CONVENE

Chair, Tim Lynch called the meeting to order December 14, 2018 at 9:12 am.

Commission Members:
Olgy Diaz, Public Member
Sepi Soleimanpour, RPh, MBA-HA
Jerrie Allard, Public Member
Matthew Ronayne, Rph
Judy Guenther, Public Member
Steve Anderson, RPh
Uyen Thorstensen, Pharmacy Technician
Kenneth Kenyon, PharmD, BCPS
Michael Sieg, PharmD
Kat Wolf-Khachatourian, PharmD
Elizabeth Jensen, PharmD
Tim Lynch, PharmD, Chair
Cheryl Adams, PharmD, Vice-Chair
Bonnie Bush, Public Member

Absent Commission Member:
Teri Ferreira, RPh

Staff:
Christopher Gerard, AAG
Tracy West, Deputy Director
Steven Saxe, Executive Director
Caitlin Gates, Deputy Director
Doreen Beebe, Program Manager
1. Call to Order

1.1 Amended Business Meeting Agenda

**MOTION:** Steve Anderson moved to remove 3.2 from the agenda for discussion in January and to approve the amended December 14, 2018 Meeting Agenda. Cheryl Adams seconded. **MOTION CARRIED: 13-0.**

1.2 Meeting Minutes – October 18, 2018

**MOTION:** Cheryl Adams moved to approve October 18, 2018 Meeting Minutes with changes. Sepi Soleimanpour seconded. **MOTION CARRIED: 13-0.**

1.3 Meeting Minutes – October 19, 2018

**Kat Wolf-Khachatourian late arrival**

**MOTION:** Steve Anderson moved to approve the October 18, 2018 Meeting Minutes with changes. Sepi Soleimanpour seconded. **MOTION CARRIED: 14-0.**

2. Consent Agenda

2.1 National Precursor Log Exchange Monthly report – November 2018

2.2 Pharmaceutical Firms Application Report Approval
   a. Closed - October 2 through November 28, 2018
   b. New/Open – October 2 through November 28, 2018

2.3 Ancillary Utilization Plans Approval (may include Specialized Functions)
   a. Acts Pharmacy and Healthcare Services
   b. Colville Community Health Center Pharmacy
   c. Columbia Compounding Pharmacy
   d. Columbia Pharmacy LLC
   e. Matrx LT Pharmacy
   f. Prime Pharmacy
   g. Quality Compounding Solutions
   h. Wellfound Behavioral Health Hospital
   i. Whole Health Pharmacy

2.4 Pharmacy Technician Training Program Approval
   a. Bi-Mart Pharmacy
   b. Healthpoint Pharmacy
   c. Spokane Community College
   d. Twin Harbor Drug
   e. Wenatchee Clinic Pharmacy

2.5 Pharmacy Technician Ratio Exemption Approval
   a. KPNW Cascade Park Pharmacy
   b. KPNW Longview Kelso Pharmacy
   c. *Pulled Item*
   d. KPNW Orchards Pharmacy
e. KPNW Salmon Creek Pharmacy  
f. Mercury Pharmacy Services  
g. Yakima Valley Memorial Hospital Pharmacy  
h. KPWA Riverfront  
i. KPWA Bellevue  
j. KPWA Burien  
k. KPWA Central Hospital Pharmacy  
l. KPWA Central South  
m. KPWA Downtown  
n. KPWA Everett  
o. KPWA Factoria  
p. KPWA Federal Way  
q. KPWA Kent  
r. KPWA Lidgerwood  
s. KPWA Lynnwood  
t. KPWA Northgate  
u. KPWA Northshore  
v. KPWA Olympia  
w. KPWA Port Orchard  
x. KPWA Poulso  
y. KPWA Puyallup  
z. KPWA Rainier  
 aa. KPWA Redmond  
 bb. KPWA Renton  
 cc. KPWA Silverdale  
 dd. KPWA South Hill  
 ee. KPWA Tacoma South  
 ff. KPWA Tacoma  
 gg. KPWA Veradale  
 hh. KPWA Mail Order Pharmacy Ratio Exception  

2.6 Tamper Resistant Prescription Paper/Pads Approval  
a. Taylor Communications Inc.  

MOTION: Matthew Ronayne moved that the Commission approve consent agenda items 2.1, 2.2 (a-b), 2.3 (a-i), 2.4 (a), 2.5 (a, c, e) and 2.6 (a) and pull Items 2.4 (b, d) and 2.5 (a-hh) for further discussion. Steve Anderson seconded. MOTION CARRIED: 14-0.  

2b. Agenda/Items Pulled from the Consent Agenda  

2.4 Pharmacy Technician Training Programs  

2.4 (b) Healthpoint Pharmacy & (d) Twin Harbor Drug  

These items were pulled due to missing documentation. The Commission tasked staff to retrieve missing documentation and make sure the packet are complete to resubmit in January.
**MOTION:** Cheryl Adams moved that the Commission deny Healthpoint Pharmacy and Twin Harbor Drugs technician training programs due to missing documentation and incomplete application packets. Staff is asked to request complete packets and resubmit for approval in January. Steve Anderson seconded. **MOTION CARRIED: 14-0.**

2.5 (a-hh) Pharmacy Technician Ratio Exemption

These were pulled due to not meeting the minimal requirements in the service plan. The Commission discussed this issue further and asked that staff prepare a template letter or email to send back to the requestor to check their documentation to meet the minimum requirements before being sent to the Commission for approval.

6.1 UPDATE to Pharmacist to Technician Ratio Rules WAC 246-901-130

The Commission decided to discuss an update on the pharmacist to technician ratio rule during the discussion on tech ratio waivers. The Commission reiterated that the suggested rule change had been stakeholdered, comments have been received, and due to this the rule needs to continue to move forward. The licensees need to be informed of the status of rulemaking to diminish the number of waiver requests. There will be a hearing scheduled in the spring of 2019.

Staff was asked to send an update via GovDelivery and in the Newsletter regarding the Pharmacist to Technician ratio rule.

**MOTION:** Cheryl Adams moved that the Commission **approve 2.5 (g) and deny** the rest of 2.5 because they didn’t provide the minimal requirements. Judy Guenther seconded. Elizabeth Jensen opposed, Matthew Ronayne abstained. **MOTION CARRIED: 12-1-1.**

3. Old Business

3.1 CDTA Decision Tree and Guidance Document, CDTA v. Protocols

a) Review updates to the Collaborative Drug Therapy Agreement (CDTA) Decision Tree and Guidance Document and discussion of CDTA v. protocols in refill authorization centers

AAG, Christopher Gerard presented the updated internal document for discussion. This was carried over from the October meeting to allow all Commissioners an opportunity to provide comment. This is an updated version to include revisions from the September meeting and comments received since the October meeting. It was decided to change the internal document title to Interim Guidance document.

**MOTION:** Ken Kenyon moved that staff publish the Interim Guidance document to the website. Steve Anderson seconded. **MOTION CARRIED: 14-0.**

b) Update on Medical Quality Assurance Commission’s (MQAC) request for Attorney General formal opinion
AAG, Christopher Gerard shared there is no update regarding the Attorney General Formal Opinion. Commissioners Ken Kenyon, Tim Lynch, Deputy Director, Tracy West and Executive Director Steve Saxe met with the Medical Commission and had a robust discussion. The Medical Commission members wanted to learn more about what a CDTA is, how CDTA’s are used in community settings and have requested to have more meetings. Collaboration between WSPQAC and MQAC will continue regarding CDTA’s.

4 Requests
Commissioners, Jerrie Allard, Uyen Thorstensen, Matthew Ronayne and Cheryl Adams: Panel C heard study plans from applicants.

4.1 Multi-state Pharmacist Jurisprudence Examination (MPJE)
Panel C was asked to consider for approval a study plan submitted by applicant A to retake the Multi-state Pharmacist Jurisprudence Examination (MPJE) – Applicant A

Panel C authorized Applicant A to retake the MPJE.

4.2 Required Internship Hours
Consider for approval a request to waive all or a portion of the required internship hours for a foreign-trained pharmacist based on the applicant’s credentials and education. – Applicant B

Panel C heard the applicants request and is requiring Applicant B to complete 400 hours in direct patient care setting before sitting for the NAPLEX and MPJE – additional 200 hours before licensure

5 Legislation, Program and Department Updates

5.1 Commission Budget
As the budget sub-committee has been diving deep into the Pharmacy Commissions budget. Ryan Black, Deputy Director of Policy and Legislative Relations, formerly Budget Manager for DOH, presented and provided information on indirect expenses and how they are allocated across Boards and Commissions. Mr. Black introduced himself and provided a Power Point presentation on indirect Expenditures to the Commission and answered questions.

Vice-Chair, Cheryl Adams
Commissioner, Cheryl Adams resigned as a Pharmacy Commission Member and read a resignation letter. She was given a certificate from Governor Inslee, and from Secretary Weisman for her service as Pharmacy Quality Assurance Commission Member. Keith Swenson, Director of Boards and Commissions for Governor Inslee read a letter from the Governor to Commissioner Adams for her time and commitment.
Open Forum

- **Jeff Rochon** shared in light of the recent news from Cheryl Adams he thanked her for listening to the regulated community and all her dedication and sacrifice. She was always willing to listen.
- **Howard Crabtree** thanked the Commission for their collaboration with stakeholders. He has his own staffing company with a wide range of clients. He has a lot of interactions with pharmacy folks.
- **Charles Ho** thanked Cheryl Adams for her work, he appreciated the way she conducted herself as a Commissioner and she will be missed.

*The Commission adjourned for Executive Session at 12:00 p.m.*

*The Commission reconvened from Executive Session at 1:30 p.m.*

5.2 Request Legislation Updates

Executive Director, Steve Saxe provided an update to the Commissioners.

The Pharmacy Commission has two request legislation bills for the 2019 session and two potential bills for the 2020 session or later. Still collecting stakeholder input prior to the beginning of the session in January 2019. There is also work being done to get support for these bills.

- Increase the efficiency of the electronic prescribing approval process and clarifying responsibility for confidentiality process and procedures – 2019 Leg Session
- Amend RCW 18.64.360 to allow the Commission to require nonresident pharmacies to submit inspection reports from a commission-recognized inspection program. – 2019 Leg Session

The Pharmacy Commission is continuing to collect input for the following two bills for consideration in the 2020 or later legislative sessions.

- Update the grounds and process for discipline and enforcement of entity licenses under chapter 18.64 RCW. 2020+ Leg Session
- Omnibus Pharmacy Practice Act Update

In addition, the Opioid Response Workgroup had two items that they asked the Pharmacy Commission to facilitate the collection of stakeholder input.

- Engaging stakeholders to discuss potential new policies to eliminate paper prescriptions.
- Develop criteria for when opioid distributors should report suspicious orders.

These two items came out of the goals of the Opioid Response Plan

5.3 Chairs of the Legislative Health Care Committees Update

Subcommittee members updated the Commission on the meeting with Senate and House Healthcare Committee Chairs. They discussed inspection changes, rule re-write project and
issues and concerns regarding statutory provisions on compounding. Committee chairs requested some draft language to consider. The Pharmacy Commission was asked to provide technical assistance to better clarify compliance related to sterile and non-sterile compounding.

**MOTION:** Cheryl Adams moved that the Commission approve draft language to consider that may better clarify compliance related to sterile and non-sterile compounding. Elizabeth Jensen seconded. **MOTION CARRIED: 14-0.**

6. Rules and Sub-Committee Reports
This was discussed with Item 2b, Consent agenda items pulled

7 New Business

7.1 USP 800 – Handling Hazardous Drugs – Hazardous Drug Storage Requirements
Deputy Director, Tracy West led the discussion with the Commission asking them to affirm that USP <800> does not require a storage area/room separate from the HD buffer room. It was brought to the attention of Commission staff there is confusion over the requirements in USP Chapter <800> regarding the storing of hazardous drug compounding materials. Information was received from licensees and CriticalPoint, that Washington is requiring a separate storage room for hazardous drug compounding materials. To date there have been no citations given for not having this in place. The Commission was asked to provide guidance to staff on how they would like to communicate to stakeholders. There was some discussion on developing a best practice document or minimal standards document. The Commission agreed at this point in time, minimum standards will be the standard, with no best practice recommendation, and that staff should draft a policy statement.

**MOTION:** Judy Guenther moved that staff draft a policy statement that USP<800> does not require a separate storage room for HD handling. Cheryl Adams seconded. **MOTION CARRIED: 14-0.**

7.2 Correspondence
The Commission discussed and reviewed correspondence received or distributed on behalf of the Commission
- NABP Program Information for NAPLEX, MPJE, and e-LTP Applicants memo
- Armed Forces Waivers and Discounts, NABP Memo Physician Concern Memo
- GovDelivery Email Notice of Epidiolex
- GovDelivery Email on Rulemaking (DOH Fee Changes/CR-101 Withdrawals)
- Safety in the Retail Pharmacy
- A Prescriber’s Guide to the New Medicare Part D Opioid Overutilization Policies for 2019
- NABP Memo on Purchasing NAPLEX or MPJE
7.3 Update on FDA Draft Memorandum of Understanding
Commissioner, Tim Lynch and Deputy Director, Tracy West attended the FDA meeting in September. The FDA was asking Boards of Pharmacy’s to buy into their Memorandum of Understanding (MOU) that they want to enter into with states around sharing information with the FDA around compliance. There were several concerns from other states. Executive Director, Steve Saxe shared that NABP has been working on a draft response to the MOU with edits that would make this more palatable for other states, related to sterile compounding. During this discussion it was realized that the initial draft was focused on 503B and the new draft seems to be focused on 503A’s. The discussion will be brought back after there is more time to review the new draft.

7.4 Election of an interim Vice-Chair
Due to the resignation of Vice-Chair, Cheryl Adams, according to the Bylaws Chair, Tim Lynch has the option to appoint a Vice-Chair, Mr. Lynch appointed Teri Ferreira as interim Vice-Chair, until the next regularly scheduled election in July 2019.

7.5 Executive Director, Steven Saxe
Executive Director, Steve Saxe updated the Commission, staff and the stakeholders that he will be retiring in October 2019.

8. Commission Reports / Open Discussion

8.2 Commission open Discussion
- Elizabeth Jensen read a letter to the Commission, staff and the stakeholders, to commemorate on her last meetings with the Commission.
- Cheryl Adams shared that a colleague/friend suggested that it would be great if there was a requirement to provide resources to dispose of medications with or on a prescription.

9. Staff Reports

Executive Director, Steve Saxe reported:
Completed:
- Withdrawal of CR 101 – Staff submitted the withdrawal of CR 101 requests following the October meeting decision. CR-101 rulemaking was withdrawn for Chapter 246-878 WAC Good Manufacturing Practices, Chapter 246-870 WAC Electronic Transmission of Prescription Information, New Chapter Donation of Prescription Drugs and Chapter 246-865 WAC Pharmaceutical Services. These will be addressed in the rule re-write project.
- Meeting with Healthcare Legislative Chairs – The meeting with the Chairs of the Senate and House Healthcare committees was held Monday, December 3.
✓ **Labeling of Outpatient Administered Drugs** – The edited document approved at the October meeting is on the website.

✓ **Complaint Intake Process** – Staff developed an online complaint intake form. This should support people to provide more consistent information to help disciplinary authorities for all programs better evaluate complaint at Case Management Team meetings. A copy of the complaint form was shared with the Commission last month.

✓ **Entity enforcement cases.** The Commission chose to use a three-member panel accompanied by a consulting Assistant Attorney General for any formal pharmacy entity enforcement hearing.

**In Process:**

- **CDTA Guidance Document** – Staff worked with the assigned commission members to edit the document based on input from the September and October meeting. It is on the December Agenda.

- **Practice Outside of a Pharmacy** – Staff are working to add the FAQs approved at the September meeting to the Pharmacy Commission website.

- **Emergency Medical Reason** – The policy edited at the October meeting is in the departments’ interpretive statement review process. This will be presented at the January meeting.

- **Practitioner Use of a Hospital DEA** – Information on how a suffix can be added to a hospital DEA number for a practitioner was in an earlier newsletter but will also be added to the Pharmacy Commission website.

- **Review of misfill grid and NCQAC chart** – The subcommittee has identified some additional work they want to complete. They will continue working on this process following other priority work.

**New Staff**

- **Caitlin Gates** is our new Rules and Legislative Consultant. Caitlin is originally from Colorado and came out to Washington to attend the University of Washington. After participating in the legislative internship she moved on to work for the House of Representatives as a Legislative Assistant. Recently she has been doing political consulting and tribal relations work. She enjoys spending time with her family and going on hikes and camping in all the many beautiful places Washington has to offer. We are very excited she is joining our team and the help and support this will provide the Pharmacy Commission and staff with its heavy rule re-writing agenda!

- **Stephanie Martin** is our new Pharmacist Inspector. Her experience in hospital as well as other pharmaceutical settings will be vital to moving the Commission’s work and mission forward. Stephanie Martin is a licensed pharmacist in Washington and Nebraska. She is board certified in Pharmacotherapy. She graduated with honors from the University of Nebraska and has practiced in Washington since that time. She has served both inpatients and outpatients, from retail to general medicine to emergency medicine patients. In her free time her family enjoys hiking, backpacking, and traveling.
There being no further business, the board adjourned at 2:02 p.m.

Respectfully Submitted by:
Leann George, Program Support for Approval January 25, 2019

Tim Lynch, Chair
Washington State Pharmacy Quality Assurance Commission