



STATE OF WASHINGTON  
Pharmacy Quality Assurance Commission  
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**Pharmacy Quality Assurance Commission Meeting  
June 4, 2021 - Minutes**

Convene: Chair, Tim Lynch called the meeting to order June 4, 2021, 9:03 a.m.

***Commission Members:***

Tim Lynch, PharmD, Chair  
Teri Ferreira, RPh, Vice Chair  
Jerrie Allard, Public Member  
Bonnie Bush, Public Member  
Hawkins DeFrance, Nuclear Pharmacist  
Patrick Gallaher, BS, BPharm, MBA, MPH  
Ken Kenyon, PharmD, BCPS  
Craig Ritchie, RPh, JD  
Uyen Thorstensen, CPhT  
Judy Guenther, Public Member  
William Hayes, PharmD, CCHP

***Staff Members:***

Lauren Lyles-Stolz, Executive Director,  
Pharmacy Commission  
Christie Strouse, Deputy Director, Pharmacy  
Commission  
Christopher Gerard, AAG  
Martin Pittioni, Director, OHP  
Marlee O'Neill, Deputy Director, OILS  
Cori Tarzwell, Regulatory Analyst  
Christie Spice, Acting Assistant Secretary,  
HSQA  
Tami Thompson, Regulatory Affairs Manager,  
DOH  
Tina Lacey, Pharmacy Inspector  
Lindsay Trant, Rules & Legislative Consultant  
Joanne Miller, Program Manager, Pharmacy  
Commission  
Amy L Robertson, Pharmacy Admin.

**1. Call to Order** Tim Lynch, Chair.

**1.1 Meeting Agenda Approval** – June 4, 2021.

**MOTION:** Craig Ritchie moves to accept meeting agenda without revisions; Patrick Gallaher, second. Motion carries, 11:0.

**1.2 Meeting Minutes Approval** – June 4, 2021.

**MOTION:** Craig Ritchie moves to accept meeting agenda without revisions; Ken Kenyon, second. Motion carries, 11:0.

## 2. **Public Hearing on SSB 5380 – convened: 9:30 a.m.**

Lindsay Trant reported that Substitute Senate Bill 5380 (SSB 5380) passed in the 2019 Washington State Legislature. SSB 5380 required prescriptions for controlled substances to be communicated to the pharmacy electronically (among other things) effective January 1, 2021 (due to the COVID-19 public health emergency the Secretary of Health issued a waiver of this requirement until January 1, 2022). The bill also tasked the Department of Health (DOH) to develop a waiver process for practitioners experiencing economic hardship, technological limitations, or other exceptional circumstances limiting their ability to prescribe controlled substances electronically. After the public hearing, the Pharmacy Quality Assurance Commission (PQAC) can consider adopting the rule language as well as authorize filing a CR-103 under joint authority with DOH. (The CR-102 was filed April 5, 2021. PQAC and DOH have 180 days to file CR-103. Once filed, the rule is effective 31 days later.)

Stakeholder's testifying:

**Jeb Shephard, Washington State Medical Association**, testifying on behalf of Shelby Wiebmann. WSMA submitted written comments for PQAC review. We really appreciate the work of the PQAC staff in accommodating our feedback and concerns of previous iterations. We feel this is a really sound rule for helping physician practices and other providers that simply will not be able to meet the mandate for various reasons. WSMA does have a few suggestions in the final comment letter we submitted and understand where the process is. I want to relay with my testimony gratitude to the staff for working with us on this. Thank you.

WSMA supports these proposed rules.

**Greg Lind, nurse practitioner**. Established numerous primary care clinics. Have now established Washington State's first firefighter clinic about 10 years ago (c. 200 firefighters wellness). Mr. Lind sees about 200 firefighters on a regular basis and cannot afford electronic medical records at this clinic. Mr. Lind needs to figure out how the waiver affects him Mr. Lind currently handwrites any controlled substance prescriptions.

Mr. Lind supports these proposed rules.

**Public Hearing adjourned: 9:40 a.m.**

Brief break for staff to prepare response to comments today and return 10:10 a.m. with PQAC response.

10:10 a.m. reconvene.

Lindsay Trant reviewed detailed comments of stakeholders and PQAC responses to the commission (Attachment #1).

**MOTION:** Craig Ritchie moves to approve the amended language for WAC 246-945-014 and authorize staff to file a CR-103 under joint authority with DOH. In addition, moves to approve PQAC staff responses to public comments. Ken Kenyon, second. Motion carries, 11:0.

**3. Consent Agenda.**

- 3.1** National Precursor Log Exchange January
- 3.2** Pharmaceutical Firms Application Report Approval
  - April 1, 2021 thru May 25, 2021– new and closed firms
- 3.3** Ancillary Utilization Plans Approval
  - 3.3.1 Providence Infusion Service
  - 3.3.2 Credena Health
  - 3.3.3 Hawks Prairie Pharmacy
  - 3.3.4 Marymoor Pharmacy
  - 3.3.5 Thrifty Payless-Rite Adi-Update
  - 3.3.6 Yakima Valley Memorial
  - 3.3.7 Walgreens-Update
- 3.4** Pharmacy Technician Training Program Approval
  - 3.4.1 Cascade RX
  - 3.4.2 Hawks Prairie Pharmacy
  - 3.4.3 Kussler Compounding Pharmacy
  - 3.4.4 Rankos Stadium Pharmacy
  - 3.4.5 Virginia Mason Medical Center

**MOTION:** Teri Ferreira moves to approve consent agenda without revisions; Ken Kenyon, second. Motion carries, 11:0.

**4. Old Business.**

**4.1 HCE Self-Inspection Worksheet Update** (information) – Christie Strouse updated PQAC on status of these worksheets. The deadline to submit comments is June 7, 2021.

**4.2 Self-Inspection Worksheets and Updates Regarding New Compounding Law**

Tina Lacey updated the commission on Substitute Senate Bill 1445 (SSB 1445) that passed the legislature this session (effective July 25, 2021). SSB 1445 changed the definition of compounding to exclude reconstitution by specifically excluding for both sterile and non-sterile reconstituted drug products. Self-inspection worksheets affected: General, Hospital/Pharmacy HPAC, and (future) Health Care Entity.

**MOTION:** Ken Kenyon moves to accept the language for the revised General, Hospital and HPAC self-inspection worksheets with the suggested staff edits. Also move we

utilize enforcement discretion to waive the requirements to complete the sterile and non-sterile self-inspection addendums for those entities only if engaging in reconstitution until August 1, 2021. Craig Ritchie, second. Motion carries, 11:0.

#### **4.3 HPAC Subcommittee Update.**

Christopher Gerard, AAG, informed the commission many of the issues on this have been resolved. The subcommittee is ready to move forward with a detailed report for the July 2021 business meeting.

#### **5. 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.*

##### **5.1 OTC wholesalers without license in home state.**

Lindsay Trant reminded PQAC that at the April 23rd business meeting, PQAC voted to accept a proof of license or evidence that the resident state does not require a license or inspections as well as temporarily defer inspections of OTC wholesalers until a method of inspection is established for both in and out-of-state OTC wholesalers. After research, staff found it may be difficult for an out-of-state applicant to meet the requirements of WAC 246-945-246(3). The question before the commission is to determine what, if any, adjustments are needed to accommodate OTC-only distributors.

Lauren Lyles-Stolz did reach out to NABP regarding the process of adding OTC wholesalers to the DDA portfolio. Still waiting on a response.

**MOTION:** Craig Ritchie moves to continue current decision of deferring in and out-of-state OTC wholesalers and accept approval of evidence of a state board not requiring license or inspection for 90 days and request staff to follow-up with NABP and review this at the next business meeting after receiving the information from NABP. Patrick Gallaher, second. Motion carries, 11:0.

##### **5.2 Delegation of Signature Authority. Delegation of Decision Making. Delegation of Appointment of a Brief Adjudicative Proceeding (BAP) Officer.**

**MOTION:** Craig Ritchie moves to approve modifications to **Delegation of Signature Authority** as made during the meeting. Hawkins DeFrance, seconds. Motion carries, 11:0.

PQAC reviewed the **Delegation of Decision Making** and **Delegation of Appointment of a Brief Adjudicative Proceeding (BAP) Officer** and did not have any recommended amendments

### **5.3 Election of Officers.**

PQAC Officers July 2021 – June 2022:

Teri Ferreira was elected Chair and Jerrie Allard was elected Vice-Chair and that their terms will run from July 2021 to June 2022

### **5.4 Review of Joint Operating Agreement (JOA)**

The commission reviewed the JOA and did not identify issues requiring amendment.

## **6. Rules and Legislative Session Updates**

### **6.1 Reauthorizing Filing of Epidiolex emergency rules.**

**MOTION:** Ken Kenyon moves to refile the Epidiolex emergency rules as is. Jeri Allard, second. Motion carries, 11:0.

### **Reauthorizing Filing of the COVID Schedule II prescribing emergency rules.**

**MOTION:** Ken Kenyon moves to refile the COVID Schedule II emergency rules as is. Hawkins DeFrance, second. Motion carries, 11:0.

Note: These rules will last 120 days.

### **6.2 Legislative Proposal Update**

Guests:

- Martin Pittioni, Director, OHP
- Christie Spice, Acting Assistant Secretary, HSQA

Martin Pittioni updated the commission on a proposal moving through the department that includes pharmacy specific items. Division leadership has endorsed both of these 2022 legislative requests and are now at the agency level.

1. Technical enhancements to PQAC operations by granting authority to delegate to a health law judge or panel for facility related cases.
2. Commission compensation – changing all boards/commissions from Class 3 to Class 5 (payroll from \$50 to \$250/day).

Board members thanked Martin for his collaboration and strong advocacy over the years for PQAC and congratulated Christie on her new role.

**7. Requests for Review by Commission Panel C (Uyen Thorstensen, Ken Kenyon, Jerrie Allard, and William Hayes)**

**Panel C convened reviews at 11:55 a.m.**

- 7.1** Pharmacist applicant requests commission approval of a study plan submitted by applicant to retake MPJE fourth time.

**MOTION:** Ken Kenyon moves to approve applicant's study plan and retake the MPJE a fourth time. Jerri Allard, second. Motion carries, 4:0.

- 7.2** Pharmacist applicant requests commission approval of a study plan submitted by applicant to retake MPJE third time

**MOTION:** Ken Kenyon moves to approve applicant's study plan and retake the MPJE a third time. William Hayes, second. Motion carries, 4:0.

- 7.3** Pharmacist applicant requests commission approval of a study plan submitted by applicant to retake NAPLEX and MPJE fourth time.

**MOTION:** Ken Kenyon moves to authorize intern credential for this applicant and require 750 hours internship hours to be conducted and completed prior to coming back to the commission to request re-sit for the NAPLEX; also, panel authorized the study plan and re-sitting for the MPJE a fourth time. Jerrie Allard, second. Motion carries, 4:0.

- 7.4** Pharmacist applicant requests commission approval of study plan submitted by applicant and to retake NAPLEX fourth time.

**MOTION:** William Hayes moves to table consideration of reauthorizing the NAPLEX until the July 2021 business meeting and notification that the applicant has successfully passed the MPJE. At that point the commission will also consider potentially requiring internship hours before granting the authorization to sit for the NAPLEX. Motion carries 4:0.

- 7.5** Pharmacist applicant requests commission approval of a study plan submitted by applicant to retake MPJE.

**MOTION:** Ken Kenyon moves to approve applicant's study plan and retake the MPJE a fourth time. Uyen Thorstensen, second. Motion carries, 4:0.

**Panel C completed reviews at 1:08 p.m.**

Roll Call 1:09 p.m.

**Commission Members:**

Tim Lynch, PharmD, Chair  
Teri Ferreira, RPh, Vice Chair  
Jerrie Allard, Public Member  
Bonnie Bush, Public Member  
Hawkins DeFrance, Nuclear Pharmacist  
Patrick Gallaher, BS, BPharm, MBA, MPH

Ken Kenyon, PharmD, BCPS  
Craig Ritchie, RPh, JD  
Uyen Thorstensen, CPhT  
Judy Guenther, Commissioner  
William Hayes, PharmD, CCHP

**8. Open Forum** – no comments.

**9. Commission Member Reports**

**9.1 Commissioner Reports** – none.

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

- Commission members and staff acknowledged and thanked Tim Lynch for his dedicated work as PQAC chair.
- Craig Ritchie recommended two books that may assist understanding what/how the commission works:
  - [Killshot](#), Jason Dearen (ISBN 9780593085783)
  - [Death in Mud Lick: A Coal Country Fight against the Drug Companies That Delivered the Opioid Epidemic](#), Erick Eyre (ISBN 9781982105310)

**10. Staff Reports *Information/Action*.**

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

Lauren Lyles-Stolz thanked Tim Lynch for his service and leadership for the commission and the program this last year.

Informed the commission virtual meetings will be held through the end of 2021.

Remind licensees telemedicine training requirements are effective June 30, 2021. This legislation was passed in the 2020 session requiring all health care professionals who offer telemedicine to seek training. We will send out a GovDelivery out next week linking resources available to the free training.

ESHB 1196 passed this year. It gives more detail on what will be reimbursed for audio only telemedicine services. Customarily perform duties of audio-only technology (not faxing or emails).

**10.2 Deputy Director** – Christie Strouse – no report

**10.3** Assistant Attorney General – Christopher Gerard – no report

Both Christie Strouse and Christopher Gerard expressed gratitude for Tim Lynch’s dedication and leadership of PQAC.

**11. Summary of Meeting Action Items**

- 2 – Authorize staff to file CR-103 under the joint authority of DOH to include the responses.
- 4.2 – Final revision of self-inspection worksheets for posting to GovDelivery with guidance from the commission.
- 5.1 – Staff follow up with NABP and include information when we have additional information from NABP
- 5.2 – Delegation...
  - ... of Signature Authority – uncheck the second statement (fourth box down)
  - ... of Decision Making – inform DOH this was approved and has no changes.
  - ... of Appointment of a Brief Adjudicative Proceeding (BAP) Officer  
BAP officer – inform DOH this was approved and has not changes.
- 6.1 – Refile the emergency rules and refile reauthorization of COVID Scheduling II
- 7.3 – Follow up with candidate needing the intern license.

**Business Meeting Adjourned. 1:25 p.m.**



**Pharmacy Quality Assurance Commission**  
**Mission Statement**

The mission of the Pharmacy Quality Assurance Commission is to promote public health and safety by establishing the highest standards in the practice of pharmacy and to advocate for patient safety through effective communication with the public, profession, Department of Health, Governor, and the Legislature.

**Vision Statement**

The Washington State Pharmacy Quality Assurance Commission leads in creating a climate for the patient-focused practice of pharmacy as an integral part of an accessible, quality-based health care system.

- As a result, the citizens of Washington State:
- Are well informed about medications;
- Take responsibility for their health;
- Utilize pharmacists and other health care providers appropriately; and
- Experience the highest level of health and wellness.

**Next scheduled business meeting:**

**July 16, 2021**  
**Business Meetings**  
9:00 a.m.  
Virtual – by Webinar

*Accessibility:* This meeting is accessible to persons with disabilities. Special aids and services can be made available upon advance request. Requests must be made no later than ten (10) days prior to the meeting. If you would like general information about this meeting, please call (360) 236-4947. If you need assistance with special services, you may leave a message with that request at 1-800-525-0127 or if calling outside Washington State call (360) 236-4052. TDD may be accessed by calling the TDD relay service at 711. If you need assistance due to a speech disability, Speech-to-Speech provides human voices for people with difficulty being understood. The Washington State Speech to Speech toll free access number is 1-877-833-6341.

**Attachment #1 – Public Comments: Public Hearing on SSB 5380**

Submitter	Organization	Subsection	Comment	Department’s Recommendations
Greg Lind	Nurse Practitioner		Cannot afford to do electronic medical records. Serves hundreds of firefighters. Support of rule but will need a waiver for this specialized practice.	<p>The department does not recommend changing the rule language because this type of practice may qualify for the exemption in (3)(c)(ii) under “other exceptional circumstances,” which does not have a waiver limit.</p> <p>The department recommends signing up for the 5380 e-prescribing rule list on GovDelivery to receive updates, including when the waivers are available.</p>
Jeb Shepard; Billie Dickinson	WSMA	2a	WSMA is concerned by language in (2)(a) that limits the waivers for economic and technical hardship to three years. This three-year limit is an arbitrary figure and is not required by SB 5380. For practices experiencing economic or technical hardships, including those due to the pandemic, it can take years to financially recover and this waiver process was designed to accommodate those circumstances.	<p>The legislature requires the Department to develop an electronic prescribing (e-prescribing) waiver process for practitioners’ experiencing an economic hardship, technological limitations not reasonably in the control of the practitioner, or other exceptional circumstance under SSB 5380. Several stakeholders expressed similar concerns during stakeholder workshops. Many of those concerns, including ones around the waiver’s lifecycle, have been incorporated into this draft rule presented today. This is notable in (2)(b), which does not prohibit the number of waivers a practitioner may apply for due to exceptional circumstances (e.g., widespread health care emergencies.) The department sees a great benefit to patients due to the mitigation of potential medication errors with e-prescribing and optimized care. Limiting the waivers is also in line with the intent of the legislation to require e-prescribing. Therefore, the department does not recommend changing the proposed rule language.</p>
Lynn Kovacevich Renne; Gail Toraason McGaffick	WSPMA	2a-b	While SB 5380 allows DOH to set the waiver time frame, it does not give DOH the authority to limit the number of times an entity may apply for a waiver. Because of that, WSPMA asks that the following changes be made to subsections (2)(a) and (b):	<p>The legislature requires the Department to develop an electronic prescribing (e-prescribing) waiver process for practitioners’ experiencing an economic hardship, technological limitations not reasonably in the control of the practitioner, or other exceptional circumstance under SSB 5380.</p>

			<p>(2) A practitioner who has submitted an attestation for a waiver from the mandate in RCW 69.50.312 is exempt from the electronic prescribing mandate for the calendar year in which the attestation is signed, beginning with the effective date of this section.</p> <p><del>(a) For any category of waiver, a practitioner may submit an unlimited number of annual attestations. economic hardship and technical limitations, a practitioner may attest to the need for a waiver up to three times, giving the practitioner three years to come into compliance with the mandate.</del></p> <p><del>(b) There is no limit on the number of other exceptional circumstance waivers under subsection (3)(c) of this section that a practitioner can submit.</del></p>	<p>Several stakeholders expressed similar concerns during stakeholder workshops. Many of those concerns, including ones around the waiver’s lifecycle, have been incorporated into this draft rule presented today. This is notable in (2)(b), which does not prohibit the number of waivers a practitioner may apply for due to exceptional circumstances (e.g., widespread health care emergencies.) The department sees a great benefit to patients due to the mitigation of potential medication errors with e-prescribing and optimized care. Limiting the waivers is also in line with the intent of the legislation to require e-prescribing. Therefore, the department does not recommend changing the proposed rule language.</p>
Jeb Shepard; Billie Dickinson	WSMA	3a	<p>The definition of economic hardship in (3)(a) is exceedingly narrow. Limiting the parameters to bankruptcy, new or closing practices, and operating a low-income clinic does not reflect the full spectrum of economic hardship that a practice may be facing, including those caused by the pandemic. We recommend striking the language in (3)(a)(i) through (3)(a)(iv).</p>	<p>This issue has received diverse input from stakeholders. The definition aligns with CMS’s Provider Application for Hardship Exception as well as other states that have implemented similar rules such as Iowa and New York. Additionally, issues imposed by the pandemic may fall under ‘other exceptional circumstance’ which does include a broad spectrum of situations that may impact practice. The department’s e-prescription waiver process is aimed at promoting increased interoperability and reducing barrier for providers and patients. The department does not recommend changing the proposed rule language.</p>
Lynn Kovacevich Renne; Gail Toraason McGaffick	WSPMA	3a	<p>The parameters for economic hardship in subsection (3)(a) are too narrow, and don’t consider the financial impact of the pandemic on provider practices. There is a wide gulf between bankruptcy/closing a practice, and significant reductions in revenue due to the pandemic. WSPMA believes that there shouldn’t be any limits for economic hardship.</p>	<p>This issue has received diverse input from stakeholders. The definition aligns with CMS’s Provider Application for Hardship Exception as well as other states that have implemented similar rules such as Iowa and New York. Additionally, issues imposed by the pandemic may fall under ‘other exceptional circumstance’ which does include a broad spectrum of situations that may impact practice. The</p>

			<p>As a result, WSPMA asks for the following changes to subsection (3)(a):</p> <p>(3) A practitioner required to electronically prescribe under RCW <a href="#">69.50.312</a> may submit an attestation for a waiver from this mandate due to:</p> <p>(a) Economic hardship <del>in the following circumstances:</del></p> <p><del>(i) A bankruptcy in the previous year or submitted an attestation for a waiver under this chapter due to a bankruptcy in the previous year;</del></p> <p><del>(ii) Opening a new practice after January 1, 2020;</del></p> <p><del>(iii) Intent to discontinue operating in Washington prior to December 31, 2021; or</del></p> <p><del>(iv) Operating a low-income clinic, that is defined as a clinic serving a minimum of thirty percent medicaid patients.</del></p>	<p>department’s e-prescription waiver process is aimed at promoting increased interoperability and reducing barrier for providers and patients. The department does not recommend changing the proposed rule language.</p>
Jeb Shepard; Billie Dickinson	WSMA	4	<p>We also request that language in (4) be amended to clarify that practitioners must have intended to file a false attestation rather than simply making a mistake while completing the paperwork. Additionally, we request that before DOH files a complaint with the relevant board or commission, that the practitioner is given an opportunity to comply. This is a new rule and a new process for practitioners and DOH alike – we can reasonably expect some confusion as to who is exempt and who is not, as well as how DOH will interpret the language related to the waivers.</p>	<p>The department recommends that the commission accept this recommendation and approve the edits made to the proposed rule, specifically adding the word “knowingly” before “submitting a false attestation” in subsection (4).The department believes this aligns with the intent of the statute.</p> <p>Additionally, providing time to come into compliance is not needed with the further clarification that the false attestation must be “knowingly” submitted to be a violation of the rule.</p>
Lynn Kovacevich Renne; Gail Toraason McGaffick	WSPMA	4	<p>Please amend subsection (4) to require that practitioners must have intended to file a false attestation, rather than simply made a mistake. In addition, prior to filing a complaint with the relevant disciplinary</p>	<p>The department recommends that the commission accept this recommendation and approve the edits made to the proposed rule, specifically adding the word “knowingly” before “submitting a false attestation” in subsection (4).</p>

		<p>commission or board, please give the practitioner an opportunity to comply. This is a new rule, and we can reasonably expect some confusion as to who's exempt and who's not, as well as how DOH will interpret the language related to the waivers.</p> <p>(4) The department may audit waiver attestations submitted by a practitioner to determine compliance with this chapter. Submitting an <u>intentionally</u> false attestation is grounds for disciplinary action against a practitioner's license by the appropriate disciplinary authority as well as fines pursuant to RCW <a href="#">69.50.312</a>(5). <u>Prior to filing a complaint, the department shall give the practitioner a reasonable opportunity to comply with RCW 69.50.312.</u></p>	<p>The department believes this aligns with the intent of the statute.</p> <p>Additionally, adding the last suggested sentence in the rule language is not needed with the further clarification that the false attestation must be “knowingly” submitted to be a violation of the rule.</p>
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