



STATE OF WASHINGTON
Pharmacy Quality Assurance Commission

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July 17, 2020

9:00 AM (Open Session)

CONVENE

Vice Chair: Teri Ferreira – called the meeting to order at 9:07.

Commission Members:

Jerrie Allard, Public Member
Steve Anderson, BSP Pharm, RPh
Bonnie Bush, Public Member
Olgy Diaz, Public Member
Patrick Gallaher, BS, BPharm, MBA, MPH
Judy Guenther, Public Member
Ken Kenyon, PharmD, BCPS
Kat Wolf Khatchatourin
Craig Ritchie, RPh, JD
Sepi Soleimanpour, RPH, MBA-HA
Uyen Thorstensen, CPhT

Staff Roll Call:

Martin Pittioni, Director
Lauren Lyles-Stolz, Executive Director
Christie Strouse, Deputy Director
Chris Gerard AAG
Lindsey Trant, Rules & Leg Coordinator
Cori Tarzwell, Policy Analyst
Marlee O'Neill, Deputy Director – Office of
Investigative and Legal Services
Adam Wood, Office of Investigative and
Legal Services
Doreen Beebe, Pharmacy Program Manager
Amy Robertson, Pharmacy Program Support

Absent Commission Members:

Tim Lynch, Chair

Meeting recording: <https://attendee.gotowebinar.com/recording/3469762237442075151>

Chris Gerard clarified earlier statement by Vice Chair – today is not a special meeting as noted; and there are no limitations of items on this agenda.

1. **Call to Order;** Meeting Agenda Approvals

1.1 **MOTION** – Steve Anderson moved to approve the amended agenda adding *1.3 May 29 Meeting Minutes*. Patrick Gallaher, second. Motion carried, 12-0.

1.2/1.3 **MOTION** – Steve Anderson moved to approve as written 1.2 and 1.3 Meeting Minutes Approval for June 19, 2020 and May 29, 2020. Judy Guenther, second. Motion carried, 12-0.

2. **Consent Agenda.**

Commissioners recuse themselves from the following: Teri Ferreira, 2.4.c. Consonus Healthcare; Uyen Thorstensen, 2.4.g. Healthcare Apprenticeship Consortium.

MOTION – Craig Ritchie moved to approve consent agenda excluding 2.4.c. and 2.4.g. Steve Anderson, second. Motion carried 12-0

MOTION – Steve Anderson moved to approve consent agenda 2.4.c. Craig Ritchie, second. Motion carried 11-0.

MOTION – Craig Ritchie moved to approve consent agenda 2.4.g. Patrick Gallaher, second. Motion carried 11-0.

3. **Old Business**

- 3.1 Lauren Lyles reviews: On June 19, 2020, the Commission approved *6086 Remote Dispensing of Opioid Use Disorders* and *CE* policy statements as well as that the *New Rules* supersede old rules.

6086 – Through internal review, minor edits/reframing (and corrected one typo) were made to *6086* to read more like a policy statement (not a rule). The content did not change. According to Chris Gerard, the Commission does not need to revote, simply be advised the edits were made as follows:

1. *Remote dispensing sites must comply with the minimum requirements of substitute senate bill 6086.*
2. *Remote dispensing sites fall within and should comply with the Commission's rules WAC 246-945-455, except for subsection 1(e).*

CE Policy Statements – no content changed in this document, simply retitled to better fit that it is a guidance document. A FAQ was released and is on the website.

New Rules Supersedes the Old Rules – one sentence edited and is now under review internal policy team with DOH.

4. **New Business**

- 4.1 Lauren Lyles: No major changes were made in the *Plan of Correction* the majority of changes were in tone – from “you” to more of a step-by-step plan of action. Also, updated to reflect the new WAC (i.e. from 14 calendar days to 10 business days). Additionally, more accurately reflect that it is a plan of correction.

MOTION – Ken Kenyon moved to approve the new *Statement of Deficiencies and Plan of Correction* as presented. Jerri Allard, second. Motion carried 11-0.

5. **Rules, Legislation, Program and Department Updates - Information/Action**

- 5.1 Chris Gerard summarized the discussion on [USP 800](#) and [USP 825](#) as it applies to chapter [246-945 WAC](#).

Action: Commissioners agree the compounding subcommittee meet and gathering stakeholder input for review and advisement for next meeting.

Chair thanked Chris Gerard for the thorough review.

Compounding Sub-Committee: Patrick Gallaher, Chris Gerard, Ken Kenyon, Tim Lynch, Uyen Thorstensen

5.2 Technical fixes to sections in [Chapter 246-945 WAC](#).

- [246-945-001\(30\)](#) – “*Electronic means*” an electronic device used to send, receive, and/or store prescription information, including computers, facsimile machines, etc. – add *means* after “Electronic means”
- [246-945-001\(44\)\(a\)](#) – replace last *technician(s)* with *pharmacy ancillary personnel or interns*

(44) “Immediate supervision” means supervision by a pharmacist who is immediately available at all times the delegated tasks are being performed; who is aware of delegated tasks being performed; and who provides personal assistance, direction and approval throughout the time the delegated tasks are being performed.

(a) “Immediately available” means the pharmacist and pharmacy ancillary personnel or interns are on the same physical premises, or if not, technology is used to enable real time, two-way communications between the pharmacist and technician(s).

- [246-945-011\(3\)\(b\)](#) – remove ‘s on *OTC’s*
(3) A prescription is considered expired when: ...
(b) The prescription is for a noncontrolled legend drug or OTC's and the date of dispensing is more than twelve months after the prescription's date of issue.
- [246-945-063\(1\)](#) – correct “*registered*” to “*restricted*”; and further definition clarified
(1) “Registered product” means any nonprescription product containing any detectable quantity of ephedrine, pseudoephedrine, and phenylpropanolamine or their salts or isomers, or salts of isomers.

MOTION – Patrick Gallaher moved to approve Technical fixes to sections in [Chapter 246-945 WAC](#) with the exception of 246-945-001(30) selecting ‘edit #2.’ Steve Anderson, second. Motion carried 11-0.

5.3 **MOTION** – Craig Ritchie moved Kat Wolf Khatchatourin continue to serve on [ESSHB 2662 Chapter 346, Laws of 2020 - Reducing the Total Cost of Insulin](#) after her term ends on January 19, 2021. Judy Guenther, second. Motion carried 11-0.

5.4 Update on Health Systems Quality Assurance Commission proposed 2021 legislation.

Presenters: **Christie Spice**, Health Systems Quality Assurance Division Deputy Secretary of Policy; and **Martin Pittioni**, Director - Office of Health Professions

Background by Lauren Lyles: Three legislative items were put forth to the Department recently: 1) Compounding definition revised to exclude reconstitution of compounding; 2) technical fixes for the Commission to delegate authority to a panel (instead of a quorum); 3) expansion of 6086 to all medications.

Christi Spice

Rumor: November Special Session – no decision has been made at this time; if this happens, the focus will be on budget and COVID-19 impact on our economy.

2021 Session will continue to revolve around balancing the budget and reduced revenue. COVID-19 will also be in the forefront and the way we are doing business, telehealth, and behavioral health. The DOH is embracing telehealth and figuring out what professions are allowed to practice in this way.

Legislative Proposals for upcoming session – no decisions have been made as to what DOH will put forward. The three legislative items PQAC put forward will not be on the Department's agenda for 2021 legislative session. They will remain on the division's policy agenda. We will be engaged and working on them with Lauren's team and PQAC doing the preparatory work necessary (stakeholder work, planning, etc.)

The following are concepts under consideration DOH executive team and the Secretary of Health.

- **Division of Health Systems Quality Assurance**
 - **Divergent Centers** – address the issue of the opioid epidemic as it relates to people struggling with behavioral health issues, homelessness, and substance use disorder. Recognizing this population was cycling in/out of jail without having underlying issues resolved. Divergent centers will provide temporary shelter and links to help this population. Divergent centers often staffed by EMTs but these are not licensed ambulance and aid services. Potentially proposing legislation that would allow EMTs to work in that setting without being a licensed ambulance and aid service.
 - **Boards and Commissions** – some of the smaller boards/commissions have difficulty in doing their regular business due to the small size. This proposal would affect dental commission, board of massage, veterinary board, board of nursing home administrators and the physical therapy board. This would include adding additional members so the growing workload such as policy and disciplinary work can be addressed in a timely manner.
- **HSQA Future Agenda(s)** – goals in the next three years. Nothing finalized, some items:

- [HB2426](#) – Safety in Psychiatric Hospitals/Health Care Facilities. Pharmacies will be included in this discussion.
- Legislature has asked us to consider a uniform facilities enforcement act similar to the [Uniform Disciplinary Act](#) we have for healthcare professions.
- Modernize/rewrite pharmacy statutes
- Pharmacy Commission operations

Martin Pittioni

- **How do we support PQAC better?**
 - Legislatively
 - Infrastructure at the Commission to support this work – staff support, hiring exemptions, etc. to support the Commission.
- **HELMS update/replacement**
 - There should be an update to the Commission in October. Topics include contract negotiations, cost of the project, impact on the professions, etc. There is a potential legislative ask for an appropriation.

(General note: commission members, staff members, stakeholders, and Martin Pittioni and Christie Spice thanked everyone at various times for the hard work and dedication of PQAC and the Department.)

Commission Questions/Comments?

- Legislation – Compounding issue:
 - Teri Ferreira mentioned concern of the three legislative items not moving forward. In part because the compounding legislation has been difficult to define.
 - Craig Ritchie – Compounding: if legislation does come in is the Department able to respond to those requests?
 - Christi – yes, as we do for any legislation that is floated that would affect the work of the Department or Boards/Commissions.
 - Ken Kenyon – the compounding definitions have been broken/antiquated for years. My request is to prioritize this issue to the top. The Practice Act is much larger than just the compounding definition. I would request the compounding RCW definition become the primary issue rather than the Practice Act as a whole.
 - Christi – the compounding issue is in the proposal. We understand this is a high priority. We are actively engaged in this issue now.
 - Martin – specifically and very publicly wanted to mention the fact that some of these are not moving forward is not at all from a lack of effort on Lauren’s part. She is very clear and a forceful advocate on the priorities of the Commission.
- Patrick Gallaher regarding “authorizing statutes” – does that step into things like the Practice Act possibly expansion role of pharmacist and care delivery?
 - Christi – yes. The proposal that Lauren brought forward was a rewrite of the Pharmacy Practice Act.

Stakeholders Questions/Comments?

- Anne Hendrickson – 1) feedback from my peers, there seems to be confusion as to what might be a legislative issue people believe it is a PQAC issue. Suggest better communication and clarity on who is in charge of an issue. 2) Also, better clarity to stakeholders on the next steps when a decision is made, i.e., the policy statement. Some thought it was finished, some are confused it is still on the table, etc. There is confusion on how some of the processes take place.
 - Teri explained policy statement was written before the rule rewrite became effective. There is some clarity needing to be updated in that policy statement. Thank you for being a voice for your peers.
 - Lauren explained stakeholders were asking for clarification the enforcement on [USP 800](#). Stakeholders are encouraged to early adopt and you will not be penalized for doing so.
 - Chris Gerard added a policy statement is not *per se* enforceable, but it is meant to reflect the approach the commission is going to take on a specific issue. Over the years, USP has not been clear on when certain things are going to become official, thereby causing additional confusion.
 - Martin applauded Chris' example of the communication challenges. With the complexity, the amount of rulemaking (and it's not over), as well as on-going work. There are two layers, pharmacy specific pieces as well as all the moving pieces, staff, legislature, etc. What can we proactively do to overcome these communication challenges?
 - Ken Kenyon suggested defining what the Commission can and cannot do and how RCWs interact with WACs in an upcoming newsletter would be helpful to stakeholders. Knowing that the Commission can only promulgate rules within the confines of the legislated RCW would empower our stakeholders to work with their legislators and associations to push for action.
 - ACTION ITEMS: Lauren and Doreen will add verbiage to address Ken's suggestion on the website, on GovDelivery, etc. The website was reconfigured recently and that language was taken off, Doreen will put it back until something more can be crafted.

- Jeff Rochon – shared the concerns of the Washington State Pharmacy Association regarding the compounding definition, all the moving parts, and the need to have legislative fixes. [House Bill 1352](#) is still on WSPA's priority list to the point a special interest group was created for compounding and working on this to move it forward with you.
 - Teri expressed appreciation for WSPA's work on this.

- Esther Park – please consider updating dispensing RCW to match the federal national definition which includes the act of delivery.

- Jerrie Allard requests the Department involve not only stakeholders, but actively engage the Commission in this process now and be transparent so this discussion is not lost and repeated three years from now.
 - Christie Spice appreciates/understands Jerrie's point. In doing all the necessary groundwork (even though it is pushed out), she believes it is ensuring success for

future legislation. Partnering with the Commission and Lauren on this is the way we intend to go.

- Judy Guenther – feels the Commission is continually being pushed off on these issues. The frustration of the Commission (and stakeholders) must be very high thinking this will never get done. Is there any assurance that the things pushed off for three years and things in the pipeline are going to actually be accomplished?
 - Christie Spice recognizes the frustration of the Commission and hard work behind everything. There are so many working parts and levels in this issue, a confirmed assurance cannot be made. However, this is now on a very narrow and high priority list. We are absolutely committed to the work and ensure the groundwork is secure and ready to go when the time comes. The COVID-19 pandemic is also having a significant impact on how we move forward.
 - Martin Pittioni – however, we can make a commitment now that it is on the policy agenda (the first critical step), we can actually work to make it happen. Timeline promises just cannot be made, but promises to move it forward can.

5.5 Further information is needed regarding the Washington State Psychological Association’s (WSPA) request for a sunrise review ([18.120 RCW](#)) related to [HB2967 \(2020\)](#) (Section 3.8, page 4). Patrick Gallaher, Craig Ritchie, Chris Gerard, Christie Strouse, and Lauren Lyles will meet before the next Commission meeting to craft the Commission’s initial response.

6. Open Forum (10 minutes) **Information Only** – No responses.

7. **MOTION** – Ken Kenyon moved to delegate items 7.1 and 7.2 to a panel of the Commission. Jerrie Allard, second. Motion carried 11-0.

Panel: Steven Anderson, chair; Judy Guenther, Patrick Gallaher, and Olgy Diaz.

7.1

MOTION – Judy Guenther moved that Consonus Healthcare be recognized/approved as an educational organization, therefore authorizing the release of contact lists for pharmacy technicians credentialed by the Department of Health, as requested. Limiting the approval until such time that the new rules are effective which requires ACPE provider courses only. Patrick Gallaher, second. Motion carried 4-0.

7.2 Hanna Chung set forth numerous actions she will take to study and pass the NAPLEX. Committee members advised her five times is the limit. Members also suggested looking into Kaplan University for more intense study.

MOTION – Judy Guenther moved that Hanna Chung be approved to take the NAPLEX a fourth time. Patrick Gallaher, second. Motion carried, 4-0.

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

Rules Rewrite items:

- **Hospital Pharmacy Associated Clinics (HPAC)** review – September – Lauren Lyles will schedule Commission meeting and stakeholders
- Lauren Lyles will schedule a New Rules projected strategic/review meeting October or December in preparation of the March meeting (after all new rules go ‘live.’).
 - FAQs are being developed PharmacyRules@doh.wa.gov
 - Use *Day 1* of the March meeting to review.
 - A number of items still need review, i.e., ASHP, CPTB, and ACPE if approved recognized program of those then they are already approved. However, PTCB program that is “passed assured,” is recognized but does not have on-the-job-training.

Plan 19 – update Plan 19 to reflect [CDC recommendations](#) (i.e, #6 re: face coverings).

9.1 **Executive Director – Lauren Lyles-Stolz**

Suspicious Orders – due to influx of questions in this new section, Chris Gerard, Christie Strouse, and Lauren Lyles will meet to evaluate. Forward any questions to PharmacyRules@doh.wa.gov.

TPP – temporary practice permit, working internally to address issues arising around this.

Interviews – Inspector Supervisor and Pharmacy Inspector Territory 6 at end of the month.

Furloughs – continue, affecting staff and workloads.

9.3 **Assistant Attorney General – Christopher Gerard**

We are trying to maintain “highest priority.” Currently, advice work continues; researching compounding regulations of the state. With the furlough restrictions there may be some delay. We will keep you updated.

10. **Summary of Meeting Action Items – Lauren Lyles-Stolz**

1. History of compounding summary to stakeholders and make it more public friendly and on website.
2. Compounding Subcommittee
 - a. Anne Hendricksen would like to help – outreach to her.
 - b. USP 800
3. HELMS – future agenda item: licensure system transitioning in 2023.
4. Policy team – Christie Spice and her team policy items and legislative agendas. Involve stakeholders.
5. Psych Bill – Patrick, Craig, and Chris meet prior to August meeting.

6. FAQ – differences between RCWs and WACs for website; define Commission’s roles.
7. Uniform Enforcement – updates as Christie Spice discussed. Some of the items: authority delegated to a panel, ability to find facilities, loss recovery potential, etc.
8. Strategic discussion at September meeting – HPAC, PTCB, and other technical items.
9. Plan 19 – update to reflect Patrick Gallaher’s email from July 4.

There being no further business, the Commission meeting adjourned at 12:25 p.m.

Respectfully Submitted by:
Amy Robertson, Administrative Assistant

A handwritten signature in black ink, appearing to read "Tim Lynch". The signature is fluid and cursive, with the first name "Tim" and the last name "Lynch" clearly distinguishable.

Approval August 28, 2020
Tim Lynch, Chair
Washington State Pharmacy Quality Assurance Commission