CONVENE

Chair, Tim Lynch called the meeting to order June 8, 2018 at 9:07 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
Teri Ferreira, RPh
Michael Sieg, PharmD
Matthew Ronayne, RPh

Absent Commission Member:
Arun Sambataro, Public Member
Olgy Diaz, Public Member

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
Lisa Roberts, Pharmacist Consultant
Call to Order

1.1 Business Meeting Agenda

MOTION: Steve Anderson moved to approve the June 7, 2018 Meeting Agenda. Judy Guenther seconded. MOTION CARRIED: 12-0.

1.2 Meeting Minutes – April 26, 2018

MOTION: Steve Anderson moved to approve the April 26, 2018 Meeting Minutes. Teri Ferreira seconded. MOTION CARRIED: 12-0.

1.3 Meeting Minutes – April 27, 2018

MOTION: Steve Anderson moved to approve the April 27, 2018 Meeting Minutes. Judy Guenther seconded. MOTION CARRIED: 12-0

Consent Agenda

2.1 National Precursor Log Exchange Monthly report – April 2018

2.2 New and Closed Pharmaceutical Firms Application Report Approval

- April 6 2018 through May 21, 2018

2.3 Ancillary Utilization Plans Approval (may include Specialized Functions)
   a) Edmonds Pharmacy
   b) Forks Community Hospital Pharmacy
   c) Geneva Woods Pharmacy
   d) Kaiser Permanente
   e) Markers Compounding Pharmacy
   f) Malleys Compounding Pharmacy
   g) Mercury Pharmacy Services, Inc.
   h) Multicare Health System – w/Specialized Functions
   i) Premier Long Term Care Pharmacy
   j) UW Medicine South Lake Union Pharmacy
   k) Valley View Health Center
   l) Lourdes Medical Center Inpatient Pharmacy
   m) Lourdes Counseling Center Pharmacy
   n) Lourdes West Pasco Pharmacy
   o) Skagit Valley Hospital – Medication Reconciliation

2.4 Pharmacy Technician Training Programs Approval
   a) Care Rx LLC
   b) CHAS
   c) Edmonds Community College
   d) North Idaho College and Lewis Clark State College
   e) North Seattle College
   f) Seattle Indian Health

2.5 Pharmacy Technician Ratio Exemption Approval
   a) Consonus Health
   b) Propac Payless Pharmacy
c) QFC Pharmacies

2.6 Electronic Prescription Transmission System Approval
   a) Tri-Essence Care

2.7 Electronic Prescription Paper/Pad Approval
   a) Computer-Rx - WinRx

**MOTION:** Teri Ferreira moved that the Commission approve consent agenda items 2.1, 2.2, 2.3 (a-o), 2.4 (a, b, c, d, f), 2.6 (a), and 2.7 (a) and pull Items 2.4 (e), 2.5 (a), (b), and (c) for further discussion. Steve Anderson seconded. **MOTION CARRIED: 12-0.**

### 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 worked with Angelica Pauley, and Lisa Roberts, Pharmacist Consultants. There was a public stakeholder meeting May 29.
- ✓ Budget / Fee Sub-committee – The sub-committee continue to meet and will be moved to a standing report under sub-committees.
- ✓ Pharmacist as a Prescriber under Collaborative Drug Therapy Agreement (CDTA) – The commission clarified that a prescription written under a CDTA should be signed by the pharmacist with prescriptive authority. This is different than hospital protocols that the prescriber reviews and signs, even retrospectively.
- ✓ Case Manager will include copies of enforcement guidelines, grids and closure codes with each agenda distribution.
- ✓ PQAC Letter to HB 1427 Opioid Prescribing Boards and Commission on importance of diagnosis information was sent to Chairs and Executive Directors.
- ✓ PQAC inspection philosophy memo was distributed to OII and posted on inspections webpage.
- ✓ The response for questions regarding OTC vending machines and registration as a shopkeeper was sent out. Doreen Beebe worked with Department of Revenue to update their webpage.

#### In-Process
- • Compounding versus Reconstitution – AAG guidance provided and discussed at April meeting. Guidance document for discuss on June agenda.
- • Notice to Inspections Webpage to check junk mail for PQAC messages. Working with DOH Web staff to identify best option.
- • Controlled Substances Wastage – Reference to WAC 246-873-080 (7)(e) that requires policies and procedures and a quarterly report of all facility drug wastage be submitted to the Pharmacy Commission was removed from the self-inspection form. An FAQ was drafted and is presented for review and approval. A message was sent to the hospital survey team regarding these clarifications. Staff working to verify
this information and determine if further guidance to the licensees and facility inspection staff is necessary. This will also inform the rule re-write project.

- Medical Commission discussion with Pharmacy Commission related to standard of care enforcement. Pharmacy Executive Director will work with the Medical Commission Executive Director to schedule time at a future meeting. Looking at having MQAC ED at the professional standards rulemaking discussion.
- Student Enrollment Definition – Staff will prepare an article for the July newsletter.
- Staff will work with Elizabeth Jensen and Kat Khachatourian on the second opioid dispensing article covering red flags and best practices.
- Medication history article for future newsletter. Ken Kenyon to work with staff to provide details for article.
- Review misfill grid, and NQAC chart with enforcement subcommittee and review with Commission in April. Marlee has met with the subcommittee and has updated documents under Subcommittee Reports. There is still some outstanding work to be done.

*Ken Kenyon arrived*

### 3.2 Continuation on declaring Gabapentin – a Drug of Concern

Pharmacist Consultant, Angelica Pauley provided the Commission some background regarding the request on declaring Gabapentin a drug of concern. At the December 15, 2017 Pharmacy Commission business meeting, the Prescription Monitoring Program (PMP) asked to add Gabapentin as a drug of concern under WAC 246-470-020. At that meeting, PMP Operations Manager, Gary Garrety gave the Commission background information about diversion and misuse associated with Gabapentin. The Commission’s motion, in December 2017, was for the PMP to request input from other health professional boards and commissions (medical, nursing, podiatry, osteopathy, dental) about adding Gabapentin as a drug of concern/controlled substance; and for the PMP to coordinate and organize a meeting with stakeholders. In addition to the five boards and commissions listed in the motion, PMP extended the opportunity for providing input to the Veterinary Board of Governors.

Chris Baumgartner, DOH Drug Systems Director, provided an update to the Commission from the Prescription Monitoring Program (PMP) based on information received from other boards and commissions related to adding Gabapentin as a drug of concern in the PMP. Chris answered questions and concerns from the Commission.

The Dental Quality Assurance Commission; Osteopathic Board; Podiatric Medical Board; and the Nursing Quality Assurance Commission are in support of adding Gabapentin as a drug of concern.

Commissioners expressed concern on the burden of pharmacist to have to track Gabapentin since electronic prescription systems would not recognize a drug of concern the same as controlled substances. Commissioners asked if there would be a financial burden to pharmacies and asked the PMP to look into this question as they proceed with rulemaking. The Commission requested the PMP engage in a robust stakeholder process and bring concerns, feedback, and potential impacts on pharmacies back to the Commission.
MOTION: Steve Anderson moved that the Commission make Gabapentin a drug of concern and allow the Department of Health, Prescription Monitoring Program start engaging in rulemaking. Jerrie Allard seconded. **MOTION CARRIED: 13-0.**

### 3.3 Inspection Process Implementation

a) Review and discuss recommendations for patient safety categories on inspection worksheets

Deputy Director, Tracy West asked the Commission to review and provide feedback on the updated self-inspection worksheets. Along with identifying patient safety focus questions, the subcommittee is recommending other editorial changes on the hospital and long-term care worksheets.

Only one worksheet, the General Self-Inspection Worksheet that is used by all pharmacies had patient safety questions highlighted. The changes make clear what information is needed during a self-inspection audit of records. Deputy Director, Tracy West asked the commission to make some adjustments to the audit pages of the worksheet to adequately reflect what was being asked. Licensees had expressed confusion regarding the audit pages because the columns did not reflect what was being asked.

The Inspection Subcommittee met on Monday, May 14th, 2018 to review and discuss the remainder of the worksheets to identify patient safety focus questions. The subcommittee made recommendations on:

1. Hospital/HPAC Self-Inspection Worksheet
2. Long-term Care Self-Inspection Worksheet; and
3. Nuclear Pharmacy Self-Inspection Worksheet

MOTION: Ken Kenyon moved that the Commission approve the hospital/HPAC self-inspection addendum with suggested edits and highlights. Steve Anderson seconded. **MOTION CARRIED: 13-0.**

MOTION: Teri Ferreira moved that the Commission approve the Long-Term Care self-inspection addendum with suggested edits and highlights. Ken Kenyon seconded. **MOTION CARRIED: 13-0.**

MOTION: Steve Anderson moved that the Commission approve the Nuclear Pharmacist self-inspection addendum with suggested edits and highlights. Ken Kenyon seconded. **MOTION CARRIED: 13-0.**

MOTION: Ken Kenyon moved that the Commission approve the General self-inspection addendum with suggested edits and highlights. Steve Anderson seconded. **MOTION CARRIED: 13-0.**

The subcommittee recommended the Compounding Sub-committee review the inspection
worksheets related to USP 795 and USP 797 for their expertise in identifying patient safety questions/statements.

**MOTION:** Ken Kenyon moved that the Commission request that the Compounding Sub-Committee review the USP 797 and USP 795 self-inspections worksheets. Steve Anderson seconded. **MOTION CARRIED: 13-0.**

b) Review and discuss directive from Commission regarding the use of photographs and videos in pharmacy inspections and investigations.

There were some inquiries on the use of photographs and videos during routine inspection. Staff worked with Chair, Vice-Chair to develop a directive to OII pharmacist investigators. The intent of the directive is to describe the practices the Commission wants the pharmacist investigators to use. The Commission wants to emphasize that the use of photographs and videos should be rare in a routine pharmacy inspections, and should be used only to document extraordinary deficiencies.

**MOTION:** Ken Kenyon moved that the Commission adopt the directive on the use of photos and videos during investigations and inspections. Judy Guenther seconded. **MOTION CARRIED: 13-0.**

3.4 Frequently Asked Questions (FAQs)
Deputy Director, Tracy West went through the responses prepared by staff related to inquiries from self-inspections with the Commission asking them to review. These responses are posted to the web as Frequently Asked Questions. During the discussion there were a few changes to the verbiage regarding a question on transferring a prescription.

3.5 Compounding
    a) Discuss Commission directive regarding enforcement of WAC 246-871-030(2)(c) & WAC 246-871-080(1)(d).

During the December 15, 2018 business meeting the Commission moved to not enforce the two chapters 246-871 and 246-878 WAC, have staff write a policy to reflect this decision and asked AAG, Christopher Gerard do a further analysis on all sections before a policy statement is moved forward.

AAG, Christopher Gerard completed this analysis which concluded that a majority of the provisions did have equivalent standards in USP or other RCWs. The only chapter recommended to stay the same and remain in full effect was Chapter 246-903 WAC regarding nuclear pharmacy.

At the March 16, 2018 business meeting the Commission took action to have program staff and AAG, Christopher Gerard, move forward and draft policy statement or equivalent document to reflect its decision to not enforce two specific provisions of WAC that held higher standards than USP.
MOTION: Teri Ferreira moved that the Commission accept the directive as written and distribute through Health Systems Quality Assurance and to the investigators and post to the webpage. Steve Andersen seconded. MOTION CARRIED: 13-0.

b) Continued discussion and development of policy regarding USP 795 and simple compounding

Deputy Director, Tracy West presented a guidance document requested by the Commission at the last meeting. AAG, Christopher Gerard and Tracy West developed the document based on Christopher Gerard’s advice. He broke down simple compounding and how USP 797 works with non-sterile compounding. This document is to be a resource for stakeholders to have an understanding on the Commission’s position.

MOTION: Ken Kenyon moved that the Commission draft a memorandum to the legislature requesting consideration of changes in the definition of compounding RCW 18.64.270 (2) and 18.64.011 – discretion/authority by Commission to define in rule. Judy Guenther seconded. MOTION CARRIED: 13-0.

MOTION: Elizabeth Jensen moved that the Commission approve the guidance document. Judy Guenther seconded. MOTION CARRIED: 13-0.

3.6 Licensing for Virtual Wholesalers and Virtual Manufacturers
AAG, Christopher Gerard provided the Commission some background regarding regulatory/licensing authority for virtual wholesalers, and virtual manufacturers. Christopher was asked to do some research and put together some advice on the Commission’s authority to require licensure for these types of practices. He opened the floor up for questions.

MOTION: Ken Kenyon moved that the Commission require licensure for virtual wholesalers and manufacturers and incorporate rules in the current rule rewrite. During the interim period request staff to write an interpretive statement/interim guidance that licensure is required for Virtual Wholesalers and Virtual Manufacturers while the Rules Re-Write Project is underway. In addition require out of state virtual manufacturers and virtual wholesalers to be licensed as wholesalers in Washington under current rules. Judy Guenther seconded. MOTION CARRIED: 13-0.

4. Legislation, Program, and Department Updates

4.1 2019 Legislative Update
Executive Director, Steve Saxe updated the Commission on the request legislation for 2019. We continue to work with the Department to present requests to move forward. We will likely request to move the two requests from last year; requiring inspection reports of non-resident pharmacies from approved inspection entities, and removing the requirement for PQAC to approve electronic prescribing systems. The Pharmacy enforcement request and comprehensive update to the practice act will not move forward for the 2019 session.
Both of these proposals will require additional stakeholder work with a focus on the enforcement bill.

5. Rules, Sub-Committee and Commissioner Reports

5.1 Sub-Committee reports

a) Technology
Commissioner, Michael Sieg briefed the Commission on the work that was done to create the Technology and Services Guidelines. All stakeholder and Commission feedback was taken into consideration while drafting this document. The intent of this is to give stakeholder guidance on these services during the Rules Re-Write Project.

MOTION: Michael Sieg moved that the Commission approve the Technology and Services guideline document with changes proposed and deletion of the second bullet under remote supervision. Cheryl Adams seconded. MOTION CARRIED: 13-0.

5.2 Commission Reports

Matthew Ronayne reported:
- Attended the Northwest Pharmacy Convention
- Idaho rewritten more and more laws, attending legislative sessions
- Panel work

Elizabeth Jensen reported:
- Sub-committee work
- Panel work

Michael Sieg reported:
- Panel calls
- Technology subcommittee

Teri Ferreira reported:
- Northwest Pharmacy Convention
- Attended Alex Adam presentation in Idaho
- Panel work
Technology sub-committee

Sepi Soleimanpour reported:
- Sub-committee work
- Panel calls

Kat Wolf-Khachatourian reported:
- Pharmacy quality alliance
- National MTM Advisory
- Professional Practice Committee
- Sub-committees
- Panel calls

Cheryl Adams reported:
- Cheryl and Tim Lynch presented at the Health Systems Leadership meeting
- Panel calls
• Sub-committees
• Cheryl and Ken Kenyon did a webinar for Health System Academy for WSPA
• Pharmacy inspection

Ken Kenyon reported:
• Webinar with Cheryl for Health System Academy for WSPA
• Budget sub-committee meetings
• Panel calls

Jerrie Allard reported:
• Panel calls

Steve Anderson reported:
• Taught the MPJE Law review

Judy Guenther reported:
• Inspection Sub-committee
• Panel
• Budget sub-committee

Tim Lynch reported:
• Tim and Cheryl Adams presented at the Health Systems Leadership meeting
• Inspection sub-committee
• Attended the NABP Annual Meeting with Steve Saxe
• Worked with Kristin Peterson Assistant Secretary of Health planning the Investigator Meeting
• Panel Calls

5.3 Commissioners’ Open Discussion
• Commissioner, Elizabeth Jensen asked for clarification regarding an update from Steve Saxe, Executive Director. He had mentioned Elizabeth Jensen and Kat Wolf-Khachatourian working with staff on the second opioid dispensing article covering red flags and best practices questions. Steve said that there was a potential for staff to reach out about this.
• Commissioner, Ken Kenyon asked is it within the scope of practice for a pharmacy technician to be taking medication history or does it need to be clarified in an AUP. After further discussion it was agreed that that this just needs to be clarified with the licensees that this is NOT a specialized function but it does need to be in the AUP.
• Commissioner, Kat Wolf-Khachatourian made a suggestion if it was possible to look into receiving information for disciplinary case via box.com as a cost savings. Staff will look in to this more for further discussion.
• Chair, Tim Lynch started the discussion regarding Pro-Tems. Deputy Director, Tracy West and Executive Director, Steve Saxe would like to have a general approach and asked the Commission for any suggestions. There was discussion on the types of cases, and work they do. It was suggested that broader Commission involvement occur in the selection process.
6. New Business

6.1 The Veterinary Board of Governors (VBOG)
Pharmacist Consultant, Angelica Pauley introduced Program Manager for VBOG, Loralei Walker and Deputy Director for Office of Health Professions, Kathy Schmitt. Angelica gave some background to the Commission regarding the request from the Veterinary Board of Governors (VBOG). VBOG is seeking an exception to the law that would allow veterinarians to order stock bottles of compounded medications for office use only (from an authorized compounding pharmacy), and to dispense from these bottles as they would any other bottle of medication on the shelf. In addition, the VBOG is interested in engaging in a dialog with the Commission on rule and law changes going forward to address their concerns.

MOTION: Kat Wolf-Khachatourian moved that the Commission form a joint sub-committee to include Kat Wolf-Khachatourian and Elizabeth Jensen to serve on a joint sub-committee to meet with members of the VBOG on issues of common interest. Elizabeth Jensen seconded. MOTION CARRIED: 13-0.

6.2 Proposed Meeting Dates
The Commission was asked to review and discuss proposed meeting dates for 2019. The Commission was asked to reach out to Program Manager, Doreen Beebe if there are any problems with these dates. The Commission agreed to commit Wednesdays to hearings in 2019 in the past Friday was committed to hearings.

6.3 Commission Travel Plans/Conferences for 2019
Chair, Tim Lynch asked the Commissioners to reach out to Doreen Beebe in any conferences or meetings they are interested in attending in 2019.

6.4 Correspondence
The Commission reviewed and discussed correspondence received or distributed on its behalf.

6.5 Pulled Consent Agenda Items
2.4 (e) North Seattle College
This item was pulled because Elizabeth Jensen had questions. She is not present at this time.

MOTION: Cheryl Adams moved that the Commission approve Consent Agenda Item 2.4 (e) North Seattle Pharmacy Technician Training Program submitted. Sept Soleimanpour seconded. Uyen Thorstensen recused herself. MOTION CARRIED: 12-0.

2.5 (a) Consonus Health
This item was pulled because Elizabeth Jensen wanted to hear more about what the outcome would be to change the ratio as requested. Teri Ferreira was able to answer Elizabeth’s question.

**MOTION:** Cheryl Adams moved that the Commission approve Consent Agenda Item 2.5 (a) Consonus Ratio waiver that was submitted. Steve Anderson seconded. Teri Ferreira recused herself. Elizabeth Jensen abstained. **MOTION CARRIED: 11-0.**

**2.5 (b) Propac Payless Pharmacy**

This item was pulled because Elizabeth Jensen wanted to hear more about what the outcome would be to change the ratio as requested.

**MOTION:** Cheryl Adams moved that the Commission approve Consent Agenda Item 2.5 (b) Propac Payless Ratio waiver that was submitted. Steve Anderson seconded. Elizabeth Jensen abstained. **MOTION CARRIED: 12-0.**

**2.5 (c) QFC Pharmacies**

This was pulled because there was not a service plan and the Commission felt they didn’t meet the minimum requirements of this waiver.

**MOTION:** Cheryl Adams moved that the Commission deny Consent Agenda Item 2.5 (c) QFC Pharmacies Ratio waiver that was submitted due to not meeting the minimum requirements on the Ratio waiver form. Steve Anderson seconded. Matthew Ronayne recused himself. **MOTION CARRIED: 12-0.**

**6.6 Election of Officers**

Ken Kenyon nominated Tim Lynch to serve as Chair and Cheryl Adams to serve as Vice-Chair.

**Vote:**
Tim Lynch as Chair **13-0.**
Cheryl Adams as Vice-Chair. **13-0.**

There was discussion that both the Chair and Vice-Chair will not be at the July meetings. Ken Kenyon will serve as interim Chair and Teri Ferreira will serve as interim Vice-Chair.

**7. Requests**

Panel A, included Steve Anderson, Michael Sieg, Teri Ferreira and Judy Guenther.

**7.1 Routine review and consider for approval a study plan to retake the North American Pharmacist Licensure Examination (NAPLEX) 4th attempt.**
MOTION: Steve Anderson moved that Panel A approve Faina Alvor Deguzman’s study plan and to complete a prep course that she is present at. Judy Guenther seconded. 
MOTION CARRIED: 4-0.

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

MOTION: Steve Anderson moved that Panel A approve Nastja Rebrin’s study plan Judy Guenther seconded. MOTION CARRIED: 4-0.

8. Staff Reports
Executive Director
Steve Saxe reported:
• NABP Resolutions from the NABP Annual Meeting will be shared.
• Deputy Director, Tracy West position has been extended until June 2019

Supervising Pharmacist Investigator
Gordon MacDonald reported:
• The new inspection process is working well and seems to be received well by the stakeholders. The report writing is much easier as well. Looking forward to getting started on the Compounding Inspections.
• Gordon is covering three areas due to being short staffed. Julie Faun left the department. Grace Cheung is doing her work at MPJE and another investigator is out on FMLA until July 2018.

Assistant Attorney General
Christopher Gerard reported:
• There was a change in assignment with the AAG office regarding the Pharmacy Commission. AAG, Eric Sonju was primary advisor and Christopher Gerard was back up. This is now switched that AAG, Christopher Gerard is primary and Eric Sonju is back up.

There being no further business, the board adjourned at 3:05 p.m.

Respectfully Submitted by:
Leann George, Program Support for Approval July 26, 2018

Ken Kenyon, Acting Chair
Washington State Pharmacy Quality Assurance Commission