



STATE OF WASHINGTON
DEPARTMENT OF HEALTH
Olympia, Washington 98504

WASHINGTON STATE PHARMACY QUALITY ASSURANCE COMMISSION

Meeting Minutes

March 8, 2019

Department of Health

P.P.E Room 152/153

Tumwater, WA

CONVENE

Chair, Tim Lynch called the meeting to order March 9, 2019 at 9:37 am.

Commission Members:

Tim Lynch, PharmD, Chair
Sepi Soleimanpour, RPh, MBA-HA
Kenneth Kenyon, PharmD, BCPS
Olgy Diaz, Public Member
Judy Guenther, Public Member
Steve Anderson, RPh
Uyen Thorstensen, Pharmacy Technician
Kat Wolf-Khachatourian, PharmD
Matthew Ronayne, RPh

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, Deputy Director,
Office of Investigations and Legal
Services (OILS)

Absent Commission Member:

Michael Sieg, PharmD
Bonnie Bush, Public Member
Jerrie Allard, Public Member
Teri Ferreira, RPh

1. Call to Order

1.1 Meeting Agenda – March 8, 2019

MOTION: Steve Anderson moved to approve the March 8, 2019 Meeting Agenda. Ken Kenyon seconded. **MOTION CARRIED: 9-0.**

1.2 Meeting Minutes – January 24, 2019 Approval

MOTION: Ken Kenyon moved to approve January 24, 2019 Meeting Minutes. Steve Anderson seconded. **MOTION CARRIED: 9-0.**

1.3 Meeting Minutes – January 25, 2019 Approval

MOTION: Steve Anderson moved approve January 25, 2019 Meeting Minutes. Judy Guenther seconded. **MOTION CARRIED: 9-0.**

2. Consent Agenda

2.1 National Precursor Log Exchange Monthly report – January 2019

2.2 Pharmaceutical Firms Application Report Approval

- a. Closed - January 11 through February 21, 2019
- b. New/Open – January 11 through February 21, 2019

2.3 Ancillary Utilization Plans Approval (may include Specialized Functions)

- a. Inchelium Health Center Pharmacy
- b. Kaiser Permanente
- c. Mason General Hospital
- d. Providence Regional Medical Center Everett – Specialized Function
- e. Tekoa Pharmacy
- f. Tonasket Pharmacy
- g. Valley Medical Center – Specialized Function

2.4 Pharmacy Technician Training Program Approval

- a. Care Health Solutions

2.5 Pharmacy Technician Ratio Exemption Approval

- a. Kaiser Permanente WA Mail Order
- b. Long Beach Pharmacy (resubmitted)
- c. Ocean Park Pharmacy (resubmitted)
- d. Tim’s Pharmacy

2.6 Electronic Prescription Transmission System Approval

- a. DrFirst - Rcopia, Sending Systems
- b. PioneerRx, Receiving Systems (resubmitted)
- c. SRS Pharmacy Systems, Receiving System

MOTION: Steve Anderson moved that the Commission approve consent agenda items 2.1, 2.2 (a-b), 2.3 (a-f), and 2.4 (a), 2.5 (a-d), and 2.6 (a-c). Olgy Diaz seconded.

MOTION CARRIED: 9-0.

MOTION: Steve Anderson moved that the Commission approve consent agenda item 2.3 (g). Matthew Ronayne seconded. Ken Kenyon recused himself. **MOTION CARRIED: 8-0.**

3. Old Business

3.1 Discuss draft Interpretive Statement Storage of Hazardous Drugs under United States Pharmacopeia (USP) 800

Deputy Director, Tracy West presented the amended draft interpretive statement to the Commissioners. In January the Commission asked staff to include examples of circumstances that would allow for more clarity to the licensees.

MOTION: Matthew Ronayne moved that the Commission approve the Storage of Hazardous Drugs under USP 800 Interpretive Statement as written with a footnote that indicates that the USP “may” statement is not a requirement. Steve Anderson seconded. **MOTION CARRIED: 9-0.**

3.2 Emergency Medical Reasons Interpretive Statement

Deputy Director, Tracy West presented the amendments made to the Emergency Medical Reasons interpretive statement after the DOH Policy Office review. During a discussion of the draft General Provisions chapter the Commission felt there needed to be clarification of “emergency medical reasons.”

Emergency medical reasons in WAC 246-879-010(10)(e) is not defined in the same way as the FDA. The Commission determined that the borrowing, lending, sale, purchase, or transferring of medications between pharmacies *to a practitioner* to alleviate a temporary shortage or for another emergency medical reason does not constitute wholesale distribution.

MOTION: Ken Kenyon moved that the Commission approve the interpretive statement regarding the definition of “emergency medical reasons.” Kat Wolf-Khachatourian seconded. **MOTION CARRIED: 9-0.**

4. New Business

4.1 NABP 115th Annual May 16 – 18, 2019 Minneapolis MN

MOTION: Kat Wolf-Khachatourian moved that the Chair, Tim Lynch be the delegate at NABP Annual Meeting and that Executive Director, Steve Saxe be the alternate delegate. Judy Guenther seconded. **MOTION CARRIED: 9-0.**

Executive Director, Steve Saxe went through the resolutions to get Commission input on their position. This will guide Washington delegate discussions at the NABP 115th Annual Meeting.

MOTION: Ken Kenyon moved that the delegate and or the alternate delegate vote in approval or oppositions on the resolutions as discussed. Matthew Ronayne seconded.
MOITON CARRIED. 9-0.

4.2 Correspondence

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

- Healthcare Enforcement & Licensing Modernization Solution (HELMS)
- Department of Health Budget and Legislative Proposals
- NABP Program Review and Training
- US Hemp Roundtable Letter re “Farm Bill”

4.3 Communication Resolution Program (CRP)

Executive Director, Steve Saxe attended a CRP Project stakeholder meeting, where there was an update of the current status of the program. They report about 20 cases have been certified by the CRP Review panel. It was mentioned that a pharmacist is part of the CRP Review Panel.

A panel presented one case and how it worked through the process. They discussed some of the challenges and learnings. This was followed by a presentation by the plaintiffs’ bar discussing how the CRP works within the existing system and some of the challenges. Also Dr. Alden Roberts, Chair of the Medical Commission discussed the process from the Commissions perspective, how they will consider the CRP report in the enforcement process and how the CRP report may influences but does not determine the Commission decision

The Pharmacy Commission has reviewed and is interested in the CRP process as a way to support continual improvement and Just Culture. Last year the Commission wanted to continue to monitor the experience of the Medical Commission. In addition the Board of Osteopathic Medicine and Surgery is considering entering into a memorandum of understanding with the CRP program.

The Commission suggested the sub-committee meet with the Medical Commission or CRP and bring back a recommendation to the Commission on whether or not they should consider an MOU. Commissioners Tim Lynch, Ken Kenyon and Olgy Diaz are identified as the sub-committee.

5. Open Forum

Carol Garrand, Director Operations of ProPacPayless Pharmacy. Wanted clarifications regarding therapeutic substitution. She feels there is contradictory language in the RCWs vs the WAC. Her concern is that they are being compliant in substituting medications. She wanted clarification on the product selection responsibilities and what a pharmacist may

utilize as a basis of their decision. Clarify that a pharmacist is not required to use one of these references in WAC 246-899-030.

Dawn Sasse, from Columbia River shared a comment regarding therapeutic substitutions that some insurance carriers are no longer covering compounds when it comes to therapeutic substitutions.

Staff will gather information and formulate a response that is more concise and encompasses the concerns brought forward.

6. Requests for Review by Commission Panel

6.1 Multi-state Pharmacist Jurisprudence Examination (MPJE)

Commissioners, Steve Anderson, Olgy Diaz and Judy Guenther: **Panel A** was asked to review and approve study plans submitted by applicants to retake the Multi-state Pharmacist Jurisprudence Examination (MPJE) for Applicants A-D.

- a. Study plan provided by applicant A
- b. Study plan provided by applicant B
- c. Study plan provided by applicant C
- d. Study plan provided by applicant D

Panel A authorized Applicants A, B, C and D to retake the MPJE.

6.2 Recognition as a Professional Association

Consider request for recognition as a professional association for the purposes of receiving lists of contact information for pharmacists, pharmacy technicians and assistants

Panel A recognized Washington Association of Pharmacist and Concerned Citizens as a professional association for purposes of receiving lists and labels from the Commission.

7. Legislation, Program and Department Updates

7.1 2019 Legislative Session Updates

Rules Consultant, Caitlin Gates and Executive Director, Steve Saxe provided the Commissioners with an update on the Legislative Session bills related to pharmacy.

As part of this update discussion, Deputy Director, Tracy West, discussed a letter received by the Commission that constitutes a rule petition. The petition requested the Commission update the Uniform Controlled Substance Act to remove hemp and industrial hemp from the controlled substance schedules in accordance with the federal 2018 Farm Bill.

MOTION: Ken Kenyon moved that the Commission deny the petition from USP Hemp Organization based on current legislative activity. Steve Anderson seconded. **MOTION CARRIED: 9-0.**

7.2 Discussion on future legislative requests considerations

Executive Director, Steve Saxe led the discussion with the Commission regarding future legislation work.

The Pharmacy Commission is continuing to collect input for the following two bills for consideration in the 2020 or later legislative sessions.

- Update the grounds and process for discipline and enforcement of entity licenses under chapter 18.64 RCW. 2020+ Leg Session
- Omnibus Pharmacy Practice Act Update

The Opioid Response Workgroup had two items that they asked the Pharmacy Commission to facilitate the collection of stakeholder input.

- Engaging stakeholders to discuss potential new policies to eliminate paper prescriptions.
- Develop criteria for when opioid distributors should report suspicious orders.

As part of the initial rule rewrite project, staff started a list of potential laws that the Commission may want to consider request legislation to address. Based on work to date on the rule rewrite project, staff will update the list of potential items to review, do stakeholder work and consider for future legislative requests.

Staff will set up a stakeholder meeting for more input in April 2019 to cover future legislative work.

7.3 Program Budget Report

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. However, a number of vacancies exist in the service units that support the Commission which is helping the budget for the short term. Tracy discussed the policies put in place to save money at the program level and how this has helped expenses as well. Transparency with the budget will continue along with budget updates and discussions.

8. Rules and Sub-Committee Reports

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

Deputy Director, Tracy West updated the Commission that the hearing will be held April 26, 2019.

The Controlled Substance CR-103 was filed and the changes will be effective April 5, 2019.

8.3 Compounding Sub-Committee Report

There was a subcommittee meeting to the FDA's draft MOU. The sub-committee decided to wait for now and will not send out a comprehensive survey to every licensee. The

Commission felt there may be additional updates to the MOU and did not want to then resurvey licensees.

9. Commission Reports / Open Discussion

9.1 Commission Reports

Kat Wolf-Khachatourian reported:

She is a diplomat for Washington State University. They are getting ready to open an Academy of Managed Care Pharmacy (AMCP). She has been supporting them through that. Exciting developments and student development in Washington State

9.2 Commission open Discussion

Judy Guenther asked if there needed to be anything on our website regarding the approval of Washington Association of Pharmacists and Concerned Citizens stating they are not associated with the Pharmacy Commission.

10. Staff Reports

10.1 Executive Director, Steve Saxe staff activity report:

Completed:

- ✓ Revised Self-Inspection Forms – The revised self-inspection forms were updated and posted to the Pharmacy Commission website. These forms should be used for the March 2019 self-inspections.
- ✓ Emergency Rules for Hospital Pharmacy Associated Clinics, chapter 246-873A WAC – These emergency rules that reapproved at the January meeting were refiled with the Code Reviser.
- ✓ Practice Outside of a Pharmacy – Staff added the FAQs approved at the September meeting to the Pharmacy Commission website.

In Process:

- FDA Memorandum of Understanding – Stakeholder meeting was held and a report of next steps will be provided at March meeting.
- Multi-State Pharmacy Inspection Blueprint – The forms have been revised with changes from the January meeting and posted to the website. Copies will now be submitted to NABP for review.
- Emergency Medical Reason – The policy edited at the October meeting completed the department's interpretive statement review process and 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.

Legislative Session Activities –

- The Legislative session was called to order January 14 and has shifted into high gear. All staff are involved in one way or another. In addition to supporting our bills and other bills of interest there are often legislative requests that have very short turnarounds. These activities impact timelines with other work activity of the Commission.
- Healthcare Committee testimony – Staff worked with policy team to prepare testimony on two bills. Chair Lynch testified on the Pharmacy Commission bill on nonresident pharmacies (HB 1331) and Commissioner Kenyon testified on the Compounding bill changing the definition and allowing Commission rule writing (HB 1352)
- Staff presented a brief overview to on the Commission to WSU (Feb 18th) and UW (Mar 4th) students at the two **WSPA legislative days**. We covered the Commission in general and some information on both bills we are supporting and bills we are following.
- Other Legislative meetings include:
 - ✓ Office of Health Professions Meet-me calls for Board/Commission representatives. (1/week)
 - ✓ Health Systems Quality Assurance Bill review meetings (2/week) to discuss bill impact and make recommendations to DOH Leadership/Policy staff.
 - ✓ Pharmacy Commission Legislative Calls – public meeting to discuss bills (1/week)
 - ✓ Health Systems Quality Assurance meeting coordination meeting (daily as needed) – coordinate cross program bills and coordinate analysis.
- Pharmacy Commission Budget subcommittee met and will report at the March meeting. In preparations there has been a lot of work with other offices and the finance staff. This includes meetings on credentialing processes, coordination of shared facility inspections, and analysis of inspection backlogs.
- Commission Appointment Packet – Staff are working with Commission leadership to review the list of applicants for appointment. Following review this material will be forwarded to the Department and sent to the Governor’s office.
- FDA Compounding Memorandum of Understanding (MOU) – Compounding subcommittee (Lynch, Kenyon, Thorstensen, Sieg) held a stakeholder meeting. The Commission will discuss next steps at the March meeting.
- Misfill Media Interview – Following a misfill complaint the Commission was contacted through the agency Center for Public Affairs for an interview. This TV interview is scheduled to air prior to the March Commission meeting.
- Health System Quality Assurance Division Executive Director meeting. Participated in this monthly meeting of the Board and Commission ED’s and Deputy ED’s to share information on issues crossing professions and disciplinary authorities.
- Washington Recovery Assistance Program for Pharmacy (WRAPP) – Executive Director Saxe participated in the Advisory Board meeting. This Board provides oversight to Program Director Will Rhodes. This meeting focused on recruitment of new Advisory Board members.
- WSPA Technician Day – Executive Director Saxe gave a law update at this CE meeting for technicians.

10.1 Deputy Director, Tracy West reported:

- Has taken over inspections and coordinating with OILS on high priority and high profile investigations. There was a conversation on unbalanced workloads with the investigators. The goal is to work on balancing out their work. OILS is working on developing a list of investigation and the priority level. There has also been discussion on the investigative reports and the format to shorten the report.
- Next week Tracy and Steve will be presenting two New Drug Law presentations and going to the MPJE writing workshop at NABP headquarters with Inspector, Tina Lacey.
- Executive Director, Steve Saxe and Tracy had a successful meeting with the University of Washington and Medical Commission representatives regarding CDTA's.

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.
- He continues to work with staff on the Rules Re-Write Project.

11. Summary of Meeting Action Items

Commissioner and staff revisited action items identified during today's business meeting.

There being no further business, the board adjourned at 12:30 p.m.

*Respectfully Submitted by:
Leann George, Program Support for
Approval April 26, 2019*



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