CONVENE

Acting Chair, Ken Kenyon called the meeting to order July 26, 2018 at 9:32 am.

Commission Members:
Elizabeth Jensen, PharmD
Kat Wolf-Khachatourian, PharmD
Judy Guenther, Public Member
Steve Anderson, RPh
Jerrie Allard, Public Member
Teri Ferreira, RPh
Kenneth Kenyon, PharmD, BCPS
Sepi Soleimanpour, RPh, MBA-HA
Michael Sieg, PharmD

Staff:
Matthew Ronayne, RPh
Christopher Gerard, AAG
Steven Saxe, Executive Director
Tracy West, Deputy Director
Doreen Beebe, Program Manager
Leann George, Secretary Senior
Lisa Roberts, Pharmacist Consultant

Absent Commission Member:
Arun Sambataro, Public Member
Olgy Diaz, Public Member
Uyen Thorstensen, Pharmacy Technician
Cheryl Adams, PharmD, Vice-Chair
Tim Lynch, PharmD, Chair

Call to Order

1.1 Business Meeting Agenda

MOTION: Steve Anderson moved to approve the July 26, 2018 Meeting Agenda. Judy Guenther seconded. MOTION CARRIED: 10-0.
1.2 Meeting Minutes – June 7, 2018

MOTION: Teri Ferreira moved to approve the June 7, 2018 Meeting Minutes. Steve Anderson seconded. MOTION CARRIED: 10-0.

1.3 Meeting Minutes – June 8, 2018

MOTION: Steve Anderson moved to approve the June 8, 2018 Meeting Minutes. Judy Guenther seconded. MOTION CARRIED: 10-0

Consent Agenda
2.1 National Precursor Log Exchange Monthly report – June 2018
2.2 New and Closed Pharmaceutical Firms Application Report Approval
   a) Closed May 25th – July 9th, 2018
   b) New – May 25th – July 9th, 2019
2.3 Ancillary Utilization Plans Approval (may include Specialized Functions)
   a) Allenmore Hospital specialized functions
   b) Geneva Woods Pharmacy
   c) HealthPoint Bothell Pharmacy
   d) Inland Northwest Behavioral Health
   e) Providence St. Mary Medical Center w/specialized functions
   f) Ready Meds Pharmacy
   g) Sid’s Pharmacy, and Sid’s Long-term Care Pharmacy
   h) Swedish Medical Center w/specialized functions
   i) Western State Hospital Pharmacy w/specialized functions
2.4 Pharmacy Technician Training Programs Approval
   a) Cost Less Pharmacy and Wellness
   b) Union Avenue Compounding Pharmacy
   c) Yakima Valley College
   d) Valley College
2.5 Pharmacy Technician Ratio Exemption Approval
   a) QFC Pharmacies

MOTION: Teri Ferreira moved that the Commission approve consent agenda items 2.1, 2.2 (a-b), 2.3 (a-i), 2.4 (a-d), and pull Item 2.5 (a) for further discussion and Commissioner Ronayne’s recusal. 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:
✓ Student Enrollment Definition – Program Manager, Doreen Beebe completed the article for the July Newsletter.
✓ Medication history article – Commissioner Ken Kenyon completed the article for the July Newsletter.
✓ Budget Subcommittee – presented their recommendation to the Commission at the June meeting. The Commission made recommendations to the Secretary. Department staff are now developing the rulemaking documents for submission.
✓ Vending Machine Communications – Response was provided to individuals requesting information on vending over-the-counter medications. Staff placed a reference on this direction on the Shopkeeper webpage.

In Process:
- Letter to Healthcare Committee chairs – Pharmacy staff are working with policy staff on a letter to the legislative health care committees. This will be an offer to share information around pharmacy issues, and specifically examples around compounding related statutes. This is on the July agenda.
- Medical Commission request for Attorney General formal opinion on Collaborative Drug Therapy Agreements - The Commission and staff held two special meetings to provide input. AAG Chris Gerard will bring a draft to review at the July meeting. This is on the July agenda
- Collaborative Drug Therapy Agreement (CDTA) – Separate from the AGO opinion the commission will discuss some questions that have come up following the April discussion and recent newsletter on signing of prescriptions under a CDTA. These questions seem to focus on refill centers. This is on the July agenda to discuss this input and finalize a document being prepared by AAG Chris Gerard.
- Opioid Dispensing Best Practice article – Staff will work with Commissioners on an opioid red flags / best practices article. This will be a follow up to the article in the April newsletter on the opioid prescribing rules process.
- Review of misfill grid and NCQAC chart – The subcommittee has identified some additional work they want to complete. They will continue working on this process following other priority work.

3.2 Policy Statement on Licensing of Virtual Manufacturers and Virtual Wholesalers
During the June 8, 2018 PQAC business meeting the Commission made a motion to license Virtual Manufacturers and Virtual Wholesalers and incorporate this requirement in the Rules Re-Write Project. Staff was tasked with drafting a policy to provide guidance until the Rules Re-Write is done. AAG, Christopher Gerard reviewed the draft and shared that it has also went through the Department of Health’s review process. The Commission was asked to review for the policy for approval.

MOTION: Steve Anderson moved that the Commission approve the policy as written. Teri Ferreira seconded. MOTION CARRIED: 10-0.

3.3 Guidance Document for CDTAs and Refill Centers
There were questions from licensees regarding who should sign a prescription under a CDTA. The Commission discussed this during the April 26, 2018 business meeting. Although, there were no changes to the CDTA policy the follow-up communication through meeting minutes, and newsletters caused some questions around the use of
Collaborative Drug Therapy Agreements (CDTA) and medical staff protocols used in some health systems.

AAG, Christopher Gerard and staff were asked to draft a guidance document that could provide guidance/clarification to some of the more complex aspects of implementing CDTA’s. Executive Director, Steve Saxe presented the draft guidance proposal to the Commission review and discussion. AAG, Christopher Gerard went through the document with the Commission.

MOTION: Steve Anderson moved that the Commission accept as a draft proposal and have it posted to the website for public comments and a notice sent out via GovDelivery with a deadline of August 17, 2018 to be brought to the next meeting to the Commission. Matthew Ronayne seconded. MOTION CARRIED: 10-0.

3.4 Medical Commission Request for AGO Formal Opinion on CDTA
The Medical Commission has asked the AGO for a formal opinion on six questions related to the proper use of CDTAs. AAG, Christopher Gerard led the discussion regarding the Pharmacy Commission’s public comment to the AGO regarding this request. The Pharmacy Commission held a second special meeting on July 23, 2018 with stakeholders and staff to provide addition input for this draft. After discussion of the new draft following the July 23 public meeting the Pharmacy commission made final edits and approved the response.

MOTION: Elizabeth Jensen moved that the Commission approve the letter as written with the addition of the number of current CDTA’s (33,283) and some grammatical changes. Kat Wolf-Khachatourian seconded. MOTION CARRIED: 10-0.

4. Legislation, Program, and Department Updates

4.1 2019 Legislative Update
Executive Director, Steve Saxe provided a brief update regarding the 2019 Legislative requests. The Commission members received draft language for their review. The two bills the Commission requested last year are being considered for the 2019 legislative session. He briefed the Commissioners on the draft language and opened up the floor for questions/feedback. The two legislative proposals are:

- Remove required approval of electronic prescription transmission systems.
- Update Inspection Criteria for Non-Resident Pharmacy

4.2 Letter to the Legislative Health Care Committees
At the June meeting the Commission ask staff to draft a letter to the Senate and House healthcare committees that the Commission would like to meet to discuss the need for modernization of the practice of pharmacy statutes and specifically discuss current challenges regarding compounding of medications facing the pharmacy community.
Executive Director, Steve Saxe presented the drafted letter to be sent to the two Legislative Health Care Committees for Commission review and discussion. Pharmacist Consultant, Lisa Roberts was acknowledged by Deputy Director, Tracy West for the great work she had put into this.

**MOTION:** Teri Ferreira moved that the Commission approve the Legislative Health Care Committee letter as written. Steve Anderson seconded. **MOTION CARRIED:** 10-0.

5. Rules, Sub-Committee and Commissioner Reports

5.1 Sub-Committee reports

a) Compounding subcommittee
Deputy Director, Tracy West led the update to the Commission on the drafted Compounding Self-Inspection worksheet addendums. The Compounding sub-committee met June 22, 2018. During that meeting they identified areas of the worksheets that would be the focus areas of an inspection. There was no change to the language, the sub-committee just highlighted the areas of focus.

i. USP 797 Self-Inspection Worksheet Addendum – discuss and approve recommended inspection highlights

ii. USP 795 Self-Inspection Worksheet Addendum – discuss and approve recommended inspection highlights

**MOTION:** Steve Anderson moved that the Commission approve USP 795 & USP 797 Compounding Self-Inspection worksheets as drafted. Judy Guenther seconded. **MOTION CARRIED:** 10-0.

**MOTION:** Steve Anderson moved that the Commission ask the Pharmacy Investigators to resume inspections of hospitals/facilities. Teri Ferreira seconded. **MOTION CARRIED:** 10-0.

iii. **Discuss proposed comments on proposed updates to USP chapter 795**
Deputy Director, Tracy West led the discussion on whether to make a formal comment from the full commission on proposed revision to Chapter 795. AAG, Christopher Gerard offered additional areas of the proposed revisions the Commission may be interested in commenting on.

**MOTION:** Steve Anderson moved that the Commission accept the draft with the changes suggested by AAG, Christopher Gerard and submit the formal comment by July 31, 2018. Judy Guenther seconded. **MOTION CARRIED:** 10-0.

iv. Discussion of defining or setting guidance on “comparable methods” and other questions regarding USP chapters

Pharmacist Consultant, Lisa Roberts led the discussion with the Commission and provided a brief background on how this came up. She received an inquiry requesting information
on what the Commission’s requirements for a ‘comparable method’ in regard to disinfecting entry points on intravenous bags, injectable vial septums, and ampuls during the process of sterile compounding. This was discussed with the compounding sub-committee during their June 22, 2018 meeting and they asked for the topic to be presented to the full Commission.

There is currently no definition of ‘comparable method’ in either USP or Washington State law. This creates challenges for licensees and staff. Staff reached out to some of CriticalPoint’s Sterile Compounding subject matter experts, as well as USP Compounding Expert Committee Member.

This was brought before the Commission for awareness and discussion. AAG, Christopher Gerard provided some input to the Commission. The Commission decided to not take any action on this topic.

5.2 Commission Reports

Steve Anderson reported:
- Participated in the CDTA webinar
- Attended the AGO CDTA response Special meeting,
- His facility just went through the VIPS Survey, after approval the facility will be able to put the Seal on its site. Very rigorous process.
- Panel calls

Teri Ferreira reported:
- Attended the CDTA Special Meeting
- Panelist for Pharmacy Investigator interviews
- Panel calls
- Acting Vice-Chair for this meeting

Ken Kenyon reported:
- Attended 340b Coalition Meeting
- Spent two days on Capitol Hill meeting with Senators and Congress on issues that are critical in Washington around 340b and that changes that would impact the state.
- Compounding sub-committee
- Acting Chair at the Special Meeting and Business Meeting

Kat Wolf-Khachatourian reported:
- Attended the kick-off sub-committee meeting with Veterinarian Board Of Governors
- Panel calls
- Disciplinary calls
- Had a great discussion with PCCA, they are looking to develop an advisory board cases, attended the special meeting
- Attended the Special Meeting

Elizabeth Jensen reported:
- Participated in the Special Meeting
- Panel Calls
Matthew Ronayne reported:
  • Panel Calls
  • Special Meeting Case management

Sepi Soleimanpour reported:
  • Panel Calls
  • Special Meeting

Jerrie Allard reported:
  • Panel Calls
  • Special Meeting
  • Spokane Opioid task force, and has advocated that pharmacy has a seat

Michael Sieg reported:
  • Panel Calls
  • Special Meeting
  • Compounding sub-committee

5.3 Commissioners’ Open Discussion
MOTION: Ken Kenyon moved that Deputy Director, Tracy West and Executive Director, Steve Saxe examine the opportunity of using an administrative law judge for entity cases. Steve Anderson seconded. MOTION CARRIED: 10-0.

6. New Business

6.1 Department of Health Midwifery Program
The midwifery program requested consultation from the Commission on behalf of the Secretary to make necessary adjustments to their rules to continue to provide safe care to patients. The midwifery program is updating its rules around legend drugs licensed midwives may purchase and use in addition to those listed in RCW 18.50.115. In 2015, the program was approached by the Department of Health Office of Prevention and Community Health and requested that they update the legend drug and devices rule to incorporate newer recommended CDC vaccinations.

MOTION: Steve Anderson moved that the Commission write a letter to support the updates to the midwifery programs rules. Teri Ferreira seconded. MOTION CARRIED: 10-0.

6.2 DOH Opioid Response Plan
Executive Director, Steve Saxe discussed the statewide opioid response plan and the two new items that directly tie to the work of the Pharmacy Quality Assurance Commission. The Opioid Response Plan Workgroup is asking for Commission assistance on these two items.

1. Begin engaging stakeholders to discuss potential new policies to eliminate paper prescriptions.
2. Develop criteria for when wholesale distributors should report suspicious opioid orders to Pharmacy Quality Assurance Commission (PQAC).

Steve Anderson, Teri Ferreira, Kat Wolf-Khachatourian, Sepi Soleimanpour and Jerrie Allard volunteered to support, stakeholder work on the statewide opioid workgroup plan specifically related to suspicious order tracking and mandating electronic prescribing of controlled substances.

6.3 Correspondence
The Commission reviewed and discussed correspondence received or distributed on its behalf. Executive Director, Steve Saxe mentioned the correspondence regarding Fluoride will be sent to all Commissioners except Commissioner Allard (recused) following the meeting.

6.5 Pulled Consent Agenda Items

2.5 (a) QFC Pharmacies

This was pulled by Elizabeth Jensen to share her concerns about removing the pharmacist to technician ratio. The representative from QFC was asked some questions for more understanding of how the stores will be using the extra pharmacy technicians.

MOTION: Steve Anderson moved to approve 2.5 (a) QFC Pharmacies Ratio waiver for seven of its stores. Kat Wolf-Khachatourian seconded. Matthew Ronayne recused himself and Elizabeth Jensen opposed. **MOTION CARRIED: 8-1.**

7. Requests
Ken Kenyon, Elizabeth Jensen and Kat Wolf-Khachatourian Panel B were asked to hear requests from applicants.

7.1 Study plan to retake the Multi-state Pharmacist Jurisprudence Examination (MPJE)
The panel Commission discussed Nastja Rebrin’s study plan. They felt she wasn’t providing any differences in her new proposed study plan and suggested she reach out to WSU Professor Julie Akers and WSPA Practice Director Jenny Arnold for suggested classes or other study options.

The panel denied her plan and suggested that she reach out to Drs Akers and Arnold as previously stated. Program Manager Doreen Beebe will provide their contact information. She can resubmit her revised plan for review at the September Meeting.

7.2 Pharmacist applicant requests approval of special internship per WAC 246-858-080
James Nguyen summarized his request, he asked if he can earn his additional 300 Intern hours participating in a clinical study as a study coordinator and feels this helps strengthen his ability in a clinical setting rather than doing these hours in a community pharmacy. He was able to support how this work would provide him with the experiences he would need to learn in any other pharmacy setting.

Panel B approved his request for special internship.

8. Staff Reports
Executive Director
Steve Saxe reported:
- Links for the NABP Resolutions from the Annual Meeting were shared.
- Deputy Director, Tracy West position has been extended until June 2019
- Pharmacist Consultant, Angelica Pauley took another job outside of DOH
- AAG, Susan Becker who supported PQAC in enforcing cases took another position within the AAG Office. AAG Christina Pfluger will be taking her place.

Deputy Director
Tracy West reported:
- Staff has been meeting regularly for a couple of hours at a time doing in depth work. We hope to have a draft to the Commissioners in two weeks. For both Professional Standards and Operational Standards. They seem to be intertwined staff feels it would be best to go through them at the same time.

Pharmacist Consultant
Lisa Roberts reported:
- Is part of the Core Team for the 1047 Drug Take Back
- Continues to participate in the Office of Health Professions strategic plan project
- Attended the June 22, 2018 compounding sub-committee meeting
- Attended the July 23, 2018 Special meeting via webinar
- Participated in a staff team behavior meeting

Assistant Attorney General
Christopher Gerard reported:
- Attended an conference in Atlanta for institute for public health lawyers
- Writing Formal Opinion for CDTA
- Special meeting

There being no further business, the board adjourned at 2:32 p.m.

Respectfully Submitted by:
Leann George, Program Support for Approval September 7, 2018
Tim Lynch, Chair
Washington State Pharmacy Quality Assurance Commission