CONVENE

Chair, Tim Lynch called the meeting to order February 2, 2018 at 9:04 am.

Commission Members:
Elizabeth Jensen, PharmD
Tim Lynch, PharmD, Chair
Cheryl Adams, PharmD, Vice-Chair
Teri Ferreira, RPh
Judy Guenther, Public Member
Steve Anderson, RPh
Michael Sieg, PharmD
Uyen Thorstensen, Pharmacy Technician
Kenneth Kenyon, PharmD, BCPS
Sepi Soleimanpour, RPh, MBA-HA
Kat Wolf-Khachatourian, PharmD

Absent Commission Member:
Olgy Diaz, Public Member
Matthew Ronayne, RPh
Arun Sambataro, Public Member
Jerrie Allard, Public Member

Staff:
Chris Gerard - AAG
Steven Saxe, Executive Director
Tracy West, Rules Coordinator
Angelica Pauley, Pharmacist Consultant
Lisa Roberts, Pharmacist Consultant
Irina Tiginyanu, Pharmacy Technician Analyst
Doreen Beebe, Program Manager
Leann George, Secretary Senior
Gordon MacDonald, Supervising Pharmacist Investigator
Marlee O’Neill, Deputy Director OLS

NOTE: This meeting was also a webinar to allow stakeholders to participate and provide their input.
Call to Order

1.1 Business Meeting Agenda

MOTION: Kat Wolf-Khachatourian moved that the Commission approve the amended meeting agenda. Amendments were to add Item 3.1 timeline discussion regarding Inspection Rule Implementation training, Change Item 4.2 Budget sub-committee formation and add Open Commission Discussion. Cheryl Adams seconded. MOTION CARRIED: 10-0.

1.2 Meeting Minutes – November 30, 2017

MOTION: Ken Kenyon moved to approve the November 30, 2017 meeting minutes. Judy Guenther seconded. MOTION CARRIED: 10-0.

1.3 Meeting Minutes – December 14, 2017

MOTION: Cheryl Adams moved to approve the December 14, 2017 meeting minutes with corrections. Steve Anderson seconded. MOTION CARRIED: 10-0.

1.4 Meeting Minutes – December 15, 2017

MOTION: Kat Wolf-Khachatourian moved that the Commission approve the December 15, 2017 meeting minutes with corrections. Steve Anderson seconded. MOTION CARRIED: 10-0.

Consent Agenda

2.1 National Precursor Log Exchange Monthly report – December 2017

2.2 New and Closed Pharmaceutical Firms Application Report Approval
   - November 30, 2017 thru January 17, 2018

2.3 Ancillary Utilization Plans Approval (may include Specialized Functions)
   a) Cle Elum Pharmacy
   b) Edmonds Pharmacy
   c) NW Prescriptions and Medical Supply
   d) Old Mill Country Store
   e) Schaffner Pharmacy
   f) UP Pharmacy
   g) Union Avenue Compounding Pharmacy
   h) Medical Center Compounding Pharmacy

2.4 Pharmacy Technician Training Programs Approval
   a) Lincoln Pharmacy
   b) Yakima Valley Memorial Hospital

2.5 Electronic Prescription Transmission Systems
   a) Indian Health Service – RPMS EHR
   b) McKesson Specialty – iKnowMed
   c) McKesson Specialty – iKnowMed Gen 2
   d) Medical Mine – ChARM EHR
MOTION: Cheryl Adams moved that the Commission approve Consent Agenda Items 2.1 thru 2.5. Uyen Thorstensen seconded. MOTION CARRIED: 10-0.

Old Business

Action Item Update
Executive Director, Steve Saxe updated the Commission on the status of tasks received during the past Commission meetings.

Completed.

✓ Bylaws – The election of officers section has been updated and a new copy of the bylaws will be distributed.
✓ Prescription Monitoring Program (PMP) – An article about the PMP was included in the January Newsletter.

In-Process

• Compounding and hazardous medication preparation – The policy statement reviewed at the October meeting was reviewed by the Department, other professions and the Department of Labor and Industries. The policy statement with corrections and additions was presented later in the meeting.
• Guidelines / Pharmacy Practice Document – The subcommittee held a planning meeting to prepare for a public stakeholder meeting.
• Third Party Notification – Staff has been working on follow-up for a document to outline the roles and responsibilities and information to answer questions that came up on the numbers and types of notifications.
• Compounding versus Reconstitution – Staff continues to develop a guidance document. They will work with the policy office to determine if a formal interpretive guideline would be more appropriate for this document.
• Pharmacist as a Prescriber under Collaborative Drug Therapy Agreement (DCTA) – Staff will contact the pharmacy and medical associations to collect any pertinent information related to the issue prior to contacting the Medical Commission.
• Budget / Fee Discussion - Working with the Division finance staff to provide additional information in follow up to the December discussion.

New Inspection Process Implementation Training
During the meeting on February 1, 2018 the Commission asked that staff prioritize their work to make the implementation of the new inspection process and new inspection rule training be the one and only priority. The Commission expected to see a full training program and due to resources this work wasn’t done. Out of concern for the public to be given an appropriate amount of time to prepare for the changes ahead the Commission elevated the priority of this work.

Executive Director, Steve Saxe ran through an updated and more detailed timeline that will be put in place immediately to get this work done.
**Action Plan**
The Commission started to go through the deliverables in the Action Plan with the intent to table some items until the high priority work is done. At this time the Commission decided the full focus needs to be completely on the new Inspection Rules and Process training and implementation. The current Action Plan was replaced with the New Inspection Process Implementation and the Rules Re-Write Project. AAG, Chris Gerard will support Program Manager Doreen Beebe and begin the work on the Licensing portion on the Rules Re-Write Project.

**MOTION**: Kat Wolf-Khachatourian moved that PQAC reconfigure the action plan into the format of a Gantt chart that is trackable and more concise, which will include utilizing the framework of the monthly webinars that Lisa Roberts created but realign the priorities to demonstrate the first priority to be the Implementation of the New Inspection Process plan and then apply that framework going forward to each initiative (Rules Re-Write Project) that will be outlined in the Gantt chart. Steve Anderson seconded. **MOTION CARRIED: 11-0.**

**Third Party Referrals**
During the discussion regarding third party referral at the December meeting Office Director of OII, Marc Defreyn was asked several questions by the Commission. Marc agreed to come back in February with some answers to their concerns and questions. Mr. Defreyn continued to answer questions regarding his responses. The topic of budget came up along with other questions prompted during this discussion. By the end of this discussion each Commissioner was able to take a moment to speak and ask further questions. Mr. Defreyn was asked to provide more data/answers which also included some financial concerns that Mr. Saxe will work with the budget folks in DOH. The Commission is trying to get some clear understanding of this process so they are able to provide some transparency to the regulated community.

**Joint Operating Agreement**
Vice Chair, Cheryl Adams shared with the Commissioners that there were a few amendments made and the JOA is still being reviewed by Dept. of Health.

**Pharmacy Intern Registration Purpose Statement**
The Commission was asked to review and approve the Pharmacy Intern Registration Policy Statement. They would like to make sure that some communication be sent out to stakeholders that this has been changed.

**MOTION**: Ken Kenyon moved that the Commission approve the updated procedural rule regarding pharmacy intern registration with the new definition of enrollment. Steve Anderson seconded. Elizabeth Jensen opposed. **MOTION CARRIED: 10-1.**

**Legislation, Program, and Department Updates**
**Update on 2018 Legislative Session**

Executive Director, Steve Saxe provided the Commission a spreadsheet with a legislative panel 2018 bill grid. He spoke on HB 2688 Non-Resident Inspection Bill and HB 2689 E-prescribing Bill. They continue to move through the process. A non-substantial amendment was made to HB 2688 clarifying the approved inspection programs needed to be comparable to in-state pharmacy inspections. DOH and the prime sponsor had received phone calls with concerns that the bill would stop DOH from conducting out of state pharmacy inspections. DOH is working with the sponsor and legislatures to clear up the misunderstanding.

**Program Finances**

During the PQAC Meeting on December 15, 2017 the Commission tasked the HSQA Financial Service Unit to provide some data for more clarity and understanding before they are asked to make decisions on other items. The Commission put together a sub-committee who will work with the Financial Service Unit to look deeper in PQAC’s budget for places to save expenses.

**MOTION:** Kat Wolf-Khachatourian moved that the Commission appoint Ken Kenyon, Judy Guenther, Sepi Soleimanpour, and Elizabeth Jensen as a sub-committee to work with HSQA Financial Service Unit to do a deeper look into PQAC budget for cost saving opportunities there are within the existing budget approach that is timely. Ken Kenyon seconded. **MOTION CARRIED: 11-0.**

**New Business.**

**Naloxone**

The Commission was asked to discuss and review draft guidance document on the dispensing/delivery of naloxone as it relates to RCW 70.41.480 and WAC 246-873-060 emergency department discharge medications. This was reviewed and approved during a special meeting January 26, 2018 and is on the website. It was kept on the agenda for acknowledgement publicly.

**Drug Supply Chain Security Act (DSCSA)**

Executive Director, Steve Saxe and AAG, Chris Gerard led the discussion with the Commission regarding issues related to the federal Drug Supply Chain Security Act (DSCSA) and third party logistics providers. Chris Gerard provided went over his findings, options he came up with and the policy that was put together.

**MOTION:** Steve Anderson moved to approve the policy presented regarding third party logistic providers.

**MOTION:** Steve Anderson substituted his motion that the Commission will not take action at this time and schedule for an executive session at the March PQAC meeting to discuss risks and options the Commission has. Judy Guenther seconded. **MOTION CARRIED: 11-0.**
The commission adjourned for Closed Session at 12:00 p.m.

The commission reconvened from Closed Session at 1:30 p.m.

Enforcement Efficiencies
Deputy Director of OLS, Marlee O’Neill presented a draft grid for the Commission to discuss. The Commission is wanting to ensure consistency and efficiency in the enforcement process which includes how it handles reports of misfills. After further discussion they agreed on putting together a workgroup to work on a grid with “all types” of complaints, investigations and cases. The workgroup includes Tim Lynch, Cheryl Adams Michael Sieg, Elizabeth Jensen, Sepi Soleimanpour and Ken Kenyon.

Ken Kenyon asked for a list of common complaints. The Commissioners were asked to send FAQs below and over threshold be sent to Marlee to also assist the workgroup.

MOTION: Ken Kenyon moved that the Commission accept recommendations from staff and initiate work on the disciplinary action. Judy Guenther seconded. MOTION CARRIED: 11-0.

Correspondence
The Commission reviewed/discussed correspondence received or distributed on its behalf:

a. 1-2018 NACDS 2688 and 2689 support letter
b. PQAC Correspondence Cover Memo Feb2018
c. Flu Vaccine Recommendation
d. HSQA@AGlance infographic2017
e. Ltr+to+Wholesalers+on+PIT
f. MEMO - EO - NABP Social Media
g. NABP MEMO – PARE
h. NABP MEMO 2017 Task Force Reports
i. The January 2018 PQAC Newsletter
j. Vaccine Announcement

Sub-Committee and Commissioner Reports

HB 1427
Kat Wolf-Khachatourian shared that as of the December meeting a draft rule is circulating. The main concern from the Commission is around the very explicit prescribing for chronic pain and prescriptions, this concern was considered the draft was received late last week.

Technician Ratio Rules
Rules Coordinator, Tracy West the sub-committee met in January with a good amount of outside interest and support. The sub-committee asked the Commission for review and
approval for the language to change the standard ratio set in rule and for authorization to submit a CR-102.

**MOTION:** Sepi Soleimanpour moved that the Commission remove the pharmacist to technician ratio set in rule and to “have the ratio set by the responsible pharmacy manager, and require the RPM to ensure the number of technicians to be satisfactorily supervised” and to authorize staff to file a CR-102. Judy Guenther seconded. Elizabeth Jensen opposed. **MOTION CARRIED: 10-1.**

**MOTION:** Ken Kenyon moved that exception requests for the pharmacist to technician rule that come to the Commission in the interim be put in the Consent Agenda for review and approval while this rule work is being done. Steve Anderson seconded. Elizabeth Jensen opposed. **MOTION CARRIED: 10-1.**

**MOTION:** Michael Sieg moved that the Commission not ask the pharmacist to technician ratio pilots come back to the Commission to provide updated reports. Steve Anderson seconded. Tim Lynch recused and Elizabeth Jensen abstained. **MOTION CARRIED: 9-0.**

**Technology Guidelines**
Sepei Soleimanpour reported that the sub-committee spent time reviewing existing documents there is a certain common area in the process of crafting the document that will only be temporary until the rules are updated.

**Standard Compounding**
Rules Coordinator, Tracy West and AAG, Chris Gerard presented the amended policy statement that was initially approved in October 2017. After, the October approval staff was asked to follow DOH’s internal review in order to file the policy statement with the Office of the Code Reviser. Staff received comments back from DOH staff and from L&I regarding the policy statement and stating pharmacies that are compliant with USP 797 and 800 will be compliant with L&I hazardous drug rules. AAG Christopher Gerard crafted additional language to be included in the policy statement to reflect this information from L&I.

**MOTION:** Ken Kenyon moved that the Commission accept the purposed policy statement and authorize staff to submit the policy statement to DOH for approval to file with the Code Reviser. Judy Guenther seconded. **MOTION CARRIED: 11-0.**

**Open Forum**
- *Rich Molitor* shared that he continues to be concerned with DSHS and one of his LTC clients. The client was told by DSHS employee that they needed to set up a med room in their corporate office or the pharmacy to deliver med to so they can compare their medication to MAR and go off and deliver these with their own staff, this seems to violate several statutes.
• Jackson DeLong shared that the DEA will be sending out a lot of DEA agents to inspect practitioners and pharmacies due to the Opioid overprescribing. This is not because of CMS reporting.

Requests

Study Plan Proposal
Panel C that included Sepi Soleimanpour, Uyen Thorstensen, Cheryl Adams were asked to review and consider a study plan proposed by Kavitha Naidu PharmD requesting authorization to retake the North American Pharmacist Licensure Examination (NAPLEX).

Study Plan Proposal
Panel C that included Sepi Soleimanpour, Uyen Thorstensen, Cheryl Adams were asked to review and consider study plans proposed by Helen Do and April Bills requesting authorization to retake the North American Pharmacist Licensure Examination (NAPLEX).

Study Plan Proposal
Panel C that included Sepi Soleimanpour, Uyen Thorstensen, Cheryl Adams were asked to review and consider study plans proposed by Jade Hass and Tuan Trinh requesting authorization to retake the Multistate Pharmacy Jurisprudence Examination (MPJE).

*Panel C authorized the study plans proposed from all of the students and authorized them to all be able to re-take the exams.

Request for List and Labels
Panel C that included Sepi Soleimanpour, Uyen Thorstensen, Cheryl Adams were asked to review and consider for recognition as an educational organization from the Yakima Extension Pharmacotherapy Department, Washington State University, College of Pharmacy; therefore granting access to contact lists of pharmacists with preceptor certification. (Lists and Labels).

*Panel C authorized the request from the Yakima Extension Pharmacotherapy Department, Washington State University, College of Pharmacy to be recognized as an educational organization.

**Sepi Soleimanpour dismissed

Executive Director
Steve Saxe reported:
• Steve Saxe spoke to the report given to the Commission in the meeting material regarding staff updates. This report included the investigators data. He also mentioned the USP memo that’s in the report.

Attorney General
Chris Gerard reported:
• He has prepared memos on: third party logistic providers, memo on legend drugs and self-serving dispensing devices,
• Worked with the technology sub-committee and worked on their guidelines
• Provided an analysis on Compounding sub-committee
• Participating in legislating calls
• Working closely with Tracy West on the USP policies
• At this point Chris will be working with Tracy West and Doreen Beebe on the General licensing rules
• He tracked all the assignments from this meeting as well
• Chris asked for clarification on how the Commission would like the AGG’s advice going forward for AAG, Eric Sonju and himself in the future. The Commission asked that they be copied on communications going forward.
• He clarified that budget was not discussed during Executive Session during the meeting on February 1, 2018.

Program Manager

Doreen Beebe reported:
• She reminded the Commission and staff that newsletter articles are coming due.

Commission Open Discussion

Ken Kenyon asked for some clarification regarding medication history. Is there a WAC or something that states a pharmacy cannot send a patience medication history to a technician?
It was discussed that Ken Kenyon and staff will draft a communication for the newsletter clearing this up, stating that a technician can receive this information and any details of compliance related.
Ken Kenyon also shared an inquiry that came to him regarding a CDTA, Does a pharmacist have to have their own DEA Number to be able to practice under a CDTA at a hospital. He shared that two organizations that he knows of are cancelling their CDTA’s because of this concern. Tim Lynch asked AAG, Chris Gerard to look into this while he works on his assignments regarding CDTA’s.

Action Item
Tim Lynch went through the assignments that were given during the meeting to clarify what was assigned and make sure nothing was missed.

There being no further business, the board adjourned at 2:46 p.m.

Respectfully Submitted by:

Leann George, Program Support