer required to approve systems prior to their use.

**MOTION:** Steve Anderson moved that the Commission no longer enforce chapter 246-870 WAC Electronic Transmission of Prescription Information. Kat Wolf-Khachatourian, seconded. **MOTION CARRIED: 10-0.**

#### **8.2 Guidance Document for Kidney Dialysis Center providers**

Steve Saxe, Executive Director presented a finalized guidance document explaining how Kidney Dialysis Centers (ESRD) could procure legend drugs. The guidance document reflected that an ESRD can possess and procure drugs via their medical director, other physician ordering and dispensing, or by obtaining a Health Care Entity license from the Commission.

**MOTION:** Teri Ferreira moved that the Commission approve draft document clarifying options for a kidney dialysis center to order, possess, and use legend drugs. The document will be distributed to Kidney Dialysis Center providers, other DOH Offices and posting on

the Commission Website. Judy Guenther seconded. **MOTION CARRIED: 10-0.**

### **Commission Reports / Open Discussion**

*The Commission had nothing to discuss at this time.*

### **Staff Reports**

#### **10.1 Executive Director, Steve Saxe staff activity report**

##### **Completed:**

*Addition to FAQ* – Staff added three FAQs after review by the Commission at the June meeting. (1) Related to a pharmacist prescribing controlled substances under a CDTA, (2) Use of a hospital DEA number with a suffix, and (3) Dispensing a 12-month supply of oral contraceptives.

*Opioid Treatment Program (OTP) Medication Guidance Document* – The Commission approved the guidance document for pharmacists and OTP on authority to order, possess and use legend drugs including changes added with SSB 5380. This document has been shared with the department, other agency partners and posted on the website.

*Hospital Pharmacy Associated Clinic (HPAC) Emergency Rule* – Staff have refiled the emergency rule to keep this active until the rule re-write project is completed with this language.

##### **In Process:**

*Statewide Opioid Response Plan Goal 1, Strategy 6.1 Begin Engaging Stakeholders to Discuss Potential New Policies to Eliminate Paper Prescriptions* – The Commission approved report is under Department review before submitting to the Chair of the Goal 1 workgroup and the Attorney General's Office.

*Implementing HB 1412 Non-resident pharmacies / inspection reports* – The Commission approved the plan for implementing this request legislation. Staff have sent approved letter to non-resident licensees. Staff will revise and post the guidance document with approved states listed and approved third-party inspection programs.

*Commission Approval of Electronic Prescription Transmission Systems* – In SSB 5380 the Legislature amended the RCWs eliminating the approval requirement for e-prescribing systems. Letters will be sent to vendors and website changed to show new law.

*Communication Resolution Program (CRP)* – The Commission approved entering into a Memorandum of Understanding with the Foundation for Healthcare Quality and the Communication Resolution Program to jointly work with them on cases using a parallel approach similar to Medical Commission. Staff will work with Contract office on language.

*Multi-State Pharmacy Inspection Blueprint* – The forms have been revised with changes from the January meeting and posted to the website. Copies were submitted to NABP for review. Staff met with NABP reps to review comments. Will work on next steps for Commission consideration.

**10.2** Deputy Director, Tracy West reported:

Ms. West shared that with Steve Saxe, Executive Director's retirement and an unsuccessful first round recruitment for a pharmacist supervisor, who would oversee the pharmacy inspectors, the program staff will be understaffed and less work might be accomplished during the period of short staffing.

**Summary of Meeting Action Items**

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

*There being no further business, the board adjourned at 12:17 p.m.*

*Respectfully Submitted by:  
Leann George, Program Support for  
Approval September 13, 2019*

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*Tim Lynch, Chair  
Washington State Pharmacy Quality  
Assurance Commission*