



STATE OF WASHINGTON
DEPARTMENT OF HEALTH
Olympia, Washington 98504

WASHINGTON STATE PHARMACY QUALITY ASSURANCE COMMISSION

Meeting Minutes

June 21, 2019

Department of Health

P.P.E Room 152/153

Tumwater, WA

CONVENE

Vice-Chair, Teri Ferreira called the meeting to order June 21, 2019 at 9:07 am.

Commission Members:

Teri Ferreira, RPh, Vice-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
Bonnie Bush, Public Member
Kat Wolf-Khachatourian, PharmD
Matthew Ronayne, RPh
Jerrie Allard, Public Member
Michael Sieg, 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
Office of Inspections and Legal
Services (OILS)

Absent Commission Member:

Tim Lynch, PharmD, Chair

1. Call to Order

1.1 Amended Meeting Agenda – June 21, 2019

MOTION: Steve Anderson moved that the Commission approve the Amended June 21, 2019 Meeting Agenda. Item 5.3 was removed and placed on the June 20, 2019 Agenda with the request that the “Executive Session” be replaced with “Closed Session” in the future. Ken Kenyon seconded. **MOTION CARRIED: 12-0.**

1.2 Meeting Minutes – April 26, 2019 Approval

MOTION: Bonnie Bush moved to approve April 26, 2019 Meeting Minutes. Steve Anderson seconded. **MOTION CARRIED: 12-0.**

2. Public Rules Hearing Continuation

Commission Discussion and Deliberations re: Proposed Rule Amendment for WAC 246-901-130 Pharmacist to Pharmacy Technician Ratio

Vice-Chair, Teri Ferreira convened the hearing at 9:11 am.

This is a continuation of the public rules hearing held on April 26, 2019. The proposed rule language for WAC 246-901-130 pharmacist to pharmacy technician ratio would authorize the responsible pharmacy manager, who is a pharmacist, to use his or her professional judgement to set staffing levels ensuring appropriate supervision and oversight of ancillary staff and the delivery of safe and appropriate pharmaceutical care. On April 26, the Commission accepted testimony from stakeholders in attendance and reviewed comments received during the official public comment period. The decision was delayed for further review.

The Commission considered and responded to the comments and testimony received on the proposed rule. The Commission acknowledged the proposed rule still had opposition at the time of the hearing, and expressed thanks to the stakeholders for their comments. The Commission further acknowledged that the comments received in opposition had been discussed during previous stakeholder meeting. Commissioner Andersen noted that the movement in other states as well as lack of evidence to support any increases in patient safety concerns in those states as reasoning to move the rule forward.

MOTION: Bonnie Bush moved that the Commission adopt the proposed rule amendment as written for WAC 246-901-130, Pharmacist to Pharmacy Technician Ratio as proposed and authorized staff to file a CR 105 expedited rule to repeal WAC 246-901-140 the requirement for a pharmacy services plan. Sepi Soleimanpour seconded. **MOTION CARRIED: 12-0.**

Rule will be effective 31 days after it is filed with code reviser office. Each person on the hearing sign-up sheet will be given a copy of comment summary.

Hearing was concluded at 9:32 a.m.

After the hearing was concluded the Commissioners took a moment to thank all involved for the hard work. Deputy Director, Tracy West provided an estimated timeline (This is anticipated to be fall 2019) There will be communication sent out via GovDelivery with updates.

3. Consent Agenda

- 3.1 National Precursor Log Exchange Monthly report – May 2019
- 3.2 Pharmaceutical Firms Application Report Approval
 - a. Closed - April 12 thru June 11, 2019
 - b. New/Open – April 12 thru June 11, 2019
- 3.3 Ancillary Utilization Plans Approval (may include Specialized Functions)
 - a. Amerita Pharmacy – specialized functions
 - b. Arbor Health
 - c. Axis Pharmacy – specialized functions
 - d. Family Health Centers
 - e. Ivara Pharmacy
 - f. Peace Health St John Medical Center – specialized functions
 - g. Peach Health United General Medical Center – specialized functions
 - h. Prosser Pharmacy
 - i. Kelley-Ross Compounding Pharmacy – specialized function
- 3.4 Pharmacy Technician Training Program Approval
 - a. Klickitat Valley Hospital Pharmacy
 - b. Lopez Island Pharmacy
 - c. Othello Pharmacy
- 3.5 Pharmacy Technician Ratio Exemption Approval
 - a. Kaiser Permanente Lidgerwood Pharmacy
 - b. Pacific NW Specialty Pharmacy
- 3.6 Electronic Prescription Transmission System Approval
 - a. PDX, In. – PDX Classic – receiving system
 - b. PDX, Inc. PDX Enterprise Pharmacy System (EPS) – receiving system

MOTION: Steve Anderson moved that the Commission approve consent agenda items 3.1, 3.2 (a-b), 3.3 (a-i), and 3.4 (a-c), 2.5 (a-b), and 2.6 (a-b). Ken Kenyon seconded.

MOTION CARRIED: 12-0.

4. Old Business

4.1 Draft Therapeutic Substitution / Interchange Guidance Document

AAG, Christopher Gerard presented a draft guidance document regarding the scope of a pharmacist's ability to engage in drug product substitution. In an effort to provide guidance to the regulated community, the intent of this document is to articulate the Commission's interpretation of a pharmacist's ability to engage in drug product substitution.

After a long discussion it was decided that AAG, Christopher Gerard and Commissioner, Steve Anderson will work with staff to make amendments around the discussion and bring it back for further review.

4.2 FAQ Discussion for Pharmacist DEA Numbers

Executive Director, Steve Saxe presented FAQ's regarding a pharmacist DEA number when prescribing controlled substances with a Collaborative Drug Therapy Agreement

(CDTA) and the use of a hospital DEA number by medical residents, pharmacists or others. The Commission discussed these items and suggested some amendments. These FAQ's will be posted to the webpage.

MOTION: Ken Kenyon moved that the Commission approve the FAQ's with amendments as discussed. Steve Anderson seconded. **MOTION CARRIED: 12-0.**

4.3 FAQ Discussion for Dispensing Limits on Oral Contraceptives

AAG, Christopher Gerard followed up with the Commission regarding the FAQ to provide guidance to licensees on whether a pharmacist is limited to a ninety-day supply of oral contraceptive drugs or can provide a twelve-month supply of oral contraceptive drugs. These FAQ's will be posted to the webpage.

MOTION: Steve Anderson moved that the Commission approve FAQ's as written. Matthew Ronayne seconded. **MOTION CARRIED: 12-0.**

New Business

5.1 Draft Guidance Related to Authority for Opioid Treatment Programs

Executive Director, Steve Saxe presented draft guidance for consideration from the Commission to be used as a consistent message to Opioid Treatment Program (OTP) providers and the pharmacy profession. By statute there is a limited number of drugs that an OTP may order, possess, and administer. This was amended in the 2019 legislative session by SSB 5380, section 30. The intent of the document is to provide guidance on the statutory authority and options for ordering, possessing and administering legend drugs to treat substance use disorder and illness secondary to substance use disorder.

MOTION: Steve Anderson moved that the Commission approve the draft guidance document as presented related to authority for OTP's. Kat Wolf-Khachatourian seconded. **MOTION CARRIED: 12-0.**

5.2 WAC 246-863-040(3), for a Foreign-Trained Pharmacist

Glen Atkinson requested that the Commission consider his education and experience to waive all or portions of the requirement internship hours based on his Foreign Pharmacy Graduate Equivalency Examination (FPGEE) score.

MOTION: Steve Anderson moved that the Commission waive all but 300 hours required for Glen Atkinson to be allowed to take his MPJE and NAPLEX exams. Judy Guenther seconded. **MOTION CARRIED: 12-0.**

5.3 Election of Officers

This item was moved to the June 20, 2019 meeting agenda.

5.4 Correspondence

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

- DEA Press Release on the results of their April 27 Drug Takeback Program.
- Opioid Response Resources
- Washington Recovery Help Line
- King County Drug Takeback Program – “Don’t Hang onto Your Meds” campaign.
- WA Poison Center Take back Your Meds
- Health Care Authority Start with One Campaign.
- NABP Executive Committee Election Results
- FDA Educational Webinar –
- NABP Approved Resolutions
- NABP Notice of the release of the United States Pharmacopeia (USP) standards
- NABP VIPPS Criteria Update

6. Legislation, Program and Department Update

6.1 2019 Legislative Session final update and discussion on implementation

a) Implementation of HB1412

The Commission’s agency request legislation, *HB 1412*, passed in the 2019 legislative session, and will take effect on July 28, 2019. This bill requires all non-resident pharmacies licensed in the state of Washington to submit an inspection report not more than 2 years old that is substantially equivalent upon initial licensure and at renewal. The Commission is now tasked with implementing this legislation. To do so the Commission considered the following:

- Approve List of Recognized States (Attached)
- Create list of recognized third party inspections – currently only the National Association of Boards of Pharmacy Verified Pharmacy Program (VPP)
- Send a letter out to licensees informing them of the changes

MOTION: Ken Kenyon moved that the Commission approve the list of recognized states, create a list of recognized third party inspection programs to include VPP, and send a letter to current non-resident licensees informing them of the changes. Kat Wolf-Khachatourian seconded. **MOTION CARRIED: 12-0.**

b) Implementation of SSB5380

The Commission’s agency request legislation, *SSB5380, Sections 13 and 15*, regarding the removal of the Commission’s requirement to approve systems used for the electronic communication of prescription information passed in the 2019 legislative session. Staff will be sending out letters to communicate the legislative changes to currently approved vendors.

c) Suicide Prevention Taskforce

The State budget bill contained a Suicide Prevention Budget proviso that continued the work of the Safer Home Task Force. This includes a Commission representative. It also requires the Commission to work with the Task Force to post patient materials for pharmacies to download and to conduct a survey of pharmacists and submit a report to the legislature by November 2020.

MOTION: Ken Kenyon moved that the Commission appoint Kat Wolf-Khachatourian to the Suicide Prevention Taskforce. **MOTION CARRIED: 12-0.**

6.2 Draft Reports to State Opioid Response Workgroup

Executive Director, Steve Saxe presented an update on report to the Opioid Response Workgroup from the Commission. These reports are to provide the input that the Commission received during stakeholder work as part of the Statewide Opioid Response Plan.

a) Mandating E-Prescribing for Controlled Substances

MOTION: Ken Kenyon moved that the Commission approved the draft provided to the Commission as the final product and authorize Executive Director, Steve Saxe to submit this work from the subcommittee. Steve Anderson seconded. **MOTION CARRIED. 12-0.**

b) Develop Criteria for Reporting Suspicious Transactions

The Commission is continuing work with stakeholders on developing criteria for wholesaler distributors to report suspicious transactions.

6.3 Future Legislative Requests and Strategy

Deputy Director, Tracy West led the discussion on legislative strategy for the Commission for future legislative session. Ms. West and Mr. Saxe recommend the Commission not propose any legislation for the 2020 legislative session which is a short session (60 days). During short session, agency request legislation is limited to technical changes, budgetary fixes, and bills previously introduced that did not make it out of the last session. The goal of pausing on legislative work for the 2020 session is to put more purposeful focus on the next long session which will be the 2021 session.

The Commission expressed frustration at the slow processes and continued delays in their legislative agenda and priorities. After discussion, the Commission acknowledged that staff and Commission workload has been quite full, which stakeholders supported, but also wanted more concrete steps outlined prior to making a decision on the 2020 legislative session. Ms. West was asked to bring a Legislative Strategy and Action Plan to the August meeting with input from the Department policy offices.

The Commission also assigned staff to work with the Department on HB 1352 regarding the definition of compounding and specific rulemaking authority regarding the same.

6.4 Executive Director Recruitment Update

Office Director, Martin Pittioni updated the Commission on the recruitment for the Executive Director. On July 1st applications will be reviewed by the interviewing panel. Mr. Pittioni informed the Commission that this recruitment is not going to be rushed, rather the panel will focus on finding and recommending the most fitting candidate for the position. Mr. Pittioni asked for the Commissioners to share their top three qualities they are looking for in a candidate. Updates to come. Chair, Tim Lynch and Vice-Chair will join staff for the interview process.

7. Open Forum

Jackson Leong from ProPac Pharmacy shared that ProPac Pharmacy is being purchased by Pharmerica and asked if the previously approved Pharmacist to Technician Ratio Exemptions can be transferred to Pharmerica since all staffing and remains the same.

MOTION: Steve Anderson moved that the Commission allow the transfer of ProPac Pharmacy Ratio Exemptions be transferred to Pharmerica until the new rule is in effect. Ken Kenyon seconded. **MOTION CARRIED: 12-0.**

Jeff Rochon from WSPA shared that during their board meeting a task force on patient access is looking at next steps to address barriers and scope of practice issues has been reinstated. No updates at this time.

8. Requests for Review by Commission Panel

8.1 Multi-state Pharmacist Jurisprudence Examination (MPJE)

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

- a) Consider for approval a study plans submitted by Applicant A to retake the North American Pharmacist Licensure Examination (NAPLEX)

MOTION: Steve Anderson moved that the Commission approve the study plan and authorize Applicant A to re-take the NAPLEX. Michael Sieg seconded. **MOTION CARRIED: 5-0.**

- b) Consider for approval a study plans submitted by applicant B to retake the North American Pharmacist Licensure Examination (NAPLEX).

MOTION: Steve Anderson moved that the Commission approve the study plan and authorize Applicant B to re-take the NAPLEX. Michael Sieg seconded. **MOTION**

CARRIED: 5-0.

- c) Consider for approval a study plans submitted by applicant C to retake the Multistate Jurisprudence Examination (MPJE).

The panel tabled this request. The Applicant must be available for discussion.

9. Rules and Sub-Committee Reports

9.1 Emergency Rules for Hospital Pharmacy Associated Clinics (HPAC)

Deputy Director, Tracy West requested reauthorization to refile the Emergency Rule for HPAC.

MOTION: Ken Kenyon moved that the Commission authorize the refiling of the Emergency Rules for HPAC. Steve Anderson seconded. **MOTION CARRIED: 12-0.**

9.2 Communications and Resolution Program (CRP) Subcommittee / Consideration of Memorandum of Understanding

Executive Director, Steve Saxe shared that the CRP subcommittee and staff met with a representative of the Washington Medical Commission to discuss their current experience. The subcommittee presented the information they have received and recommended the Commission enter into a memorandum of understanding with the Foundation for Health Care Quality and the CRP.

MOTION: Steve Anderson moved that the Commission authorize staff and the subcommittee to work with the Departments contract office to develop and finalize a memorandum of understanding. Judy Guenther seconded. **MOTION CARRIED: 12-0.**

10. Commission Reports / Open Discussion

Teri Ferreira reported:

- This is her first meeting she has chaired covering for Chair, Tim Lynch.

Ken Kenyon reported:

- Attended the WSPA Health System Leadership Meeting.

10.2 Commission open Discussion

Ken Kenyon attended the WSPA Health Systems Leadership Meeting and shared comments he heard regarding the new inspection process. It seems to be more collaborative, a smoother process and assists the pharmacists to better understand the rules. He feels that consolidating the self-inspection process and making it a more interactive document, like allowing for hyperlinking policies and procedures should also streamline inspections. Another challenge identified at that meeting was hospitals wanting documentation stating the pharmacy is in good standing. Additionally, concerns around the

6 month notification letters being received multiple times and not knowing when their blackout dates are applicable. Finally, there were some concerns repeated around the HPAC and DEA process.

Deputy Director West, stated pharmacies should be receiving a letter that states their Statement of Corrections has been approved. This could be used to show a satisfactory inspection. Staff will look into options for additional documentation of a satisfactory survey.

11. Staff Reports

11.1 Executive Director, Steve Saxe staff activity report

A written report was included in the packet. In addition, action items from prior meetings include:

Completed:

- ✓ Report from Drug System - the commission requested update was presented at the April meeting.
- ✓ Report from Healthcare Enforcement & Licensing Modernization Solution (HELMS) – the commission requested update was presented at the April meeting.
- ✓ Repackaging – The Commission asked that current gaps regarding repackaging be addressed in Commission’s future legislation stakeholder work. This was added to work plan of the future legislation subcommittee.

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 met with NABP reps to review comments. Will work on next steps for Commission consideration.
- Review of misfill grid and NCQAC chart – The subcommittee has identified some additional work they want to complete. In April the Commission reviewed some completed cases and asked staff to edit the guidance documents and bring to a future meeting.
- Pharmacist Responsibility of Compounding by Health Professionals – This was discussed at the April 2019 meeting. Staff are asked to make changes to draft rule and edit a policy statement with the addition of health systems and long term care examples. To be discussed at the June meeting.
- Quantity/Dispensing Prescription Supply Limitations – This was discussed at the April 2019 meeting and staff are asked to prepare an FAQ document related to oral contraceptives.
- Therapeutic Substitution / Interchange – This issue was discussed as part of rule re-write project at April 2019 meeting. Staff are also asked to draft an informational document around ACA requirements and generic and therapeutic interchange definitions.

11.1 Deputy Director, Tracy West reported:

- Attended the NABP Annual Meeting.
- Attended the NWPC.
- Ms. West complimented the great work staff did while she was out of the office for these meetings.
- The transition of the inspectors has been going great. The inspectors are providing support where they can. This is very encouraging as we continue to grow as a team. She is enjoying working more closely with the inspectors.
- The team in general is just doing a great job.

11.2 Assistant Attorney General, Christopher Gerard reported:

- He will not be at the August meeting. Eric Sonju will attend the meeting in his absence.
- Chris is looking at the new language for USP 795 and USP 797 language. He believes there may be an option to clarify the definition of compounding around reconstitutions. He will look into this and provide the Commission with options.

12. Summary of Meeting Action Items

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

There being no further business, the board adjourned at 1:50 p.m.

*Respectfully Submitted by:
Leann George, Program Support for
Approval August 2, 2019*



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