



STATE OF WASHINGTON
DEPARTMENT OF HEALTH
Olympia, Washington 98504

WASHINGTON STATE PHARMACY QUALITY ASSURANCE COMMISSION

Meeting Minutes
April 26, 2019
Department of Health
P.P.E Room 152/153
Tumwater, WA

CONVENE

Chair, Tim Lynch called the meeting to order April 26, 2019 at 8:50 a.m.

Commission Members:

Tim Lynch, PharmD, Chair
Sepi Soleimanpour, RPh, MBA-HA
Kenneth Kenyon, PharmD, BCPS
Michael Sieg, PharmD
Judy Guenther, Public Member
Steve Anderson, RPh
Uyen Thorstensen, Pharmacy Technician
Kat Wolf-Khachatourian, PharmD
Bonnie Bush, Public Member
Jerrie Allard, Public Member
Teri Ferreira, RPh

Staff:

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

Absent Commission Member:

Olgy Diaz, Public Member
Matthew Ronayne, RPh

1. Call to Order

1.1 Meeting Agenda – April 26, 2019

MOTION: Ken Kenyon moved to approve the Amended April 26, 2019 Meeting Agenda. Steve Anderson seconded. **MOTION CARRIED: 11-0.**

1.2 Meeting Minutes – March 7, 2019 Approval

MOTION: Ken Kenyon moved to approve March 7, 2019 Meeting Minutes with suggested amendment from AAG, Christopher Gerard. Steve Anderson seconded.
MOTION CARRIED: 11-0.

1.3 Meeting Minutes – March 8, 2019 Approval

MOTION: Ken Kenyon moved to approve March 8, 2019 Meeting Minutes. Steve Anderson seconded. **MOTION CARRIED: 11-0.**

2. Rules Re-Write Follow-Up

Deputy Director, Tracy West and AAG, Christopher Gerard provided the Commission with topics that have been previously discussed but now need direction from the Commission to incorporate into the Rules Rewrite or to provide other forms of communication for clarification to licensees.

2.1-2.2 Draft Chapters for General Provisions and Operational Standards

a. Pharmacist Responsibility of Compounding by Healthcare Professionals

MOTION: Ken Kenyon moved to waive the attorney client privilege on this document. Kat Wolf-Khachatourian. **MOTION CARRIED: 11-0.**

What degree is pharmacist responsible for compounding by other health care professionals? Pharmacy laws generally cannot restrict the practice of another practitioner. However, the Commission needs to do a case by case analysis on when the Commission may be able to hold a pharmacy accountable for the compounding by other professions.

MOTION: Ken Kenyon moved that staff make the changes appropriately in rule and craft a policy statement with the addition of some cases to include Health Systems and Long-Term Facility aspects along with an example of what falls within the realm of crossing the line in reconstitution. Kat Wolf-Khachatourian seconded. **MOTION CARRIED: 11-0.**

b. Quantity/Dispensing-Prescription Supply Limitations and birth control prescriptions

MOTION: Teri Ferreira moved to waive the attorney client privilege on this document. Kat Wolf-Khachatourian seconded. **MOTION CARRIED: 11-0.**

Does the topic of pharmacist supply limits on contraceptive drugs need to be included in the rule rewrite Or FAQ?

MOTION: Bonnie Bush moved that staff create a FAQ document outlining pharmacist supply limits on contraceptive drugs for the webpage. Steve Anderson seconded.
MOTION CARRIED: 11-0.

c. Therapeutic Substitution/Interchange

MOTION: Teri Ferreira moved to waive the attorney client privilege on this document. Kat Wolf-Khachatourian. **MOTION CARRIED: 11-0.**

Pharmacists don't do therapeutic substitution/interchange independently –unless by CDTA protocol. What direction does the Commission want to take with this topic?

MOTION: Ken Kenyon moved that staff draft an informational document with dialogue around Affordable Care Act requirements to include a hypothetical interchangeable biologics, adopt generic and therapeutic interchange definitions and engage in rule writing to capture the Commissions intent on this topic. Steve Anderson seconded. **MOTION CARRIED: 11-0.**

d. Repackaging

Discussion centered on whether the Commission could write rules on repackaging for all practice settings. Based on the legal analysis and discussion it was determined that the Commission could not write these rules based on the current definition of manufacturing and the legislature's previous amendments via HB 1800 passed in 2013 to exempt certain repackaging related compounded products.

The Commission acknowledged there's a gap that needs to be closed regarding repackaging and directed staff to include this to the future legislative requests.

e. OTC

The discussion focused on state law regarding drug imprinting must be equivalent to federal law. Based on legal analysis it was determined that federal law preempted state law on this topic, and that the federal law should be incorporated by reference in the rule rewrite.

MOTION: Steve Anderson moved that the Commission will incorporate by reference federal standards around drug imprinting Chapter 69.60 RCW. Judy Guenther seconded. **MOTION CARRIED: 11-0.**

f. Identifying Legend Drugs

MOTION: Ken Kenyon moved to waive the attorney client privilege on this document. Kat Wolf-Khachatourian. **MOTION CARRIED: 11-0.**

The concern is that the legend drugs in Washington need to mirror the federal standards.

The Commission agreed that including the federal references in the draft language under General Provision chapter to include language supporting that as of January 1st of each year these references are applicable to rule.

g. Supervision

This discussion was tabled for another time.

3a. Consent Agenda

- 3.1** National Precursor Log Exchange Monthly report – March 2019
- 3.2** Pharmaceutical Firms Application Report Approval
 - a. Closed - February 22 – April 11, 2019
 - b. New/Open – February 22 – April 11, 2019
- 3.3** Ancillary Utilization Plans Approval (may include Specialized Functions)
 - a. Klickitat Valley Hospital Pharmacy
 - b. MENS Pharmacy
 - c. Paktia Pharmacy
 - d. Sixth Avenue Medical Pharmacy
 - e. Unity Care NW – Ferndale and Bellingham locations
 - f. PeaceHealth St. John Medical Center – Tech ck Tech
- 3.4** Pharmacy Technician Training Program Approval
 - a. Carrington College
 - b. Clark College
 - c. Skidmore Pharmacy
- 3.5** Pharmacy Technician Ratio Exemption Approval
 - a. Sixth Avenue Medical Pharmacy
 - b. ProPac Payless Pharmacy
- 3.6** Electronic Prescription Transmission System Approval
 - 3.6.1 Kalos-CIPS - sending and receiving
 - 3.6.2 PETNET Solutions – PETNET Direct - sending

MOTION: Ken Kenyon moved that the Commission approve consent agenda items 3.1 through 3.6. Steve Anderson seconded. **MOTION CARRIED: 11-0.**

3b. Consent agenda Items Pulled

MOTION: Ken Kenyon moved that the Commission retroactively approve the Clark College Pharmacy Technician Training Program to June 2018. Judy Guenther seconded. **MOTION CARRIED: 11-0.**

4. New Business

4.1 Prescription Monitoring Program Updates

Office Director of OHP, Martin Pittioni began the presentation with introduction of Deputy Director of OHP, Blake Maresh and Drug Systems Director, Sasha De Leon. Sasha De Leon leads the prescription monitoring program (PMP), secure drug disposal program, and the medical marijuana program.

Mr. Maresh updated the Commission on key topics of the PMP program.

- **Contract:** The vendor that we utilize offers several products. The Department is considering a migration to a platform that provides enhanced functionality, programming, and other add-ons that provide visualization of the data and a gateway product that allows interstate data sharing.
- **Integration:** Washington has been successful to date in promoting PMP-Electronic Health Record (her) integration via OneHealthPort. Currently, 25 systems, representing 1,183 locations in Washington have integrated PMP data into their EHRs through the Health Information Exchange (HIE). Four systems are currently in testing or planning. Stakeholders would like PMP-EHR integration options independent of HIE.
- **Interstate Connectivity:** Two data hubs currently exist to share PMP data between jurisdictions, RxCheck and PMPi. The Governor’s opioid bill (Section 22(6)) will make explicit our ability to share data with other jurisdictions. There is a CDC grant funding opportunity that allows use of either hub but appears to require connectivity via RxCheck. DOH has already been approached by Oregon and Department of Defense to become data trading partners via PMPi. DOH will be seeking to connect with contiguous and neighboring states in particular.
- **Funding:** PMP is currently funded by 11 different sources. In addition, program is investigating four additional sources of funding:
 - FMAP (part of federal SUPPORT Act)—CMS funding through HCA.
 - OD2A (part of federal SUPPORT Act)—CDC funding through DOH PCH.
 - 2019 legislative decision package.
 - 2019 DOJ BJA Cat 5 grant.

To enhance the current system while also conducting a competitive bid process, the program will need to utilize multiple funding sources while maintaining current operations. OHP believes strongly that in the long term there is a need to consolidate and simplify PMP funding source(s), while finding permanent funding streams

4.2 Healthcare Enforcement & Licensing Modernization Solution (HELMS) Update

Stephanie Goebel, DOH IT Project Program Manager provided an overview of the Healthcare Enforcement and Licensing Modernization Solution (HELMS) project to the Commission. This is a new technology solution to support the licensing and regulatory work of the department. Ms. Goebel discussed the functionality that will be supported by HELMS. HELMS functions will include licensing credentialing and approvals, enforcement functionality, and the policy and administration support. Ms. Goebel also provided an overview of benefits the constituents will get from HELMS. Stephanie closed her presentation with an update on what DOH is doing to make HELMS happen, next steps and questions.

4.3 Dispense Assist Review

Executive Director, Steve Saxe introduced David Owens from the Department of Health’s Emergency Preparedness and Response (DOH EPR) and Michelle Campbell from the Office of Immunization and Child Profile. They provided an overview to the Commission

regarding the Dispense Assist Review, a tool proposed for use in the distribution of medication in a government declared emergency.

The software program automates some of the time consuming aspects of collecting and documenting necessary to support the assessment of patients to make sure they can safely take these medications. By allowing this to be done at home, via computer, smartphone, or other electronic device should speed processing the high number of people that may be impacted by an emergency. Further the automated system will allow the patient information to be uploaded to to document the distribution of drugs and supplies. This would still allow for an assessment at the distribution center but it should be quicker if only verifying the information input by the person.

MOTION: Ken Kenyon moved that the Commission support the software DISPENSE ASSIST and DOH EPR to communicate broadly to our pharmacists and others regarding DISPENSE ASSIST. Steve Anderson seconded. **MOTION CARRIED: 11-0.**

4.4 2020 Meeting Dates Discussion

Program Manager, Doreen Beebe led the discussion with the Commission regarding the two options for 2020 Business meeting dates. Mrs. Beebe also asked if the Commission wanted to continue with two day meetings.

MOTION: Chair, Tim Lynch moved that the Commission chose option two for meeting dates to accommodate the Rules Re Write Timeline in March 2020 and the Commission would like to continue two day meetings. Ken Kenyon seconded. **MOTION CARRIED: 11-0.**

4.5 Correspondence

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

- Naloxone Distribution
- Target Zero
- Syringe Service Programs
- Interpretive Statement on Emergency Medical Reasons definition
- Rules Petition by US Hemp Roundtable: *Update* a bill just passed to remove hemp from scheduling in the legislature.
- NABP Task Force Reports
- FDA Webinar

6.1 Multi-state Pharmacist Jurisprudence Examination (MPJE)

Commissioners, Steve Anderson, Sepi Soleimanpour, Uyen Thorstensen and Jerrie Allard: **Panel C** was asked to review and approve study plans submitted by applicants to retake the Multi-state Pharmacist Jurisprudence Examination (MPJE) for Applicants A-B.

- a. Study plan provided by applicant A

b. Study plan provided by applicant B
Panel C authorized Applicants A and B to retake the MPJE.

8. Legislation, Program and Department Updates

a. 2019 Legislative Session Updates

Rules Consultant, Caitlin Gates updated the Commission on the Legislative Updates. Ms. Gates presented the following:

- The budget agreement will be considered tomorrow April 27, 2019.
- Non-Resident Bill HB 1412 passed effect July 28, 2019. Ms. Gates has been compiling a list of states that already meets the Commissions requirements. Next steps will be discussed at the next meeting.
- The Governors Opioid Bill HB 5380 passed out of the house on April 26, 2019. This bill contained the Pharmacy Commission request legislation from 2018 that eliminated Commission approval of electronic prescription transmission systems was included in this bill. The agreed version also has a requirement for e-prescribing for all controlled substances, effective 2021. There are some exceptions in the bill and it requires the Department to develop a waiver program for this requirement. Other parts of the bill include Partial fill of C-II and standing order expansion for opioid reversal medication.
- HB 1198 requiring health care providers sanctioned for sexual misconduct to notify patients passed, effective Oct 1, 2019.
- HB 1049 regarding whistleblowers passed, effective July 28, 2019.
- HB 1224 one of many drug cost transparency went to conference committee and passed senate.
- Last day of the Legislative Session is April, 28, 2019.

b. Discussion on future legislative requests considerations.

- Deputy Director, Tracy West led the update regarding the Stakeholder meeting held on April 12, 2019. Two topics discussed mandating e-prescribing and suspicious transactions because the Commission was asked to stakeholder those as part of the State Opioid Response Workgroup.
- The Commission previously had mandating e-prescribing of all legend drugs on its priority list. It was agreed that the Commission should let the requirement discussed earlier in SSB 5380 to become effective and implemented prior to moving forward on seeking legislation for all legend drugs to be sent electronically.
- There was discussion on the discipline or entity enforcement. Deputy Director, Tracy West will work with Rules Consultant, Caitlin Gates to update previous draft language.
- The Commission also discussed prescriptive authority for pharmacists. Deputy Director, Tracy West advised the Commission that this concept should come from another entity, not the regulatory authority of the profession.

- The Commission approved the staff recommendation to hold monthly legislative stakeholder meetings. This will allow legislative work to be accomplished in a timely manner.

c. Executive Director recruitment Process

Office Director of OHP, Martin Pittioni updated the Commission on the Executive Director recruitment. He is following the timeline provided to the Commission in January. Mr. Pittioni has been working on updating the position description. The advertisement for the Executive Director position will begin in May/June. There is a plan for a national outreach for the position.

7. Public Rules Hearing WAC 246-901-130 Pharmacist to pharmacy technician ratio

The Commission held a public rules hearing to take testimony related to the proposed amendments to WAC 246-901-130 Pharmacist to Pharmacy Technician Ratio.

MOTION: Steve Anderson moved that the Commission accepts the testimony given during the hearing on April 26, 2019 and will delay the deliberations and decision until the June 2019 business meeting. Kat Wolf-Khachatourian seconded. **MOTION CARRIED: 11-0.**

Commission staff had received a legislative inquiry on staffing levels in pharmacies just before the Commission meeting was to take place. Prior to the hearing starting, staff were made aware of additional concerns related to the inquiry and other staffing bills being considered by the legislature from internal partners. Based on this information Deputy Director, Tracy West recommended the deliberations and vote be delayed to the June meeting, to ensure all concerns were received and the Commission had all information for deliberation.

The Commission is postponing the deliberations and decisions to reflect on additional feedback received this week from our policy office and constituents.

Hearing was concluded at 1:48 p.m.

9. Rules and Subcommittee Reports

9.1 Authorization to file CR-102 permanent rules for Hospital Pharmacy Associated Clinics (HPAC) (currently emergency rules enforce)

Deputy Director, Tracy West has been in working with the Office of the Secretary and the HSQA Rules Office on how to proceed with this rule. The plan was to include the permanent HPAC rule into the rules re-write. However, with the delay in the timeline of the project staff was advised to consider adopting the HPAC rules with amendment to change the definition of compounding to match the definition found in RCW 18.64.011. This rule can be amended as it is added into the rules re-write.

There are concerns that licensees are recently been getting different direction from the DEA and Commission regarding the requirements for transferring controlled substances between HPAC's and the hospital pharmacy. Ms. West has contacted the DEA office to reaffirm the conversation between the Commission and DEA on this subject. There hasn't been any response at this time.

Ms. West will request authorization for permanent rules at the June business meeting.

10.1 Commissioner Reports

Kat Wolf-Khachatourian reported: She is pleased to report that as of March 18, 2019 Washington State University's Academy of Managed Care Pharmacy (AMCP) is now nationally recognized.

11. Staff Reports

11.1 Executive Director

Steve Saxe Reported:

- Chair Tim Lynch testified March 15 at the Senate Healthcare Committee on HB 1412 Nonresident pharmacy inspections.
- Our pharmacy section staff coordinated an Office of Health Professions All Staff meeting. This provided an opportunity for the inspectors to give a presentation of what they do since this is "new" work for the Office of Health Professions.
- Deputy Director Tracy West and Pharmacist Inspector Tina Lacey were at NABP for an MPJE (law exam) item writing session.
- The changes to the draft rules from the March 7 meeting were finalized and the crosswalk was completed. The draft rules and crosswalk was distributed to the commission. They were also distributed to the licensees / public through the email distribution.
- Staff continued ongoing work and meetings related to the opioid response. This included the Bree Collaborative which is planning an opioid conference August 8th and a CDC webinar on the problem.
- Staff did preparation work for both the upcoming future legislation stakeholder meeting and the Commission business meeting and trainings.
- Staff are continuing to track changes at a federal and state level from the FARM bill and associated state legislative actions.
- Staff have been involved in required training on working with our tribal partnerships.
- Law Updates – Staff gave a law update at the WSPA New Drug New Law courses in Seattle and Spokane as well as to the SW Washington Pharmacy Association.
- Transition Work – Staff from both OHP and OILS continue work to support the transition of the Pharmacy Inspectors to OHP and the Pharmacy section.

Completed:

- ✓ **Emergency Medical Reason** – The policy completed the department's interpretive statement review process and was approved at the March meeting. It has been posted to the website.

- ✓ **US Hemp Roundtable** – Letter denying the rulemaking petition given current legislative activity of SB 5276 addressing the suggested changes to Chapter 69.50 RCW. This letter was sent.

In Process:

- **FDA Memorandum of Understanding** – Stakeholder meeting was held. Will monitor both FDA and NABP for any changes that might impact next steps for the Commission.
- **Multi-State Pharmacy Inspection Blueprint** – The forms have been revised with changes from the January meeting and posted to the website. Copies were submitted to NABP for review. Staff have responded to some follow up questions.
- **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.

11.2 Deputy Director

Tracy West reported:

- She will be posting a recruitment for the Pharmacist Supervisor position through HR over the next week.
- Transition is going well, some staff was able to attend this meeting.

11.3 Assistant Attorney General

Christopher Gerard reported:

- He attended the Legal Economic Regulatory Environment of Pharmaceutical Industry in Virginia for two days. He shared that it was incredibly interesting. He made several contacts. The discussions were useful. He is interested in looking into additional opportunities for himself. He will share a summary at the June meeting.

12. Summary of Meeting Action Items

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

5. Open Forum

Julie Akers respectfully requested that the Commission make any additional information public if it is going to be used in the final decision of the rules hearing.

There being no further business, the board adjourned at 2:27 p.m.

*Respectfully Submitted by:
Leann George, Program Support for
Approval June 21, 2019*

A handwritten signature in black ink that reads "Teri Ferreira". The signature is written in a cursive style with a horizontal line above the text.

*Teri Ferreira, Vice-Chair
Washington State Pharmacy Quality
Assurance Commission*