



STATE OF WASHINGTON
DEPARTMENT OF HEALTH
Olympia, Washington 98504

WASHINGTON STATE PHARMACY QUALITY ASSURANCE COMMISSION

Meeting Minutes

January 25, 2019

Highline Community College

Building 2

2400 S. 240 St.

Des Moines, WA

CONVENE

Chair, Tim Lynch called the meeting to order January 25, 2019 at 9:00 am.

Commission Members:

Tim Lynch, PharmD, Chair
Sepi Soleimanpour, RPh, MBA-HA
Jerrie Allard, Public Member
Teri Ferreira, RPh
Judy Guenther, Public Member
Steve Anderson, RPh
Uyen Thorstensen, Pharmacy Technician
Kat Wolf-Khachatourian, PharmD
Elizabeth Jensen, PharmD

Staff:

Christopher Gerard, AAG
Tracy West, Deputy Director
Steven Saxe, Executive Director
Caitlin Gates, Rules Consultant
Doreen Beebe, Program Manager
Stephanie Martin, Inspector
Leann George, Secretary Senior
Marlee O'Neill, Director for
Office of Inspections and Legal
Services (OILS)

Absent Commission Member:

Kenneth Kenyon, PharmD, BCPS
Michael Sieg, PharmD
Olgy Diaz, Public Member
Matthew Ronayne, Rph
Bonnie Bush, Public Member

1. Call to Order

1.1 Meeting Agenda – January 25, 2019

MOTION: Steve Anderson moved to approve the January 25, 2019 Meeting Agenda. Judy Guenther seconded. **MOTION CARRIED: 10-0.**

1.2 Meeting Minutes – December 13, 2018 Approval

MOTION: Steve Anderson moved to approve December 13, 2018 Meeting Minutes. Judy Guenther seconded. **MOTION CARRIED: 10-0.**

1.3 Meeting Minutes – December 14, 2018 Approval

MOTION: Steve Anderson moved approve December 14, 2018 Meeting Minutes. Judy Guenther seconded. **MOTION CARRIED: 10-0.**

2. Consent Agenda

2.1 National Precursor Log Exchange Monthly report – December 2018

2.2 Pharmaceutical Firms Application Report Approval

- a. Closed - November 28 through January 11, 2019
- b. New/Open – November 28 through January 11, 2019

2.3 Ancillary Utilization Plans Approval (may include Specialized Functions)

- a. Clarks Pharmacy
- b. Grays Harbor Community Hospital
- c. Highland Pharmacy
- d. Hoagland Long Term Care Pharmacy
- e. Infusion Solutions
- f. Kirkland Compounding Pharmacy
- g. Ocean Beach Hospital
- h. Providence Infusion Services Spokane
- i. Providence Infusion Services Tukwila
- j. Sy Pharmacy and Wellness

2.4 Pharmacy Technician Training Program Approval

- a. Columbia Basin Job Corps
- b. Darrington Pharmacy
- c. Geneva Woods
- d. Healthpoint
- e. Pima Medical Institute

2.5 Pharmacy Technician Ratio Exemption Approval

- a. Long Beach Pharmacy
- b. Mercury Pharmacy Services
- c. Ocean Park Pharmacy

2.6 Electronic Prescription Transmission System Approval

- a. Liberty Software, Inc.
- b. PioneerRx

MOTION: Steve Anderson moved that the Commission approve consent agenda items 2.1, 2.2 (a-b), 2.3 (a-j), and 2.4 (a-d) and pull Items 2.4 (e), 2.5 (a-c), and 2.6 (a-b) for further discussion. Teri Ferreira seconded. **MOTION CARRIED: 10-0.**

2b. Agenda/Items Pulled from the Consent Agenda

2.4 (e) Pima Medical

This item was pulled to recommend back dating the approval to June 1, 2018. Pima Medical submitted their Technician Training Program documents for approval in a timely manner, due to some misunderstanding they thought they were approved and found out otherwise.

MOTION: Steve Anderson moved that the Commission back date the approval date for Pima Medical Pharmacy Technician Training Program to June 1, 2018. Sepi Soleimanpour seconded. **MOTION CARRIED: 10-0.**

2.5 (a & c) Long Beach Pharmacy & Ocean Park

These items were pulled due to the Commissions concern that these two locations were separated by a wall and were two different types of pharmacies. They felt if one of the two pharmacist wasn't on duty that the supervision would be very limited. Due to their concerns they had some questions.

MOTION: Elizabeth Jensen moved that the Commission deny the request for exemption to the Pharmacy Technician Ratio rule for Long Beach Pharmacy and Ocean Park Pharmacy pending clarification of the Utilization Plan when one out of two pharmacist is out. Kat Wolf-Khachatourian seconded. **MOTION CARRIED: 10-0.**

2.5 (b) Mercury Pharmacy Services

MOTION: Steve Anderson moved to approve Mercury Pharmacy Services request to be exempt from the Pharmacy Technician Ratio rule. Teri Ferreira seconded. Elizabeth Jensen opposed. **MOTION CARRIED: 9-1.**

2.6 (a-b) Liberty Software, Inc. & PioneerRx

These items were pulled for further discussion regarding the different responses on the applications that are both receiving systems. The Commission discussed the potential differences but still needed some clarification from one of the PioneerRx.

MOTION: Steve Anderson moved to approve Liberty Software, Inc. electronic prescription system. Kat Wolf-Khachatourian seconded. **MOTION CARRIED: 10-0.**

MOTION: Steve Anderson moved deny PioneerRx's electronic prescription system pending further information. Kat Wolf-Khachatourian seconded. **MOTION CARRIED: 10-0.**

3. Old Business

3.1 Update on FDA Draft Memorandum of Understanding

Deputy Director, Tracy West and Executive Director, Steve Saxe consulted with AAG, Christopher Gerard to discuss the focus of the MOU being drafted by the FDA. The focus of this MOU is trying to address 503A pharmacies that are acting similar to 503B facilities, and sending significant amounts of products across state lines without having to meet Current Good Manufacturing Practices.

If the Commission doesn't enter into the MOU, all in-state 503A pharmacies would be restricted on the amount of compounded products they could distribute out-of-state and if the Commission did enter into the MOU the restriction on distribution would go up.

Ms. West shared that staff will send a survey sent out to pharmacies to get an idea of how many pharmacies, if any this would impact. Commissioners asked the Compounding sub-committee to convene and bring back information and recommendations to the full Commission.

3.2 Draft United States Pharmacopeia (USP) 800 Policy Statement

Deputy Director, Tracy West presented the first draft policy statement to the Commission for input. The Commission provided direction in December for staff to draft a policy statement to clarify to licensees that USP <800> does not require a separate storage room for hazardous drugs or materials used in the compounding of hazardous drugs. This policy statement is to clarify that Washington is *not* requiring a separate storage room for hazardous drug compounding materials.

The Commission agreed the policy was well written but felt it would be more helpful to include examples of circumstances. This would allow for more clarity to the licenses. Staff will redraft the policy with suggestions discussed and bring it back for Commission review.

4. New Business

4.1 Licensing of Dialysis Centers as Health Care Entities

Executive Director, Steve Saxe provided information about the concern from the Office of Health Systems (OSHO) Facility unit. The OSHO Facility unit conducts inspections on Kidney Dialysis Centers. OSHO contacted pharmacy staff inquiring whether or not these facilities needed to be licensed as an HCE to possess drugs. The statute states that to possess drugs you must have the authority to do so. This brings up the question on whether or not these facilities need an additional license. Historically, they have not had an HCE license. The question to resolve is what options are available for a kidney dialysis center to possess drugs. This is a question that researched and answered jointly by the Pharmacy Commission and the Department of Health. This issue is significant enough to get stakeholder input. Mr. Saxe is working with OSHO and will bring back an interpretive

statement that once it is approved will move through the Department of Health review process.

4.2 National Association of Boards of Pharmacy's (NABP) Multistate Inspection Blueprint

Bill Cover, Member Relations and Government Affairs Director for NABP presented information to the Commission on the inspection programs that were established by NABP. He specifically spoke about the Multistate Inspection Blueprint and Verified Pharmacy Program (VPP). He also provided a brief overview of other inspection programs provided such as the Verified-Accredited Wholesale Distributor (VAWD). Mr. Cover shared what other states requires are for inspections of both in-state and out-of-state pharmacies.

After recently changing the inspection rules and inspection process this is information for the Commission to consider as they are proposing legislation to require inspection reports from non-resident pharmacies during renewal. The Inspection Blueprint may assist the Commission in determining if another State Board of Pharmacy exam is substantially equivalent.

MOTION: Kat Wolf-Khachatourian moved that the Commission send revised Inspection Forms to NABP for evaluation to make sure they meet the blueprint criteria. Steve Anderson seconded. **MOTION CARRIED: 10-0.**

MOTION: Steve Anderson moved that the Commission recognize VPP as a third party inspection tool for resident and non-resident pharmacies. Teri Ferreira seconded. **MOTION CARRIED: 10-0.**

MOTION: Steve Anderson moved that the Commission reaffirm Verified-Accredited Wholesale Distributor (VAWD) to be recognized as a third party inspection tool for resident and non-resident wholesaler. Teri Ferreira seconded. **MOTION CARRIED: 10-0.**

4.3 2019 Self-Inspection Worksheet Annual Review

Deputy Director, Tracy West led the Commission through the suggested revisions of all six inspection forms. The inspectors provided their input from their experience out in the field. The Commission and the licensees also provided input during this discussion.

MOTION: Teri Ferreira moved that the Commission approve suggested revisions to the Inspection Forms. The forms will be updated for use in March 2019. Steve Anderson seconded. **MOTION CARRIED: 10-0.**

4.4 Correspondence

The Commission discussed and reviewed correspondence received or distributed on behalf of the Commission

- NABP 2019 Survey of Pharmacy Law
- NABP Website Help Section

- Federal FACTSHEET: Washington State’s Oversight of Opioid Prescribing and Monitoring of Opioid Use

6. Requests for Review by Commission Panel

Commissioners, Jerrie Allard, Uyen Thorstensen, and Sepi Soleimanpour: Panel C heard a study plan for Applicant A.

6.1 Multi-state Pharmacist Jurisprudence Examination (MPJE)

Panel C was asked to consider for approval a study plan submitted by applicant A to retake the Multi-state Pharmacist Jurisprudence Examination (MPJE) – **Applicant A**

Panel C authorized Applicant A to retake the MPJE.

7. Legislation, Program and Department Updates

7.1 Request Legislation Updates

Rules and Legislative Consultant, Caitlin Gates and Executive Director, Steve Saxe provided the Commissioners with an update on the Legislative Session on bills related to pharmacy. Mr. Saxe followed up with some suggestions regarding the discussion with the Commissioners during the January 24, 2019 meeting regarding future legislation. He also shared that there is a possibility that the Commission may be asked to share its position on 69.50 Controlled Substance Act.

7.2 Commission Budget

Deputy Director, Tracy West discussed the budget document that was sent to the Commissioners. She discussed the charts that show the Commission is ahead of its goal. The vacant positions have been helpful along with more efficient work with the AAG. She discussed other pieces to the report and answered questions. The Commissioners asked staff to look into what other offices are doing to decrease their costs and take a closer look at what positions are necessary to fill and if any can remain vacant. Transparency with the budget will continue along with budget updates and discussions. The Budget sub-committee continues to do its work.

8. Rules and Sub-Committee Reports

8.1 WAC 246-901-130 Pharmacist to Pharmacy Technician Ratio Update

Deputy Director, Tracy West shared that due to unforeseen issues the rules package for WAC 246-901-130 Pharmacist to Pharmacy Technician Ratio was not filed by January 23, 2019 as proposed. Staff working on this had done all the work to meet deadlines. Unfortunately, it was delayed in the Policy Office and came back with unexpected suggested changes. Tracy was assured this will be filed February 6, 2019 and will be brought to the April Meeting for hearing.

The Commissioners shared their frustration about this being something that is consistent and seems to be unnecessary. They are concerned these delays consistently reoccur within

DOH support staff and will impact the Rules Re-Write Project that has already been set back.

8.2 Hospital Pharmacy Associated Clinics Emergency Rules

Deputy Director, Tracy West asked the Commission to consider reauthorization of emergency rules for Hospital Pharmacy Associated Clinics Chapter 246-873A. Current rule filed as WSR 18-24-055. This rule will be updated with the rules re-write project.

MOTION: Elizabeth Jensen moved to reauthorize for filing emergency rules for Hospital Pharmacy Associated Clinics Chapter 246-873A. Sepi Soleimanpour seconded. **MOTION CARRIED. 10-0.**

9. Commission Reports / Open Discussion

9.2 Commission open Discussion

Commission Chair, Tim Lynch recognized Commissioner, Elizabeth Jensen for 8 years of dedication to the Pharmacy Commission and the safety of the patients in the state of Washington. Elizabeth always brought a view that forced the Commissioners to really look at the decisions and work they do. At times her questions initiated conversations that were challenging the group to not fall into just moving forward with decisions.

10. Staff Reports

10.1 Executive Director, Steve Saxe reported:

Action Items

Completed:

- ✓ **Meeting with Healthcare Legislative Chairs Follow-up** – Staff submitted draft compounding legislation language based on the request from the Healthcare Chairs at the meeting.
- ✓ **CDTA Guidance Document** – Staff finalized the document and posted on the website.

In Process:

- **Practice Outside of a Pharmacy** – Staff are working with the department’s web development staff to add the FAQs approved at the September meeting to the Pharmacy Commission website.
- **Emergency Medical Reason** – The policy edited at the October meeting is in the department’s interpretive statement review process. Staff recently provided feedback on questions posed by Assistant Secretary Peterson. After her review the document will go to the Secretary’s office for review and any changes will come back to the Commission at the March meeting.
- **Practitioner Use of a Hospital DEA** – Information on how a suffix can be added to a hospital DEA number for a practitioner was in an earlier newsletter but will also be added to the Pharmacy Commission website.

- **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.
- Mr. Saxe referred to the report he submitted to the Commission describing the work and meetings staff has been involved in. There was discussion regarding the transition work with the pharmacy inspectors. Leadership is continuing to work on new work flows, communication, and teambuilding.

10.1 Deputy Director, Tracy West reported:

- Attended a lunch and learn regarding Collaborative Drug Therapy Agreements (CDTA) with the Medical Commission. It was interesting, they were thankful to PQAC for being collaborative and being good partners. We do need to continue to work with them regarding this topic.

10.2 Assistant Attorney General, Christopher Gerard reported:

- Nominated to go to a symposium on Legal Economic Regulatory Environment of Pharmaceutical Industry in Virginia for two days. This is no cost to the Commission.
- Christopher wanted to personally thank Elizabeth Jensen. He’s been working with the Commission for three years and has truly valued all Elizabeth’s input and really great questions that challenged him in ways that were difficult at times. He realizes the amount of work and sacrifice it is to serve on the Commission. He shared he was grateful for his opportunity to work with her.

11. Summary of Meeting Action Items

Commissioner and staff will revisit action items identified during today’s business meeting

- Consent Agenda Items 2.5 (a & c) and 2.6 (b) denied and requesting more information.
- Redraft USP <800> document providing examples.
- Look into how other offices in DOH are reducing costs.
- Send revised Inspection Forms to NABP to see if they meet the Blueprint criteria.
- Develop inspection sheets for other licensees.
- Create a template for compounding compliance.

There being no further business, the board adjourned at 1:35 p.m.

*Respectfully Submitted by:
Leann George, Program Support for
Approval March 8, 2019*

A handwritten signature in black ink, appearing to read "Tim Lynch". The signature is fluid and cursive, with the first name "Tim" and the last name "Lynch" clearly distinguishable.

*Tim Lynch, Chair
Washington State Pharmacy Quality
Assurance Commission*