



STATE OF WASHINGTON  
Pharmacy Quality Assurance Commission

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Meeting Minutes  
January 31, 2020  
Department of Health  
111 Israel Road SE  
Tumwater WA 98501

**CONVENE**

Chair, Tim Lynch called the meeting to order January 31, 2020 at 9:15 am.

***Commission Members:***

Teri Ferreira, RPh, Vice-Chair  
Craig Ritchie, RPh, JD  
Jerrie Allard, Public Member  
Judy Guenther, Public Member  
Kat Wolf-Khachatourian, PharmD, MBA  
Patrick Gallaher, BS, BPharm, MBA, MPH  
Sepi Soleimanpour, RPh, MBA-HA  
Steve Anderson, BSPHarm, RPh  
Uyen Thorstensen, CPhT  
Olgy Diaz, Public Member

***Staff:***

Lauren Lyles-Stolz, Executive Director  
Tracy West, Deputy Director  
Chris Gerard, AAG  
Doreen Beebe, Program Manager  
Stephanie Martin, Pharmacist Inspector  
Adam Woods, Investigations Supervisor  
Marlee O'Neill, Director of Office  
Inspection and Legal Services

***Absent Commission Members:***

Kenneth Kenyon,  
PharmD, BCPS  
Bonnie Bush, Public Member

**Call to Order**

- 1.1 Meeting Agenda Approval – January 31, 2020
- 1.2 Meeting Minutes Approval – December 19, 2019
- 1.3 Meeting Minutes Approval – December 20, 2019

**MOTION:** Steve Anderson moved to approve the January 31, 2020 meeting agenda. Sepi Soleimanpour second. **MOTION CARRIED.** 10-0.

Before the motion, Jerrie Allard commented that the December 19 and 20 meeting minutes listed Michael Sieg in attendance and absent. **MOTION:** Teri Ferreira moved to approve the meeting minutes with the proposed correction. Steve Anderson seconded. **MOTION**

**CARRIED: 10-0.**

**MOTION:** Teri Ferreira moved to approve December 20, 2019 meeting minutes as amended. Judy Guenther seconded. **MOTION CARRIED: 10-0.**

**2. Consent Agenda**

- 2.1 National Precursor Log Exchange Monthly Dashboard –December 2019
- 2.2 Pharmaceutical Firms Application Report Approval
  - a. Closed - December 10, 2019 thru January 20, 2019
  - b. New/Open – December 10, 2019 thru January 20, 2019
- 2.3 Ancillary Utilization Plans Approval (may include Specialized Functions)
  - a. Eastern’s Pharmacy
  - b. Optum Infusion Services/specialized functions
  - c. Oroville Pharmacy
  - d. Overlake Pharmacy
  - e. Seattle Cancer Care Alliance Peninsula/specialized functions
  - f. Sixth Avenue Medical Pharmacy/specialized functions
  - g. Tri-State Memorial Hospital/specialized functions
- 2.4 Pharmacy Technician Training Programs
  - a. Harbor Drug Company
  - b. K-C Pharmacy
  - c. Mercury Pharmacy Services Inc.
  - d. Whitestone Pharmacy

**MOTION:** Steve Anderson moved that the Commission approve the consent agenda items 2.1, 2.2 (a-b), 2.3 (b-g), and 2.4 (a-d) and pull item 2.3 (a) for further discussion. Patrick Gallaher seconded. **MOTION CARRIED: 10-0.**

Teri Ferreira recused herself from the vote and discussion on item 2.3(a). **MOTION:** Steve Anderson moved that the Commission approve 2.3(a) ancillary utilization plans for Eastern’s Pharmacy. Craig Ritchie second. **MOTION CARRIED: 9-0 and 1 abstained.**

**Prescriptions Stored Outside of Pharmacy for Patient Pick-up.** *Follow-up from December meeting.*

At the December 20, 2019, meeting the Commission heard a proposal from Walgreens to provide medications to employees of Microsoft by having pharmacy technicians deliver medications to the Microsoft campus through a secure locker system. The Commission asked staff for more information related to common carriers, delivery of medications outside of the pharmacy, patient counseling, and supervision of pharmacy technicians. Key elements of the discussion included:

- Can a pharmacy technician deliver drugs outside a pharmacy? Yes, a pharmacy technician can deliver dispensed drugs to patients outside of a pharmacy. The delivery must be under the supervision and control of a pharmacist.
- WAC 246-869-130 prohibits the pharmacy from returning to stock any prescriptions (and other items) after the medications have been taken from the premises where sold, distributed or dispensed. If the patient does not pick up a prescription medication, the medication can be placed in the pharmacy’s “will call” area, but then must be destroyed if not picked up.
- A locker or other delivery space is not an extension of the pharmacy license if it is not located within the pharmacy’s physically licensed space.

- For prescriptions delivered outside of the pharmacy, the pharmacist shall offer in writing, to provide direct counseling and information about the drug, including information on how to contact the pharmacist.
- As with mail order, the pharmacy must take necessary steps for medications with special storage needs e.g. temperature controls.

**MOTION:** Steve Anderson moved to approve the proposal by Walgreens. Kat Wolf-Khatchatourian second. Motion Steve to approve the proposal Kat second. Jerrie Allard added that the Commission is setting a precedence and guidance for future approvals/practices is needed. This practice is permissible under current laws and rules. A policy statement will outline the guardrails or parameters of the practice.

**MOTION AMENDED:** Steve Anderson moved to amend his motion to direct staff to draft a policy statement to outline the guardrails for an organization or pharmacy to delivery for medications outside of the pharmacy. Sepi Soleimanpour recused herself from the discussion and the vote. **MOTION CARRIED** 9-0 and 1 recused.

**Correspondence** Lauren Lyles-Stolz, Executive Director, briefed the Commission on correspondence received from in the fall of 2019 regarding custom flavoring. The Commission and state boards were sent letters from American Society of Health-System Pharmacists (ASHP) National Alliance of State Pharmacy Associations (NASPA), Walgreens and Walmart to United States Pharmacopeia regarding the conflict around custom flavoring and USP 795, requesting clarification that this is not non-sterile compounding.

In addition, Lauren shared that she will be working with staff and commissioners in March regarding the National Association of Boards of Pharmacy (NABP) Multi-state Pharmacy Jurisprudence Examination workshop (MPJE).

**2020 Self-Inspection Worksheets** Tracy West asked that the commission to approve the approach to update the self-inspection worksheets as needed and focus on revamping the forms following the rule rewrite hearing/adoption.

Suggested Changes:

- Direct pharmacies on which addendums are required.
- Added signature line and date for cover page of each addendum to make sure the forms are completed timely and calling out the requirement for self-inspection within 30 days of the change of responsible manager.
- Calling out reconstitution to ensure the pharmacy is completing the non-sterile 795 addendum.
- PDF fillable forms

**MOTION:** Moved Kat Wolf Khatchatourian moved to support the approach of the limited revamping of the forms and moved to approve the revised self-inspection sheets for 2020 as proposed and revisit the forms in the summer as part of the rule rewrite. Teri Ferreira second. **MOTION CARRIED.** 10-0.

### **2020 Legislative Update**

- *SB6110 – importation of prescription drugs from Canada.* The Health Care Authority will seek a federal waiver. Pharmacy Commission represented in workgroup. *Position*

*neutral and monitor.*

- *SSB6086 and SHB2385 – increasing access to opioid treatment.* Creates a registration for remote dispensing site to a license of location for a pharmacy with the use of technology to dispense federally approved medications for the treatment of opioid use disorder. (limited to opioid disorder due to restrictions of the title of the bill) House passed bill with amendments as proposed.
- *SB6113 – Central insulin purchasing program.* Creates a workgroup, which includes a representative from the pharmacy commission, and members appointed by the governor. The workgroup must design a purchasing strategy and provide a report to the governor and legislature detailing the strategy to allow the Prescription Drug Consortium to be the single purchaser of insulin for the state. Health Care Authority is lead and provides staff support to workgroup. Referred to Fiscal Committee. Position neutral and monitor.
- *HB2251 - Expiration date for notification of dispensing interchangeable biological products.* Changes the expiration date of the law RCW 69.41.193 to August 1, 2025. (currently August 1, 2020) Position – support.
- *SB6159 - Tableting and encapsulating machines and controlled substance imitation materials.* Adds language prohibiting the possession, purchase, delivery or selling of tableting machines, and encapsulating machine or controlled substance imitation materials unless authorized by the Controlled Substances Act. (Felony) Chapter 69.52 RCW. Position: *Support concept and monitor. (illegal practice also implicated in counterfeit Fentanyl)*
- *SB6303 Testing and treatment for sexually transmitted infections.* Trained pharmacist may dispense 60-day supply of HIV pre-exposure prophylaxis w/o a prescription if patient meets the criteria in the bill. Trained pharmacist may dispense post exposure prophylaxis w/o a prescription if patient meets the criteria in the bill. • Pharmacist must notify patient's primary care provider or if none provide a list of providers. • Pharmacy Commission will develop training in collaboration with the Medical Commission. • The Department of Health will partner with King County HIV/STD program and King County Correctional facilities on 12 month pilot testing inmate at booking for HIV and Hep C unless refused. Refer to public health department for partner testing/treatment. • Pharmacy Commission member of workgroup appointed by governor re: funding and policy initiatives to address the spread of sexually transmitted infection in WA. • Support for workgroup provided by DOH. (May require amending 69.41.030 definition of prescriber – pharmacist w/o CDTA). Position: *Neutral and available for questions.*
- *HB2662 - Reducing the total cost of insulin.* The bill establishes a workgroup with several representatives from the pharmaceutical industry as well as health carriers, drug purchasing groups, and state agencies (AGO, HCA, PQAC). The workgroup is tasked with designing strategies for reducing the cost of and total expenditures on insulin in WA. Position: *neutral and monitor.*
- *SB6526 – Prescription drug reuse.* The bill requires the commission to adopt rules to allow the dept. of corrections pharmacy to accept for return medications in unit dose packaging or full or partial multiple dose medication cards from facilities it serves and reuse unexpired medication. (working with sponsor of the bill with concerns regarding changes to the drug donation law chapter 69.70 RCW) Position: *High Concern*

*Commissioner Olgy Diaz arrives.*

- *HB2786 - Opioid epidemic response advisory council.* Bill asks for a representative of the pharmacy commission will act as a member of an advisory council convened by the AGO. The advisory council is convened within 30 days from the date the state receives money from litigation against a wholesaler or manufacturer for acts or omissions to its contribution to the increase in opioid addiction. The advisory council has 30 days to make recommendations to the legislature on how best to use the funds to prevent opioid addiction or treat victims of opioid additions. Position *neutral and monitor*.
- *SSB6061- Training standards for telepharmacy* - Beginning January 1, 2021, health care professionals who provide clinical services through telemedicine, other than physicians and osteopathic physicians, must complete a telemedicine training made available by the telemedicine collaborative or alternative training. Position *neutral and monitor*.
- *HB2428 - Students' life-threatening allergic reactions. No Impact to Pharmacy*
- *SB6111 - Creating Pharmacy Tourism Program.* By January 1, 2021, the Public Employees' Benefits Board (PEBB) and the School Employees' Benefits Board (SEBB) must develop a pharmacy tourism program available to enrollees of their health plans. When designing the program, PEBB and SEBB must establish a list of prescription drugs eligible for the program, including, but not limited to insulin, and contract with at least one clinic or pharmacy in Canada. The program must reimburse participants for necessary transportation and other travel expenses and provide a participation incentive, which may include premium discounts, rebates, or a reduction in out-of-pocket expenses.
- *HB1401 – Related to hemp productions – dead bill – exempted last year and in the farm bill. No impact.*
- *SB6609 - Expanding the role of certain pharmacists in the delivery of behavioral health services.* Establishes the title “psychiatric pharmacist practitioner” means a licensed pharmacist who enters into a CDTA with a psychiatrist or child psychiatrist that included collaborative assessment, evaluation, and management of behavioral health conditions. Concerns by other practitioners due to no notation of additional training for pharmacists. Nursing Commission confirmed a number of certifications exist. Concerns related to calling out a type of CDTA and whether it would impact how CDTAs function in general.

### **Reauthorize Emergency Rules - Hospital Pharmacy Associated Clinics Chapter 246-874A**

**MOTION:** Teri Ferreira moved to reauthorized filing emergency rules for Hospital Pharmacy Associated Clinic rules. Craig Ritchie second. **MOTION CARRIED.** 11-0.

### **Commission Panel – Craig Ritchie, Patrick Gallaher, Kat Khatchatourian, and Tim Lynch**

**MOTION** Teri Ferreira moved to delegate items 6.1 through 6.4 to a designated panel. Steve Anderson second. **MOTION CARRIES.** 11-0.

- Study Plans. Commission panel approved study plans for two applicants to retake the MPJE and one applicant’s study plan for MPJE and NAPLEX.

### **Rule Re-write implementation.**

Lauren Lyles-Stolz highlighted four phases on how to get the right messaging out and receive feedback. What do we want to get out, is it received well and are people are informed?

- Phase 1 Messaging, Planning, Stakeholder insights, and Awareness (Jan. – Mar.)
- Phase 2: Education and Academic Detailing (Mar. – June)
- Phase 3: Implementation (July – until)

- Phase 4: Evaluation

Lauren led an exercise with participants on the web to respond to the following:

What words best describe the purpose for the updated rules?	What does the first phase of implementation look like?
<p>A word cloud on a dark blue background with a globe. The most prominent words are 'modernize' (center, large), 'clarify' (below it), 'streamline' (left side), 'contemporary' (top center), 'progressive' (bottom left), and 'simplify' (bottom center). Other visible words include 'standard of care', 'care', 'safety', 'simplification', 'improvement', 'contemporary', 'forward thinking', 'professional integrity', 'patient safety', 'informing', 'standard', 'align', 'guidance', 'update', 'broad', 'feature', 'relevance', 'modernized', 'open forums', 'social media', 'why', 'simplicity', 'roadshow', 'social media marketing', 'email', 'publication', 'notifying', 'webinars', 'student education', 'public input', 'interpretive guidelines', 'web reference', 'understanding', 'non-prescriptive', 'fixing', 'lead with why', 'improvement', 'marketing', 'include larger employers', 'recognition', 'license renewal-resources', 'streaming', 'webinars', 'open forum', 'newsletter', 'mail', 'education', 'town hall meetings', 'roadshow', 'email', 'publication', 'notifying', 'webinars', 'student education', 'public input', 'interpretive guidelines', 'web reference', 'understanding', 'non-prescriptive', 'fixing', 'lead with why', 'improvement', 'marketing', 'include larger employers', 'recognition', 'license renewal-resources', 'streaming', 'webinars', 'open forum', 'newsletter', 'mail', 'education', 'town hall meetings', 'roadshow', 'email', 'publication', 'notifying', 'webinars', 'student education', 'public input', 'interpretive guidelines', 'web reference', 'understanding', 'non-prescriptive', 'fixing', 'lead with why', 'improvement', 'marketing'.</p>	<p>A word cloud on a dark blue background with a globe. The most prominent words are 'education' (center, large), 'town hall meetings' (below it), 'newsletter' (top center), 'mail' (left of center), 'roadshow' (bottom center), and 'email' (right side). Other visible words include 'streaming', 'webinars', 'open forum', 'newsletter', 'mail', 'education', 'town hall meetings', 'roadshow', 'email', 'publication', 'notifying', 'webinars', 'student education', 'public input', 'interpretive guidelines', 'web reference', 'understanding', 'non-prescriptive', 'fixing', 'lead with why', 'improvement', 'marketing', 'include larger employers', 'recognition', 'license renewal-resources', 'streaming', 'webinars', 'open forum', 'newsletter', 'mail', 'education', 'town hall meetings', 'roadshow', 'email', 'publication', 'notifying', 'webinars', 'student education', 'public input', 'interpretive guidelines', 'web reference', 'understanding', 'non-prescriptive', 'fixing', 'lead with why', 'improvement', 'marketing', 'include larger employers', 'recognition', 'license renewal-resources', 'streaming', 'webinars', 'open forum', 'newsletter', 'mail', 'education', 'town hall meetings', 'roadshow', 'email', 'publication', 'notifying', 'webinars', 'student education', 'public input', 'interpretive guidelines', 'web reference', 'understanding', 'non-prescriptive', 'fixing', 'lead with why', 'improvement', 'marketing'.</p>

**Rule Rewrite Awareness Discussion:**

- Consider online acknowledgement of the rules rewrite
- Consider notice on renewal notices
- Consider partnerships with WSPA

**Open Forum**

*Cindy Wilson – question regarding health care entity license of location, suites, etc.*

Each organization must obtain a separate license for each of its locations. One organization occupying multiple suites in one facility is deemed to be occupying one location requiring one license, except when the suites or clinics contain controlled substances than separate HCE licenses are required. Separate organizations occupying the same location must obtain separate licenses

*Cindy Wilson – HCE license – must the monthly inspection be conducted by pharmacy personnel? Unclear in the rules. Pharmacist manager/consultant, what is the relationship and responsibilities? Need clarification*

Historically the practice is for the responsible pharmacist manager to ensure and be responsible for the completion of the monthly inspections; however, on site/clinic staff may conduct the inspection with oversight by the pharmacist. Staff will draft a policy statement to offer clarification to solidify the position of the commission.

*Jenny Arnold - preparing communication focused on community pharmacies on the Coronavirus and other pandemics strategies planning (e.g. fit testing for I95 mask, etc.) to keep health care going.*

*Craig Pederson - Pharmedium 503B facility exited the market 503B - unable to meet FDA requirements – What can be done to ensure outsourcing compounders quality and safety standards?*

## **Sub-Committee and Commission Member Reports**

**Tim Lynch** – Attend NABP meeting. Other states are grappling with similar issues as Washington such as examinations and how questions are formulated. Many states include commissioners in this process. Not suggesting a change – the process is established and is working well for us.

Other shared issues - CBD regulations; medical marijuana; pharmacist testing positive for marijuana – treated similar to alcohol impairment; kiosks – licensed as drug outlets and rules on delivery; wholesaler licenses which we may need to look at in more in depth; interstate compacts (not supported by NABP); federal Food and Drug Administration memorandum of understanding; meal breaks (IL just passed law); staffing levels.

**Patrick Gallaher** – regarding breaks and staffing issues, we have expectations of pharmacists on what they need to do, is the time provided enough to ensure patient safety? (*Potential Stakeholder topic*)

**Kat Khachatourian** – tracking on national level of pharmacists becoming providers (Centers for Medicaid and Medicare Services (CMS) including the Center for Medicare and Medicaid Innovation(CMMI).

Lauren Lyles-Stolz - need to develop strategic planning to prioritize the commission's policy agenda.

## **Staff Reports**

**Lauren Lyles-Stolz** – staffing update – new pharmacist inspector in Spokane area; hiring for rules coordinator; and administrative staff.

**Tracy West** – Eleanor Doss moving to an investigator position; (Kudos from Tim Lynch). Tracy distributed a inspection statistical report since the staff have joined the program team.

**Congratulations** Commissioner Sepi Soleimanpour. Tim Lynch recognized Sepi for her dedicated service and critical member of many subcommittees in the past. She has served on the Commission since 2012. As well as her expert contribution and knowledge in transforming pharmacy with her role in the rule rewrite.

## **Summary of Meeting Action Items.**

- Guidance document of delivery of drugs at off-site location
- Adding notice to renewals and on-line renewals to check or affirm awareness of the rule rewrite.
- Interpretation statement document regarding HCE license of location clarification, and to include:
  - Pharmacy oversight
  - Pharmacy consultant role
  - Update application to add clinic information

- Workplace safety stakeholder work
- CMS position around pharmacist provider

There being no further business, the Commission meeting adjourned at 12:59 p.m.

*Respectfully Submitted by:*  
*Doreen Beebe, Program Manager*  
*Approval March 6, 2020*

A handwritten signature in black ink, appearing to read "Tim Lynch", written in a cursive style.

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