CONVENE

Chair Tim Lynch called the meeting to order March 30, 2017.

Commission Members:  Guest / Presenters:
Elizabeth Jensen, PharmD  Cheryl Pell RPh, VP of Pharmacy Management of
Tim Lynch, PharmD, Chair  Medication Review
Steve Anderson, RPh  Hengameh Golchin, PharmD
Kenneth Kenyon, PharmD, BCPS
Cheryl Adams, PharmD, Vice-Chair
Christopher Barry, RPh
Sepi Soleimanpour, RPh, MBA-HA
Matthew Ronayne, RPh
Maureen Sparks, CPhT
Arun Sambataro, Public Member

Absent Commission Member:
Jerrie Allard, Public Member
Teri Ferreira, RPh
Judy Guenther, Public Member
Olgy Diaz, Public Member

Staff Members:
Joyce Roper, AAG
Steven Saxe, Executive Director
Irina Tiginianu, Pharmacy Technician Analyst
Doreen Beebe, Program Manager
Leann George, Secretary Senior
Gordon MacDonald, Chief Investigator
Lisa Roberts, Pharmacist Consultant
Angelica Pauley, Pharmacist Consultant
Tracy West, Rules Coordinator
Call to Order
1.1 Approval of Business Meeting Agenda
1.2 Approval of February 16, 2016 Meeting Minutes
1.3 Approval of February 17, 2016 Special Meeting Minutes

MOTION: Steve Anderson moved to approve the March 30, 2017 Business Meeting Agenda. Elizabeth Jensen seconded. MOTION CARRIED: 9-0.

MOTION: Cheryl Adams moved to approve the February 16, 2017 Business Meeting Minutes. Steve Anderson seconded. MOTION CARRIED: 9-0.

MOTION: Steve Anderson moved that the Commission approve the February 17, 2017 Special Meeting Minutes. Elizabeth Jensen seconded. MOTION CARRIED: 9-0.

Public Rules Hearing WAC 246-873-060 Suicide Prevention Continuing Education
The public hearing is to take testimony to create a new rule for WAC 246-861-105 Suicide Prevention Education, to establish a one-time continuing education requirement for pharmacists in suicide prevention awareness.

MOTION: Matthew Ronayne moved that the Commission add some non-substantive verbiage to WAC 246-873-060 to add clarity. Steve Anderson seconded. MOTION CARRIED: 9-0.

- A licensed pharmacist must complete a one-time suicide prevention training course by the end of first full continuing education reporting period after January 1, 2017 or during first full continuing education reporting period after initial licensure whichever is later, into the first paragraph.
- Changing word “chapter” to “section” in sub section three.

NOTE: There will be communication sent out with examples to assist in further clarity when the continuing education is due.

MOTION: Cheryl Adams moved that the Commission adopt WAC 246-873-060 as purposed with non-substantive changes. Steve Anderson seconded. MOTION CARRIED: 9-0.

The hearing concluded at 9:17 a.m.

Consent Agenda
2.1 NPLEx Monthly Report Acceptance
2.2 Pharmacies and Other Firm Application Approval
- New and Closed Pharmaceutical Firms Report
2.4 Ancillary Utilization Plan Approval/Technician Specialized Functions
a) Bainbridge Island Community Pharmacy  
b) Centralia Pharmacy  
c) Legacy Cancer Institute with Specialized Function  
d) Mary Bridge Specialized/Regular  
e) Pakita Pharmacy LLC  
f) Peninsula Community Health  
g) Propac, Payless Specialized Functions  
h) Tri-Area Pharmacy  
i) Walgreens Specialized Functions  
j) Bartell Drug Pharmacy

Christopher Barry asked to remove Consent Agenda Items 2.4 b, c, d, e, f, g, h, i, and j for discussion.

Christopher Barry asked that staff research why a blood infusion center has a pharmacy license.

**MOTION:** Matthew Ronayne moved to approve Consent Agenda Items 2.1, 2.2, and 2.4 a. Elizabeth Jensen seconded. **MOTION CARRIED: 9-0.**

*Arun Sambartaro joined the meeting*

**MOTION:** Steve Anderson moved to approve Consent Agenda Items 2.4 b. Elizabeth Jensen seconded. Ken Kenyon and Cheryl Adams recused themselves. **MOTION CARRIED: 8-0.**

**New Business**

**Direction of Pharmacy**

Carmen Catizone, Executive Director, National Association Boards of Pharmacy (NABP) came to the Commission to discuss the direction of pharmacy. He started an open dialogue sharing what NABP sees nationally and to reassured the Commission that WSPQAC is not alone in the challenges being faced in Washington State. Mr. Catizone opened the floor up for the Commission Members to discuss issues and challenges and ways that other states deal with them. He offered the full support of himself and NABP to assist WSPQAC as they examine the way pharmacy is regulated in Washington State. The discussion with Mr. Catizone ignited a conversation within the Commission on the direction and goals they have in regulating pharmacy today.

**MOTION:** Ken Kenyon moved that the commission look at crafting rules, changes in RCW’s and how the Commission reviews requests. In so doing, have the focus be on outcomes and general guidelines that set the guard rails to ensure safe patient care. Adopt the 2011 NABP Task Force’s recommendation encouraging Boards/Commission of Pharmacy to adopt specific requirements to assist in system assessments by filling in the blank before “system” as a general framework that can apply to everything. Sepi Soleimanpour seconded. **MOTION CARRIED: 10-0.**
Statutory / Regulatory Review
AAG, Joyce Roper did an extensive review to provide the Commission a list of what they are required by statute or rule to approve. She arranged the variety of required approvals into categories and went through each item briefing the Commission on what type of approval was required. The materials presented will allow the Commission to focus and set priorities in regulating the practice of pharmacy but continue to encourage innovation with a focus on patient care and safety. The Commission asked Joyce if she could put together a grid of the types of requests that are received and connect them to the RCWs or WACs to help efficiently streamline the reviewing process while we are changing direction in our way of regulating.

MOTION: Christopher Barry moved that the Commission assign a sub-committee to look at agency legislation request for 2018 that must include Joyce Roper and Steve Saxe. Sepi Soleimanpour seconded.

After further discussion Christopher Barry withdrew his motion

MOTION: Cheryl Adams moved that the Commission consider how to explore processes and options to develop guidelines or guardrails, and should include existing guidelines. This should be done so guidelines and processes do not become out dated or prescriptive as processes, procedures and technology changes, and will allow the Commission to meet its responsibilities of protecting the public health, safety and welfare in the delivery of pharmaceutical services in this state and assigning this to a sub-committee. Steve Anderson seconded. MOTION CARRIED: 10-0.

The Commission further discussed if the Commission wanted to continue to see proposals that we are not required to approve. The Commission took turns sharing their views on this and decided to continue to see proposals while guidelines were being worked on.

The commission adjourned for Closed Session at 12:02 p.m.

The commission reconvened from Closed Session at 1:00 p.m.

New Guideline Discussion Based on Review of Other States
   a) Remote Supervision
   b) Remote Order Process
   c) Central Fill

Pharmacist Consultants, Lisa Roberts and Angelica Pauley put together this information as a background and reference point to start these conversations in building guidelines. Each Commission Member provided feedback. They thanked the consultants for work and research to collect this information. The stakeholders also provided their feedback. Some thought the guidelines were final drafts for review and approval. The Commission reminded everyone that this is strictly a starting point and that there will be stakeholder input in the process of putting together all guidelines. Commissioner Kenyon mentioned
that in keeping with the open and transparent process, commissioners are seeing these drafts for the first time as well and have not had an opportunity to review and deliberate.

**Pharmacy Intern/Brief Adjudicative Proceedings:** Marlee O’Neill, Deputy Director for Office of Legal Services presented a proposed procedure that would give the Commission a choice besides revoking and intern’s license when an intern is no longer making timely progress toward graduation. Historically, when the Commission received notice that an intern was no longer enrolled in school, it authorized a Statement of Charges and an Agreed Order revoking the intern’s registration. This situation typically doesn’t occur because of any unprofessional conduct. The Commission previously expressed a desire to have an alternative to a Statement of Charges/Agreed Order. The policy presented outlined an alternative which would be to notify the registrant that his/her pharmacy intern registration will be placed in an inoperable status. Should the individual resume pharmacy school, they can reapply for the registration. If the registrant disagrees with this, they can request a Brief Adjudicative Proceeding (BAP) which is a hearing based on documentary evidence that both the Commission and the registrant have an opportunity to provide to the BAP Officer. The commission would maintain the option to revoke if the intern left school for situations of unprofessional conduct.

**MOTION:** Elizabeth Jensen moved that the Commission approve the Pharmacy Intern Registration Procedure to provide the Commission a choice to revoke an intern’s registration or change the status to inoperable based on the fact of each case. Arun Sambataro seconded. **MOTION CARRIED: 10-0.**

**Consent Agenda Pulled for Discussion**

2.4 Ancillary Utilization Plan Approval/Technician Specialized Functions

(b) Bainbridge Island Community Pharmacy

**MOTION:** Christopher Barry moved that the Commission approve 2.4 (b). Cheryl Adams seconded. **MOTION CARRIED: 10-0.**

(c) Legacy Cancer Institute with Specialized Functions

The policy & procedure have not been reviewed in two years and there was nothing about the supervising pharmacist knowledge or training to USP 797.

**MOTION:** Christopher Barry moved that the Commission approve 2.4 (c) with a recommendation that they review and updated their policy & procedures. Sepi Soleimanpour seconded. Cheryl Adams recused herself. **MOTION CARRIED: 9-0.**

(e) Pakita Pharmacy LLC

The concern was there are no pharmacy technicians just pharmacy assistants.
MOTION: Christopher Barry moved that the Commission approve 2.4 (e) with clarification that they are just using pharmacy assistants and not pharmacy technicians. Steve Anderson seconded. **MOTION CARRIED: 10-0.**

(f) Peninsula Community Health

MOTION: Christopher Barry moved that the Commission approve 2.4 (f) with a requirement that they clarify that pharmacy technicians are not stocking the crash. Steve Anderson seconded. **MOTION CARRIED: 10-0.**

(g) Propac, Payless Specialized Functions

There was discussion on why we would approve an application with an Oregon address. The company is out of Oregon but the pharmacy is located in Washington State.

MOTION: Christopher Barry moved that the Commission approve 2.4 (g) with the removal of the Oregon site from the application. Steve Anderson seconded. Cheryl Adams recused herself. **MOTION CARRIED: 9-0.**

(h) Tri-Area Pharmacy

There was confusion around why the Commission received two applications because the original application submitted was the old application. The old application was sent in error and a new application was included for review.

MOTION: Christopher Barry moved that the Commission approve 2.4 (h). Elizabeth Jensen seconded. **MOTION CARRIED: 10-0.**

(i) Walgreens Specialized Functions

The Commission discussed “intercom plus” and how the pharmacist reviews information.

MOTION: Christopher Barry moved that the Commission approve 2.4 (j). Matthew Ronayne seconded. Sepi Soleimanpour recused herself. **MOTION CARRIED: 9-0.**

(j) Bartell Drug Pharmacy

There was a question about the Pharmacist-In-Charge being a district manager and if that was appropriate. This scenario is acceptable.

MOTION: Christopher Barry moved that the Commission approve 2.4 (j). Cheryl Adams seconded. Steve Anderson recused himself. **MOTION CARRIED: 9-0.**

**Correspondence**

The Commission discussed correspondence received or distributed on its behalf.

- Joint Commission Medication Certification
- Long Term Care letter to PQAC
Old Business

Long-Term Care Rules
Tracy West led the discussion on guidelines for Long-Term Care to address practices authorized by statute but not defined in rule:

a) Closed Door Long-Term Care Pharmacy Personnel Pharmacy Technicians – Administrative Use
b) Chart Orders and the Use of Practitioner Authorized Agent Signatures in Long Term Care Settings
c) Other Long Term Care Guidelines
Tracy is working on “other LTC guidelines” that will be brought forward to the Commission at a future meeting.

MOTION: Cheryl Adams moved that the Commission approve 3 (a) and (b) guidelines for LTC. MOTION CARRIED: 10-0.

Final Review of Drafted Guidelines
These procedural guidelines came to the Commission after some minor amendments and formatting asked of staff after the final discussion in February 2017.

a) Non-Resident Pharmacy #50

MOTION: Cheryl Adams moved that the Commission approve the guidelines for Non-Resident #50. Matthew Ronayne seconded. MOTION CARRIED: 10-0.

b) Patient Counseling

MOTION: Steve Anderson moved that the Commission approve the guidelines for Patient Counseling. Matthew Ronayne seconded. MOTION CARRIED: 10-0.

c) Diversion-Lessons Learned
The Commission was interested in what will be done with the data? Will there be data gathered to prevent these situations from happening and/or for best practices. This could be a great intern project in the future.
MOTION: Steve Anderson moved that the Commission approve the Diversion-Lessons Learned guideline. Cheryl Adams seconded. **MOTION CARRIED: 10-0.**

NOTE: These three documents will be posted to the website.

**Medication Review Report Back**
Cheryl Pell RPh, VP of Pharmacy Management of Medication Review provided the yearly report back on pilot project Remote Monitoring of Technicians by Medication Review at the following hospitals: Othello Community Hospital, East Adams Rural Hospital, Quincy Valley Hospital, Columbia Basin Medical Center, Prosser Memorial Hospital, North Valley Hospital, Klickitat Valley Health, Odessa Memorial Health Care If approved, we would continue to provide pharmacy technician services to our current Critical Access Hospitals. Ms. Pell reported that the Quality Assurance process was improved based upon past input from the Commission during the last report back.

**MOTION:** Steve Anderson moved that the Commission approve Medication Reviews’ report back and asked them to report back again in three years unless policy changes or rules are written. Cheryl Adams seconded. **MOTION CARRIED: 10-0.**

**Requests/ Proposals**

**Study Plan Proposal**
Tim Lynch, Elizabeth Jensen, Arun Sambataro and Ken Kenyon from Panel B reviewed and considered a study plan proposed by Hengameh Golchin who requested authorization to retake the Multistate Pharmacy Jurisprudence Examination (MPJE). The panel had some concern she was using the same material and similar study plan that she used in the previous studying along. There was also discussion on the potential of the proposed long study times each day.

**MOTION:** Ken Kenyon moved that the panel authorize Hengameh Golchin to re-take the MPJE and suggested she make her study plan a bit more robust. Arun Sambataro seconded. **MOTION CARRIED: 4-0.**

**Legislative, Program and Department Updates**

**2017 Legislative Session**
Executive Director, Steve Saxe briefly went over the legislative bills the Commission has been following. The Commission has been holding Friday Legislative calls weekly. With the legislative focus moving to the budget, activity on the policy bills should slow down. The Governor budget, Senate budget and the House budget have all been released and currently being negotiated. The WSPQAC Decision Package is in the Governor budget and House budget but not in the Senate budget.
Agency Request Legislation
The Commission discussed items to propose as Agency Request Legislation. This included both the 2018 Legislative session and a list for future session. Any potential request legislation must have the program begin some work including stakeholder input before proposing to the Secretary of Health. The Commission members each spoke of their preferences and after further discussion they came up with a list of priorities:

Potential for 2018
- Adding Pharmacies under the Uniform Disciplinary Act or other changes to give more options for facility related enforcement action. Consider fining authority.
- Consider changes in the requirements for non-resident pharmacies and the ability to require meeting certain standards. Consider inspection options or accreditations in lieu of state inspections. Consider potential accreditation options, especially in non-resident facilities. These include VAWD, VIPP, VPP, JC, or other accreditation.
- Revise the electronic prescription transmission system PQAC approval requirement.

High Priority but later Legislative Session
- Require all prescriptions to be transmitted electronically between prescribers and dispensers. (Similar to New York State).

Financial/Budget Report/Discipline Impacts
Staff is continue to monitor. Two areas that continue to negatively impact the PQAC budget at this time are credentialing and discipline.

Discretionary Budget Planning
Executive Director, Steve Saxe asked the Commission for their input as staff begin developing a spending plan for next year’s budget. This includes meetings, conferences and training and other expenses. The Commission agreed that these are opportunities that WSPQAC need to continue to be engaged and continue to be a part of the pharmacy community such as NABP.

Sub-Committees, Rules and Action Plan

Adjudicative Proceedings
Tami Thompson, Regulatory Affairs Manager for Department of Health briefed the Commission on the background of the revisions to Chapter 246-11 WAC Model Procedural Rules for Adjudicative Proceedings. The intent of this rulemaking is to modernize the language and update the rules to reflect current practices.

MOTION: Steve Anderson moved that the Commission approve revisions to Chapter 246-11 WAC Model Procedural Rules for Adjudicative Proceedings. Matthew Ronayne seconded. MOTION CARRIED: 10-0.
Hospital Pharmacy Affiliated Clinic Emergency Rule
Tracy West, Rules Coordinator asked the Commission to authorize re-filing emergency rule for 120 days until the permanent rule is written. Staff has suggested gaining experience with the emergency rule to make adjustments to the rule before moving forward with the permanent rulemaking process. Rich Cieslinski is compiling a spreadsheet of stakeholder comments. Staff will also follow up with the DEA on the question of how to get a registration for an HPAC. The Commission asked that there be a follow up meeting scheduled as soon as possible.

NOTE: The Commission would like the investigators to give pharmacies time to do whatever they need to while WSPQAC waits for a response from the DEA regarding the problem of these pharmacies getting a DEA registration.

MOTION: Christopher Barry moved to authorize the filing of a third emergency CR-103 to continue the emergency rule with list of follow-up items for staff. Steve Anderson seconded. MOTION CARRIED: 10-0.

Inspection
Tracy West shared proposed draft language recommended from the Inspection Subcommittee for full Commission consideration. She provided an updated, and recommended amendments to the subcommittee draft language. This included removing the bifurcated plan of correction system and having the rule solely focus on setting up a notice of deficiency/plan of correction model. The amendments would allow for more flexibility for the Commission and licensees. She asked for Commission direction on these amendments along with authorization to move the CR-102 forward with amended language.

MOTION: Cheryl Adams moved that the Commission approve the amended language and to file the CR-102. Ken Kenyon seconded. MOTION CARRIED: 10-0.

E-prescribing
Staff asked for some clarification to the motion approved at the last meeting.

MOTION: Cheryl Adams moved that the Commission allow fail over faxes, electronic faxing, to allow the three vendors who are currently prohibited from utilizing this functions to utilize it given rulemaking is ongoing, allow electronic signatures for electronic prescriptions, and maintain the requirement for hard copy prescriptions and faxes to be manually signed. Pharmacist are to continue to use professional judgement to validate prescriptions and will not be subjected to discipline for filing a non-controlled substance prescription that otherwise appears to be valid given due diligence and the pharmacists professional judgement. Steve Anderson seconded. MOTION CARRIED: 10-0.
Commission Member Open Discussion & Reports

Member reports

Maureen Sparked reported:
- She has chosen not to re-apply for her appointment on the Commission but will continue to serve until someone else is appointed.
- She participated as a guest surveyor for ASHP regarding Pharmacy Technician Accreditation.
- Has participated on panel call.

Steve Anderson reported:
- He attended the Technology stakeholder meeting in Kent, WA.

Cheryl Adams reported:
- She attended the Inspection Meeting in Tumwater.
- Participated on Conference call on the Joint Operating Agreement.
- Panel calls.

Elizabeth Jensen reported:
- She is drafting a document to assist pharmacists in the field address controlled substance prescription and whether it is valid. She will bring this to the Commission for review.

Ken Kenyon reported:
- Participated in panel calls.

Sepi Soleimanpour reported:
- Participated in panel calls.
- Attended the Inspection stakeholder meeting.

Tim Lynch reported:
- Attended the Inspection Committee stakeholder meeting.
- Worked on the MOU.
- Many calls with Steve Saxe, Lisa Hodgson and other DOH staff regarding PQAC business.
- Participating in creating a check list for USP 800 for potential consideration.
- WSPA Health System Leadership Meetings planning in process. The meeting is May 5, 2017 in Yakima. Call WSPA for more information

Open discussion

Cheryl Adams commented that she would love to hear more from staff during the reports agenda item during Commission meetings. She provided a template that possibly staff could use to provide reports on what types of projects or work they are doing.

Steve Anderson found something on the West Virginia newsletter has to do with comprehension addiction and recovery act and a conflict (CARA) with filling CII prescriptions. If a patient doesn’t want to fill a full CII prescription they have 30 days to fill
the remainder, also if there isn’t enough of a CII they can pick up within 72 hours but if that 72 hours is after that 30 days it is no longer valid and can’t be filled

Ken Kenyon would like to honor the OPEN FORUM agenda item before lunch. He feels that some attendees who may want to share during this opportunity aren’t getting that chance.

Staff reports

Executive Director
Steve Saxe reported:
- Provided a written report to the Commission that was handed out.
- Will work with Pharmacy Commission subcommittee to meet with the Nursing Commission regarding their Advisory Opinions. He met with staff and has asked the sub-committee to formulate question for the Nursing Commission.
- The Governor’s office is still reviewing Commission appointments.
- Steve asked that the Commission to identify who will be attending the NABP Meeting and need to vote for a voting member and a delegate.

MOTION: Tim Lynch moved that Steve Saxe act as the WSPQAC voting member and the delegate will be chosen after confirming the Commission Member who will attend with him. Ken Kenyon seconded. MOTION CARRIED: 10-0.

Assistant Attorney General
Joyce Roper reported:
- She introduced AAG, John Macejunas, who will be learning PQAC’s work, so there will be a back up to assist PQAC when Joyce is unavailable.

Pharmacist Consultants
Lisa Roberts reported:
- Lisa attended inspection stakeholder meeting.

Angelica Pauley reported:
- Continue to provide advice for team.

Chief Pharmacist Investigator
Gordon MacDonald reported:
- He now has two investigators.

Tim Lynch gave a plaque to Maureen Sparks recognizing and thanking her for all of her work on the Commission. Maureen was the first Pharmacy Technician that has ever served on the Commission.

There being no further business, the board adjourned at 4:45 p.m.
Respectfully Submitted by:

Leann George, Program Support
Approved May 11, 2017

Tim Lynch, Chair
Washington State Pharmacy Quality Assurance Commission