



STATE OF WASHINGTON
Pharmacy Quality Assurance Commission

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Meeting Minutes

March 6, 2020

Double Tree by Hilton Olympia

415 Capitol Way North

Olympia WA

Commission Members:

Kenneth Kenyon, PharmD, BCPS
Michael Sieg, PharmD
Teri Ferreira, RPh, Vice-Chair
Craig Ritchie
Patrick Gallaher, RPh
Tim Lynch, PharmD, Chair
Sepi Soleimanpour, RPh, MBA-HA
Olgy Diaz, Public Member
Bonnie Bush, Public Member
Judy Guenther, Public Member

Staff:

Lauren Lyles-Stolz, Executive Director
Pharmacy
Chris Gerard, AAG
Doreen Beebe, Program Manager
Bonita Campo, Office Manager
Marlee O'Neill, Director of Office
Inspection and Legal Services
Cori Tarzwell, Policy Analyst
Adam Wood, Investigative Supervisor
Pharmacy

Absent Commission Members:

Kat Wolf-Khachatourian, PharmD - excused
Jerrie Allard, Public Member - excused
Uyen Thorstensen, Pharmacy Technician-
excused
Steve Anderson, RPh - excused

CONVENE

8:15 a.m. – 9:26 a.m.

CLOSED SESSION - CASE PRESENTATION

During this time, the Commission will be in closed session to discuss proceedings concerned with discipline of license holders pursuant to RCW 42.20.140(1). **Closed Session.**

1. Call to Order - Tim Lynch convened the meeting at 9:32 a.m. Introductions were made. Cori Tarzwell introduced herself to the Commission

1.

1.1 Meeting Agenda Approval – March 6, 2020

MOTION: Ken Kenyon moved to approve the March 6, 2020 business meeting agenda. Sepi seconded. **MOTION CARRIED: 10-0.**

1.2 Meeting Minutes Approval – January 31, 2020

March 6, 2020

Pharmacy Quality Assurance Commission

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1.3 MOTION: Pat moved to approve the January 31, 2020 meeting minutes. Craig seconded.
DISCUSSION: Chris Gerard suggested edits to the minutes and will provided them to Doreen. Bonnie mentioned a typo to be corrected on third bullet of second page.
MOTION: Patrick Gallagher moved to revoke the previous motion and submit a new motion to approve the January 31, 2020 meeting minutes to include proposed edits by Chris and Bonnie. Chris seconded.
MOTION CARRIED: 10-0.

2a. Consent Agenda Items listed under the consent agenda are considered routine commission matters and will be approved by a single motion of the Commission without separate discussion. If separate discussion is desired, that item will be removed from the consent agenda and placed on the regular business agenda. *Action item.*

Tim asked that 2.3A be pulled and that he is excluded from 2.4B

MOTION: Tim motioned to approve items 2.2 and 2.3 except for 2.3a and 2.4. Sepi seconded.
MOTION CARRIED: 10-0

2.1 National Precursor Log Exchange Monthly Dashboard –January 2020

MOTION: Teri motioned. Sepi seconded. **MOTION CARRIED: 10-0.**

2.2 Pharmaceutical Firms Application Report Approval

- a. Closed - January 20, 2020 thru February 19, 2020
- b. New/Open – January 20, 2020 thru February 19, 2019

2.3 Ancillary Utilization Plans Approval (may include Specialized Functions)

- a. Amazon Pharmacy - Pulled
- b. Arbor Health
- c. Gibbons (multiple locations)
- d. McCleary HealthMart Pharmacy
- e. Olympi Medical Center Pharmacy
- f. RuMed

2.4 Pharmacy Technician Training Programs

- a. Jefferson Family Pharmacy
- b. SeaMar
- c. Yakima Neighborhood Health

2b. Regular Agenda/Items Pulled from 2a. The Commission will discuss items removed from the consent agenda and placed on the regular agenda for separate discussion.

2.3 Ancillary Utilization Plans Approval (may include Specialized Functions)

- a. Amazon Pharmacy

MOTION: Tim motioned to approve the Amazon AUP with the removal of the specialized function language. In addition add language that states that it is a requirement that the use of calibrated canisters must be verified by a pharmacist before putting into operation and the removal of all language referencing an assistant can fill canisters. Sepi seconded. **MOTION CARRIED: 10-0.**

3. Old Business – The Commission will discuss for clarification or decision ongoing topics and revisited issues from previous meetings.

3.1 Update on Communication and Resolution program (CRP) – statement of understanding. **NO ACTION**

3.2 Review guidance document for delivery of drugs to off-site locations.

DISCUSSION:

- Remote supervision
- Location of license
- Storage of meds outside physical location of pharmacy
- Example of agents
 - Walgreen workflow
- Undelivered meds cannot be returned to stock

Ken moved to approve the draft guidelines with the examples given at the meeting today and to solicit feedback and bring to next meeting. Judy seconded.

Lauren suggested a subcommittee to:

1. Post draft online with examples
2. Solicit feedback
3. Bring to next meeting

Ken amended his motion to approve the draft for posting online with providing further examples of what the agent is around controlled substance piece, accept feedback and place on next agenda for final approval. Judy seconded. MOTION CARRIED: 10-0

Break 10:55 – 11:09 am

- 3.3** Review guidance document with details on what specific training and other requirements for ancillary utilization plans to including pharmacy technicians administering immunizations.

DISCUSSION: Lauren Lyles-Stolz and Chris Gerard discussed the development of the guidance document and how to make an ongoing requirement. Chris explained that the guidance document is not going to be enough to deny an AUP based on the training component and would need to go to a rule. However the statute does allow the ability to modify an AUP and then approve it.

DECISION: Preferences for framing analysis

1. The Commission wants to be able to require the training discussed at the last meeting
2. Examine the ability to dovetail into existing rule writing vs and individual rule

4. New Business – The Commission will review items of interest related to pharmacy practice for discussion, clarification, information or action by or on behalf of the commission.

Information/Action.

- 4.1** Presentation by Darrin Grondel, Director of the Washington Traffic Safety Commission re: work related to impaired driving. The goal is to bring awareness and the potential partnership with the Commission as impairment that relates to prescription drugs.

DISCUSSION:

- Target Zero by 2030 Campaign
- Clear impairment labeling on all drugs
- Increasing conversations regarding impaired driving
- Discussions with doctors and nurses as part of office visit
- Require as part of pharmacy consultation
- Roadside Strategies:

- Roadside site searches
- Medical phlebotomy
- Assessing and doing field sobriety tests
- Challenges are meds that are not being looked at for impaired driving capacity
- Roadwise Rx Website promotion

DECISION: Lauren/Doreen will be the point of contact to post on PQAC website and put in newsletter

4.2 Commission will review interpretive statement to clarify location licenses for health care entities and oversight of clinic inspections.

Lauren explained the HCE license requirements in regard to controlled substances requiring separate HCE licenses. She recommended that the 2020 legislative piece be removed from the interpretive statement until after this legislative session.

MOTION: Teri motioned to approve the interpretive statement with the removal of the 2020 legislative position. Judy seconded. MOTION CARRIED: 10-0

4.3 Presentation by Executive Director on preliminary discussions regarding a future Partnership Forum with MQAC, NQAC and others to discuss the future state of regulations in health care.

Lauren relayed that she has been in conversations regarding ideas on how to stay on task in the regulatory environment with MQAC and NQAC. **NO ACTION**

4.4 Consider a request to waive a portion of the internship hours required by a pharmacist applicant applying as a foreign pharmacist graduate.

Emily provided a lengthy synopsis of her background and experience.

MOTION: Tim motioned to deny the request to waive the required internship hours. Judy seconded. MOTION CARRIED: 10-0

MOTION: Tim motioned. Sepi seconded. MOTION CARRIED: 10-0

4.5 Correspondence –The Commission may discuss any correspondence sent or received on its behalf and updates on activities of other boards and commissions.
No questions

4.6 Discussion related to COVID-19 (coronavirus).

DISCUSSION:

- How do licensees follow USP rules with impending shortages of PPE
- How to creatively continue to serve patients when they may not be able to be physically present
- Impending drug shortages
- Short/long term direction to licensees
- Employee safety conducting hazardous drug compounding with inadequate PPE
- Crisis of standards list
- PQAC has statutory duty to enforce laws placed under their authority
 - Commission does not have authority to waive or suspend laws but does have the authority to exercise prosecutorial discretion
 - Would PQAC cite inspections or take actions against an entity/person for violation of a law/rule that has been brought about due to COVID-19

STAKEHOLDER COMMENTS:

- Cindy Wilson from Multicare Health System was concerned about information that was

posted from Critical Point regarding reusing masks

- Lauren will post a disclaimer on GovDelivery that PQAC does not endorse Critical Point and that the post was only meant to be a resource
- Chris Gerard added that if clients can identify issues securing supplies and need assistance from the state to secure and ration supplies he can pass that on to the SEOC
- Craig Peterson from Virginia Mason commented on supply chain shortages, following USP rules in today's climate, non-sterile to sterile and meeting ISO-7 standards.
- Erica Anderson on behalf of herself voiced concerns re suggestions critical points and 12 hour dating and lack of garb. She also talked about the immediate use provision, low-risk compounding and what would be acceptable.
- Jennifer Arnold mentioned the OIC's authorization of early refills, pharmacy chain contingency plans, PPE shortages, and guidance they sent out about low-risk exposure and social distancing

DISCUSSION: There was a short discussion about staffing shortages and possible quarantine causing the need to extend the deadline for self-inspections.

MOTION: Ken motioned to postpone pharmacy self-inspections until the next meeting.

DISCUSSION: Martin Pittioni commented that any relief the Commission could provide would be helpful.

MOTION: Ken motioned to extend deadline for completing pharmacy self-inspections to April 30. Sepi seconded. MOTION CARRIED: 09-1 Patrick Gallaher opposed

Tracy West was acknowledged by the Commission for her diligent work and dedication to PQAC. Tracy shared that she enjoyed serving the PQAC for the past 4 and a half years. Judy added that the Commission is where it's at because of Tracy. Tracy was invaluable during the rules rewrite and all the other work the Commission accomplished under her direction

12:49 p.m. – 1:06 p.m. (Break to get lunches - Members/Staff Working Lunch)

5. Rules, Legislation, Program and Department Updates

5.1 Legislative Update

Doreen gave an update on current legislation

5.2 Rules in Progress or Implementation

a. Chapter 246-945 WAC

- Lauren informed the members that the rules hearing has been postponed due to IMT. Staff filed a continuance and extended the comment period to March 31.
 - b. E-prescribing Controlled Substance – SSB5380 Chapter 314, Laws of 2019
- Teri had asked re long-term care requiring e-prescribing (Virginia Mason) LTC pharmacies don't require a hard copy and it's a challenge of work flow and transition of care.
 - Asking if it is okay to send paper prescriptions with the patients as an exemption. Asking for guidance
- Craig Peterson, Virginia Mason explained that when discharging a pt they don't know what pharmacy fills the Rx for the LTC, it's a contractual arrangement between the LTC and their pharmacy. Difficult because they wouldn't know what pharmacy is used.
 - They offer paper prescriptions that are forwarded on to the contractual pharmacy.

- Tim questions what the Commission could do about this. Perhaps the pharmacy partners with the LTC if they know where to send them

(Panel C)

6. Requests for Review by Commission Panel

Tim asked for motion to delegate 6.1 ad 6.2 to panel including Sepi, Teri, and Ken. Judy seconded.

MOTION CARRIED: 10-0

- 6.1** Consider for approval a study plans submitted by applicant to retake the North American Pharmacist Licensure Examination.

MOTION: Tim motioned. Sepi seconded. MOTION CARRIED: 10-0

- 6.2** Request for Recognition as an Educational Organization – Washington State Pharmacy Association – Lists and Labels request.

MOTION: Tim motioned. Sepi seconded. MOTION CARRIED: 10-0

7. Open Forum

The purpose of the open forum is to provide the public an opportunity to address the Commission on issues of significance to or affecting the practice of pharmacy. Discussion items may not relate to topics for which a hearing has or will be scheduled.

8. Sub-Committee and Commission Member Reports

8.1 Sub-Committee and Commissioner Reports

- Self-Inspection Sub-Committee - **Nothing**

8.2 Commissioners’ open discussion related to items or issues relevant to Commission business/pharmacy practice

DISCUSSION:

- Craig suggested protocol for investigations to include request for recommended actions and that complaint reviews identify potential violations to save time. He will bring suggestions to next meeting.
- Teri wanted to finish COVID-19 discussion. She feels that the 797 has features and situations that need to be reviewed. Pharmacists can enter orders from off-site and would like the Commission to consider prosecutorial permission for technicians to work remotely submitting order entry or billing offsite. Entering new prescriptions or refills as long as the DUR’s are visible to the pharmacist.
- Chris asked them to consider what the parameters would look like, and is it a policy geographically limited to King Co.? Would need clear parameters to implement. Policy #62 talks about the use of technology and technicians working remotely using audio and/or video. Chris feels there are some limits, it allows pharmacists to be on site physically to provide counseling. Temporal and geographic limitations should apply.
- Tim suggests directing them to policy statement
- Pat G commented that inspectors used to give a report or summary talking about trends that offered real time feedback. Tim said that practice was stopped due to budget restrictions. Pat suggested phoning in would take less time and resources.
- Ken said immediate supervisor used to bring the reports in but they are under the Deputy Director now. Tracy presented yearly reports at January meeting. Can look into when supervisor is hired.
- Judy agreed that the supervisor could report it.

9. Staff Reports

9.1 Executive Director – Lauren Lyles-Stolz

- Lauren addressed the GovDelivery noticed based on critical point webinar she drafted
 - Tim supported message but wants to be clear what we are telling people
 - May need to look at what comes in the next few days
 - 24 hr notice required for an emergency meeting if needed
 - Chris says it is inevitable that pharmacies will fail to maintain compliance with USP.
 - Lauren needs guidance how to move forward.
 - The Commission would not take enforcement action or cite facilities if failure to comply is caused by COVID-19
 - Emergency meeting to consider options to lessen prosecutorial
 - The only condition about phone meeting is that DOH offered a location with a speakerphone so public could come to listen.
 - All will be prepared to participate in a call within 24 hour notification
- Tim suggested scheduling a subcommittee meeting to develop recommendations.
 - Tim requested a GovDelivery message be sent to stakeholders soliciting experts in USP to join an emergency subcommittee meeting to evaluate USP standards and potential options in case of an acute shortage. Target date for Wed
- Working on staffing for rules coordinator and the pharmacy supervisor position.
- Suicide prevention survey went out yesterday. Closes in May
- The rules survey people aware but want more information

9.2 Office Director, Health Professions – Martin Pittioni

- Received direction to increase social distancing at DOH
- Next Commission meeting can't be in King Co
- Rules hearing has to be rescheduled, will need to be refiled
- Kristin is in IMT for several weeks so Christie Spice is acting Assistant Secretary
- Significant transition in Pharmacy. Great opportunity for Lauren to build her team. Blake has been reassigned to pharm on a part-time basis to help Lauren.
- Thank you for personal roles as part of confirmation hearings. Rallied around issue with Lauren. All helped and was a clear signal that they aren't any boundaries here.
- Session has been brutal, amount of legislation re pharmacy
- Scam calls continue. Be vigilant

DISCUSSION:

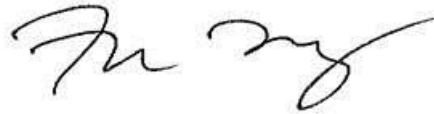
- Rules hearing could be April 23-24 if filed by March 18
- Tim asked if we could move Commission meeting and rules together.
- AGO has conference rooms available will check with LNI
- Teri we have extended our inspection will we have enough time to extend it again?
- Chris suggested holding a meeting by phone.
- Will schedule an emergency meeting for the first week of April to determine what to do.
- Has to be done by the time Cori has to file on March 18th.
- Schedule meeting for March 17th at 7:30 AM for 60-minutes to approve the language for the technician vaccine requirement

9.3 Assistant Attorney General – Christopher Gerard
No report

There being no further business, the commission meeting adjourned at 2:55 p.m.

Respectfully submitted by:

Approval April 24, 2020

A handwritten signature in black ink, appearing to read "Tim Lynch", written over a horizontal line.

Tim Lynch, Chair

Washington State Pharmacy Quality Assurance Commission