CONVENE

Chair, Tim Lynch called the meeting to order April 27, 2018 at 9:11 am.

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

Absent Commission Member:
Arun Sambataro, Public Member
Matthew Ronayne, RPh
Olgy Diaz, Public Member
Michael Sieg, PharmD
Teri Ferreira, RPh

Staff:
Eric Sonju, AAG
Christopher Gerard, AAG
Steven Saxe, Executive Director
Tracy West, Deputy Director
Doreen Beebe, Program Manager
Leann George, Secretary Senior
Gordon MacDonald, Supervising Pharmacist Investigator
Marlee O’Neill, Deputy Director OLS
Angelica Pauley, Pharmacist Consultant
Brad Dykstra, Pharmacist Investigator
Call to Order

1.1 Business Meeting Agenda

MOTION: Jerrie Allard moved that the Budget Sub-Committee discussion be moved to section 4. Legislation, Program, and Department Updates, and add 4.3 for legislative update, on the agenda. Ken Kenyon seconded. **MOTION CARRIED: 10-0.**

1.2 Meeting Minutes – March 15, 2018

MOTION: Cheryl Adams moved to approve the March 15, 2018 Meeting Minutes with the correction of Matthew Ronayne was in attendance. Steve Anderson seconded. **MOTION CARRIED: 10-0.**

1.3 Meeting Minutes – March 16, 2018

MOTION: Cheryl Adams moved to approve the March 16, 2018 Meeting Minutes with the correction of Matthew Ronayne was in attendance. Steve Anderson seconded. **MOTION CARRIED: 10-0**

Consent Agenda

2.1 National Precursor Log Exchange Monthly report – February 2018

2.2 New and Closed Pharmaceutical Firms Application Report Approval
   • March 1 – April, 2018

2.3 Ancillary Utilization Plans Approval (may include Specialized Functions)
   a) Edmonds Pharmacy Stevens Health Center
   b) Jail Health RJC
   c) Lakewood Pharmacy
   d) Medicine Mart Westside
   e) NW Hospital Pharmacy
   f) NW Medication Management Services
   g) Othello Station Pharmacy
   h) RX Pharmacy LTC
   i) Genoa Healthcare

2.4 Pharmacy Technician Training Programs Approval
   a) Genoa Healthcare

2.5 Pharmacy Technician Ratio Exemption Approval
   a) Kaiser Permanente, Northwest Region

2.6 Electronic Prescription Transmission System Approval
   a) CVS Caremark – RxConnect
   b) Epic – EpicCare
   c) GE Healthcare – Centricity EMR
   d) GE Healthcare – Centricity Practice Solutions
   e) Senderra Rx Partners, LLC
   f) Softwriters, Inc – Framework LTC
   g) Surescripts
MOTION: Elizabeth Jensen moved that the Commission approve all consent agenda items except 2.3 (i), 2.5 (a), and 2.6 (b). Steve Anderson seconded. MOTION CARRIED: 10-0.

Old Business

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

Completed.

- Guidelines / Pharmacy Practice Document – The Sub-Committee held a public stakeholder meeting April 9. They will review or develop technology and service guidance for the Commission to consider.
- Tech Ratio Exemption – FAQ’s were developed and posted to the “What’s New” webpage with direction for licensees wishing to request an exemption while rules are underway.
- Pharmacist as a Prescriber under Collaborative Drug Therapy Agreement (CDTA) – This has two components; Who/how are prescriptions signed under a CDTA and Challenges around payment for prescriptions prescribed under a CDTA. The AGO has provided advise to the Commission for the Commission to move forward on this discussion.
- Budget / Fee Subcommittee – The subcommittee have met and continue to review details of the PQAC revenue and expenses.
- Review misfill grid, and NCQAC chart with enforcement subcommittee and review with Commission in April. To be presented by Marlee O’Neil for review and approval.
- PQAC Letter to HB 1427 Opioid Prescribing Boards and Commission on importance of diagnosis information will be presented later in the meeting for Commission review and approval.
- PQAC inspection philosophy memo, distribute to OII and post on inspections webpage. Memo has been distributed to OII and pharmacy investigators, request has been made to have memo added to the webpage.
- Compounding versus Reconstitution – Staff is working with the advising AAG team on a legal review. This will be used for a discussion/decision at the April meeting.

In-Process

- Controlled Substances Wastage – This is related to WAC 246-873-080(7)(e) that requires a quarterly report of all facility drug wastage be submitted to the DEA and a copy of the report to the Pharmacy Commission. The guidance has been drafted, anticipate sending to OII staff week of April 16th.
- Medical Commission discussion with Pharmacy Commission related to standard of care enforcement. Looking at having MQAC ED at the professional standards rulemaking discussion.
- Student Enrollment Definition – Staff will have this article for the July newsletter.
- Medication history article for future newsletter. Ken Kenyon to work with staff to provide details for article which will likely be in the July newsletter.

Pending Action
• Commissioners meeting with legislators, will work with DOH Government Affairs staff.
• Work/strategize with DOH policy units on potential legislative proposals
• USP 797 training/educational draft – investigators were to develop a CE that focused on what is seen in the field, Commission asked for status – will address at a later date.

3.2 Board of Optometry Rulemaking regarding adjuvant analgesics
Deputy Director, Tracy West led the discussion providing some background on the initial request from the Board of Optometry. At the Oct 27, 2017 business meeting the Board of Optometry requested clarification from the Commission on whether gabapentin and pregabalin could be considered “analgesics” under their drug list in WAC 246-851-580(j) for use in treating post-herpetic neuralgia and Zoster ophthalmicus. The Commission suggested they go through the rulemaking process to add these drugs to their drug list. The Board of Optometry filed the CR-101 and are now requesting that the Commission review and suggest draft language. Loralei Walker, Program Manager and William Prothero, Optometry Board Member discussed this language with the Commissioners’ collaborating on final draft rule language.

MOTION: Elizabeth Jensen moved that the Commission approve amended language to the Board of Optometry’s desired changes to the Board’s drug list in WAC 246-851-580. The Board added adjuvant analgesics to WAC 246-851-580 and the Commission suggested the Board change WAC 246-851-590(9) to reflect the drug list in WAC 246-851-580 will be consistent with FDA on and off label indications. Ken Kenyon seconded. MOTION CARRIED: 10-0.

3.3 Update on implementation/communication of new pharmacy inspection rules
Deputy Director, Tracy West updated the Commission on outcome to date of the New Inspection process. During the month of March staff received a number of calls most of them related to WAC interpretations. Tracy and Pharmacist Consultant, Lisa Roberts were the key responders to the inquiries to keep all answers consistent. Staff asked for guidance and possible changes to the forms to improve the form and support stakeholders and investigators with these issues during inspections.

The Commission discussed several non-significant items in the current rule that will likely be eliminated in a rule re-write. Examples included Question 32, information on the face of the prescription, or question 40 regarding a prescription mail slot. The Commission does not want to force changes to address obsolete standards unless there is clear risk of patient harm. The self-inspection form is color coded to clearly identify what the Commission wants the investigators to focus on during inspections.

The investigators asked the Commission to provide guidance on how to address these items on inspection during the interim while the Rules Re-Write Project is in process. The Commission weighed the resources to draft a policies versus work on the Rules Re-Write Project.
Top four inquiries:

1. **Auxiliary Recordkeeping requirement:** there should be a procedure in place for
downtime with the intention that patients care is not compromised.

2. **Information required on the face of a prescriptions:**

The Commission continued discussing several options on how to provide support to the
stakeholders and investigators with these issues.

**MOTION:** Cheryl Adams moved that the Commission staff begin an inspection guideline
and add to the guideline based on questions brought to the Commission. The first to be
added in terms of WAC 246-869-100(2) information required on a prescription is readily
available with example being either electronically or back or front of the prescription.
Steve Anderson seconded. **MOTION CARRIED: 10-0.**

3. **Mail slot/drop box:**

Ken Kenyon moved that the Commission add this to the guideline list. In terms of WAC
246-869-020(3), the Commission will not requires mail slots or drop box and if there is one
in the pharmacy it must be secured but does not need to be relocated since this WAC will
be updated. The Commission recognizes many of its rules are dated and with current Rules
Re-Write in progress this WAC is seen as an extremely low enforcement priority. Sepi
Soleimanpour seconded. The Commission continued the discussion, the motion died.

The Commission chose to make the self-inspection form a living document at this point. It
will be amended during each meeting after review and discussion of each inquiry brought
forward. Guidance will be provided for staff if there is a low priority item that comes up
during an inspection. It can be put in the plan of correction and the Commission will go
through the process.

**MOTION:** Ken Kenyon moved that the Commission continue with the FAQ/guideline
living document identifying current WACs that the Commission considers significantly
outdated and a very low enforcement priority the Commission doesn’t have the resources
allocated to take enforcement action. The Commission will pause Nuclear, Hospital, and
Long Term Care inspections until the inspection forms are revised. Steve Anderson
seconded. **MOTION CARRIED: 10-0.**

3.5 **Joint Operating Agreement**
Chair Tim Lynch touched on the background and process that has been done to develop
this Joint Operating Agreement. He and Vice Chair, Cheryl Adams presented the final draft
and asked their fellow Commissioners for their feedback and approval.

**MOTION:** Steve Anderson moved that the Commission accept the Joint Operating
Agreement as written. Judy Guenther seconded. **MOTION CARRIED: 10-0.**
5.2 Sub-Committee Reports

b) Finance
Commissioner, Ken Kenyon led the update for the Budget Sub-Committee. The Department has not raised pharmacy related fees on a number of licenses since 2005. Before recommending a fee increase the sub-committee is working to understand the budget and expenses of PQAC to raise fees appropriately.

The sub-committee has started a deep dive of looking into details of PQAC revenues and expenses. Ken presented the data from the information they have received. They are identifying a list of actions that could cause a positive effect on the budget immediately. They Subcommittee and Commission expect to be fully educated before they make any decisions on recommendations to the Secretary.

The Budget Sub-Committee would like to have a special meeting in May to present a proposal to the full Commission.

The Budget Sub-Committee asked that this committee be memorialized as an ongoing committee. The Budget Sub-Committee will be an ongoing committee that continues to look at the budget on a quarterly basis. The subcommittee will also evaluate commission policies or other decisions for fiscal impact.

3.4 Discussion on Compounding Standards

Enforcement of compounding standards
The Commission is considering repealing WAC 246-871-030(2)(c) and 246-871-080(1)(d) entirely during the Rules Re-Write Project. However, the sterile compounding committee wants to do something in the interim. AAG, Christopher Gerard provided the Commission with some guidance and recommended a policy statement.

**MOTION**: Cheryl Adams moved that staff work with AAG to develop a policy statement by the May special meeting stating the Commission will not enforce WAC 246-871-030(2)(c) and 246-871-080(1)(d). Ken Kenyon seconded. **MOTION CARRIED: 10-0.**

Simple compounding v. reconstitution
AAG, Christopher Gerard provided the Commissioners written guidance on non-sterile compounding and USP 795 regarding the different standards. He opened up the floor for the Commissioners to ask questions.

If a pharmacy engages in simple compounding you do need to use the USP 795 self-inspection check list. There will be a stakeholder meeting scheduled in June or July.

**MOTION**: Cheryl Adams moved that PQAC staff and AGG work on a guidance documents that provides guidance for licensees and staff with regard to USP 795. The Commission will make the document provided by Christopher Gerard an unprivileged document that can be shared with the public. Judy Guenther seconded. **MOTION CARRIED: 10-0.**
4. Legislation, Program, and Department Updates

4.1 Opioid Prescribing Rules (ESHB 1427-2017), Letter to Boards and Commissions
Executive Director, Steve Saxe presented a letter that was drafted for the commission to address Commissions concerns that the requirement for a diagnosis, indication of use or ICD code was excluded on the draft opioid prescribing rules. The Commission asked to include a reference to identify the pharmacist as a being part of the healthcare team. It was suggested that Commissioners attend rule meetings to represent PQAC.

MOTION: Elizabeth Jensen moved that the Commission approve the letter with changes proposed to support the Commission’s concerns on the draft ESHB 1427 rules. Kat Wolf-Khachatourian seconded. MOTION CARRIED: 10-0.

4.2 Opioid Overdose Reversal Medication Distribution from Emergency Department
Executive Director, Steve Saxe and PQAC staff worked with AAG, Eric Sonju to update the policy for Opioid Overdose Reversal Medication Distribution from Emergency Department. The updates were to address concerns with some of the language in the original policy adopted January 2018. The reference to a federal law had an unintended consequences of decreasing the distribution of Naloxone for opioid overdose reversal. Further the statement was included that the policy also aligned well with recent CDC guidelines and the Surgeon General directive that encourages broad distribution of naloxone to people at risk of overdose or people in a position to assist a person overdosing.

MOTION: Cheryl Adams moved that the Commission approve the updated policy with changes stating the Commission’s policy is in alignment with recent federal guidance. Steve Anderson seconded. MOTION CARRIED: 10-0.

4.3 Legislative Update
Executive Director, Steve Saxe updated the commission on the request legislation for 2019. This “omnibus” request legislation includes many of the changes identified during the Rules-Re-Write work to date. It also includes the three request bills from last year. These three, elimination of Commission approval of e-prescribing systems, requiring inspection reports of non-resident pharmacies from approved entities, and updating the enforcement process for pharmacy related firms is the packet of request legislation is now with department for consideration and prioritization with the Governor’s legislative priorities.

5. Rules, Sub-Committee and Commissioner Reports

5.1 Hospital Pharmacy Associated Clinics Emergency Rule Revisions
Deputy Director, Tracy West reviewed the discussion from the March meeting. The Commission was asked to consider renewing the existing emergency rules, Chapter 246-873A WAC entitled Hospital Pharmacy Associated Clinics (HPACs). Reviewing the definitions around compounding and reconstitution have led to a discussion on which definition of compounding needed to be used in the HPAC emergency rules. Updates to the
language need to be filed with the code revisers office to keep an emergency rule in place while permanent rulemaking is underway as required by law.

After further discussion the Commission asked that staff work with AAG, Christopher Gerard hold a stakeholder meeting and then draft a statement and provide guidance.

*Elizabeth Jensen was dismissed*

5.2 Sub-Committee Reports

a) Technology
Sepi Soleimanpour updated the Commission that the technology committee had a stakeholder meeting April 9 and has received input from stakeholders. They are close to having a document ready to present to the Commission for review and approval. They would like to have another stakeholder meeting. All comments should be forwarded to Pharmacist Consultant, Angelica Pauley who is lead staff on the committee.

b) Enforcement Efficiencies
Office of Legal Services Deputy Director, Marlee O’Neill worked with a Commission subcommittee and revised the misfill grid and presented it for review and approval. She clarified that this is just a guide to assist in efficient disciplinary decisions. The Commission went through and there were some suggested changes made to the document.

MOTION: Sepi Soleimanpour moved that the Commission approve the misfill grid with changes. Cheryl Adams seconded. **MOTION CARRIED: 10-0.**

5.4 Commissioners’ Open Discussion
Cheryl Adams discussed:
- Proposed that Deputy Director attend the ASHP Conference in Anaheim, CA.
- Asked what should be done about the remote supervision pilot projects required to come back to the Commission. Deputy Director, Tracy West found the motions made in August last year. These pilot projects do not need to come back to the Commission however, they must be compliant to all the rules and statutes.
- Inquired about the requirements to be a Pro Tems. Who makes the decision? Is the Commission involved in this decision? Executive Director, Steve Saxe responded that a Pro Tem does not have to be a former Commission member. However former members **have a better understanding of the work done by the Commission.** Cheryl proposed due to the fact that former members are no longer attending our meetings and don’t know our direction it should be an option to make it open to others such as those that attend our meetings. Deputy Director, Tracy West offered to look into this.

6. New Business

6.3 Consent Agenda Items Pulled
2.3 (i) Genoa Healthcare
This item was pulled because Elizabeth Jensen had questions. She is not here.

**MOTION:** Sepi Soleimanpour moved that the Commission approve Consent Agenda Item 2.3 (i) Genoa Healthcare’s AUP that was submitted. Ken Kenyon seconded. **MOTION CARRIED: 9-0.**

2.5 (a) Kaiser Permanente - Northwest Region

This was pulled because there was question around this being a call center. The Commissioner wanted clarity. This is a call center and it is located in Oregon. It is assisting their Washington pharmacies on answering calls.

**MOTION:** Ken Kenyon moved that the Commission approve Consent Agenda Item 2.5 (a) Kaiser Permanente – Northwest Region that was submitted. Steve Anderson seconded. **MOTION CARRIED: 9-0.**

c) 2.6 (a) Epic – EpicCare

This was pulled because Elizabeth Jensen and Tim Lynch have to recuse themselves.

**MOTION:** Steve Anderson moved that the Commission approve Consent Agenda Item 2.6 (b) Epic – EpicCare that was submitted. Judy Guenther seconded. Tim Lynch recused himself. Elizabeth Jensen was dismissed early. **MOTION CARRIED: 8-0.**

**6.1 NABP 114th Annual Meeting May 5 - 8, 2018 in Denver CO**

- Commission will discuss final preferences on proposed resolutions

The Commission was asked if they had any more input to provide Chair, Tim Lynch who is the voting delegate at the NABP Annual Meeting.

- Changes to Constitution and Bylaws
  The Commission didn’t have any further changes to provide to Chair, Tim Lynch.

**6.1.1 Post-Verification of Prescriptions Filled by Robotics and Automation**

Deputy Director, Tracy West led this discussion sharing with the Commission that there are quite a few inquiries about these types of robotics and staff is looking for guidance from the Commission.

It is hard to contemplate the type of technology being utilized. The responsible pharmacy manager and pharmacists are responsible for the accuracy of the prescription and all appropriate steps are taken to ensure patient care and safety. The Commission made it very clear there must be verification in the process of dispensing prescriptions but left it up to the responsible manager and pharmacist on duty as to the process for this to be addressed.
**MOTION:** Ken Kenyon moved that there has to be verification to ensure the correct product labeling, drug integrity, etc. There is not specific language that states how, when, or where in the dispensing process the verification occurs. Steve Anderson seconded. **MOTION CARRIED: 9-0.**

### 6.2 Correspondence
The Commission reviewed/discussed correspondence received or distributed on its behalf.
- CriticalPoint Peer Network for Inspectors
- Recognition Resolutions
- CDC Vital Signs
- Surgeon General’s Advisory on Naloxone and Opioid Overdose
- Doctor Shopping Email
- Working Conditions

### 6.4 Sanford Broadway Pharmacy for exemption from licensure under RCW 18.64.360
Sanford Broadway Pharmacy is requesting to dispense a one-time 30 day dose of Xolair to a patient that is relocating to Washington State. The request is due to insurance/billing issues. A Pharmacy located in Fargo, North Dakota is requesting that the Commission grant an exemption from requiring a non-resident pharmacy licensure for an isolated transaction.

**MOTION:** Steve Anderson moved to approve and allow Sanford Broadway Pharmacy dispense a one-time 30 day dose of Xolair to a patient that is relocating to Washington State. Sepi Soleimanpour seconded. Judy Guenther, Kat Wolf-Khachatourian, Jerrie Allard, Uyen Thorstensen abstained. **MOTION CARRIED: 5-0.**

**Steve Anderson was dismissed**

### Open Forum
*Julie Akers* thanked the budget subcommittee for looking at the detailed expenses. She suggested that the Commission look at the Medical, Nursing and Chiropractic Commissions’ pilot reports to see how they saved money.

*Pamela Hansen* thanked the Commission for their service. She stated there is a tremendous amount of experience and the Commission does very important work. She thanked the Commission again for the work they do and asked that they keep all pharmacists safe.

### 7. Requests
Panel B Tim Lynch, Ken Kenyon Kat Wolf-Khachatourian

#### 7.1 Review and consider for approval a study plan to retake the Multi-state Pharmacist Jurisprudence Examination (MPJE) 6th Attempt.

Ken Kenyon strongly suggested that Minju Lee contact both Julie Akers and Jenny Arnolds regarding the law review sessions they are hosting.
*S Minju Lee was given authorization to re-take the MPJE

7.2 Routine review and consider for approval a study plan to retake the Multi-state Pharmacist Jurisprudence Examination (MPJE) 4th Attempt.

*Vasudevroy Bhuvanagiri was given authorization to re-take the MPJE.

8. Staff Reports

Executive Director

Steve Saxe reported:
• Steve Saxe was contacted by APHA regarding CDTA’s and vaccines
• Work has begun on HB 1047 Drug Take Back
• There was a Washington Opioid response meeting

Deputy Director

Tracy West reported:
• She and Steve met with the Labor and Industries (LNI) Hazardous Medication Advisory Committee. Tracy is working with LNI staff to draft a joint message about compliance with LNI hazardous medication rules if compliant with USP 800

There being no further business, the board adjourned at 4:18 p.m.

Respectfully Submitted by:

Leann George, Program Support
Approved June 8, 2018

Tim Lynch, Chair
Washington State Pharmacy Quality Assurance Commission