



STATE OF WASHINGTON  
**Pharmacy Quality Assurance Commission**  
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Rules Hearing Minutes  
April 23, 2020  
9:05 Open Session Webinar

**CONVENE**

Chair, Tim Lynch called the hearing to order April 23, 2020 at 9:05 a.m.

***Commission Members:***

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

***Staff:***

Lauren Lyles-Stolz, Executive Director  
Chris Gerard, AAG  
Lindsay Trant, Legislative Analyst, Rules  
Coordinator  
Caitlin Gates, Rules Consultant  
Cori Tarzwell, Policy Analyst  
Martin Pittioni, Director, Office of Health  
Professions (OHP)  
Blake Maresh, Deputy Director, OHP  
Davis Hylkema, Program Support  
Dan Frank, Management Analyst

**1. Public Rules Hearing re: Chapter 246-945 Washington Administrative Code (WAC) – titled: Pharmacy Quality Assurance Commission**

The Commission holds the public rules hearing to receive testimony related to the proposed new chapter of rules.

Chair, Tim Lynch read the housekeeping and ground rules of the hearing. Executive Director, Lauren Lyles-Stolz gave a summary of the rules proposed. The proposed new chapter of rules consolidate multiple chapters of existing rules into one administrative chapter covering four areas in the practice of pharmacy including general provisions, general licensing, professional standards, and operational standards.

At 9:20 a.m., the hearing opened to receive public testimony. Nine public attendees offered testimony. All voiced support for the proposed rules. The following requests were included:

- WAC 246-945-430 – Clarification is needed to specifically reference automated pharmacy system dispensing technology can be used to provide pharmacy services without a pharmacist physically on site.

- WAC 246-945-233 – The language as written may cause issues for hospital pharmacy associated licensees as it remains unclear as to which clinics must be registered as an HPAC. The Commission is requested to clarify whether locations with the four walls of hospital could be licensed as HPACs in contrast to clinics located at a different physical address.
- WAC 246-945-330 – Request to remove subsection (2). If the Commission chooses to keep the section, it is recommended that the language be limited to a prescription refill rather than a renewal.
- WAC 246-945-016 and 017 – Request clarification to the process of outpatient and hospital inpatient labeling.

Upon receipt of all public testimony, Chair, Tim Lynch explained the Commission's next steps in the process. All comments received in writing as well as those just heard will be summarized and become part of the official rulemaking file. The public comment portion ended at 9:45 a.m. The Commission will return at 10:45 a.m. to discuss and deliberate the proposed new chapter rules

**At 10:48 a.m.** Chair, Tim Lynch called the Washington State Pharmacy Quality Assurance Commission rules discussion to order. The Commissioners members introduced themselves.

***Those present:***

Teri Ferreira, RPh, Vice-Chair  
Bonnie Bush, Public Member  
Craig Richie, RPh, JD  
Jerrie Allard, Public Member  
Judy Guenther, Public Member  
Kat Wolf-Khachatourian, PharmD, MBA

Kenneth Kenyon, PharmD, BCPS  
Olgy Diaz, Public Member  
Patrick Gallaher, BS, BPharm, MBA, MPH  
Sepi Soleimanpour, RPh, MBA-HA  
Steve Anderson, BSPHarm, RPh  
Uyen Thorstensen, CPhT

Executive Director, Lauren Lyles-Stolz read each comment with corresponding suggested response for the Commission's consideration. The comments were considered individually, grouped within the four areas (parts) of the practice of pharmacy, which are (1) general provisions, (2) general licensing, (3) professional standards, and (4) operational standards.

**Part 1, general provisions covering WAC 245-945-001 through WAC 246-945-100**

**MOTION:** Steve Anderson moved to approve the non-substantive changes recorded below. Second by Teri Ferreira. **Motion carried.** 12-0

- WAC 246-945-001 Definitions – Renumber definitions in alphabetical order ("License Transfer" and "Therapeutic Substitution")
- WAC 246-945-001 Definitions – (29)(a-d) Include drug-device evaluations, i.e., syringe
  - WAC 246-945-001 Definitions – (64) Prescription drug. Strike the language, " Except for blood and blood components intended for transfusion or biological products that are also medical devices,"
- WAC 246-945-001 Definitions – (46) Change language to read "...any article drug that has an investigational drug application (INDA) and has been approved by the FDA."

- WAC 246-945-001 Definitions – (69) Expand the definition of "Readily retrievable" to include any records, electronic or written.
- WAC 246-945-001 Definitions – Add a definition of HIPAA. (See WAC 246-945-430.)
- WAC 246-945-001 Definitions – Adjust the definition of “prescription drugs” so that treatments like IVIg are included appropriately, without including blood supply in the definition. Strike "Except for blood and blood components intended for transfusion or biological products that are also medical devices."
- WAC 246-945-013 Partial filling of prescriptions – In subsection (2), add “as applicable” to the end of the sentence. The rule will read: “A pharmacist may partially fill a prescription for a controlled substance listed in Schedule II within the limits of RCW 18.64.265, 21 U.S.C. Sec. 829, and 21 C.F.R. Sec. 1306.13 as applicable.”
- WAC 246-945-016 Prescriptions - Outpatient labels - minimum requirements – Include "as applicable" after “<825>” to clarify that only the applicable USP chapter(s) applies to the prescription.
- WAC 246-945-017 Prescriptions - Hospital inpatient labels - minimum requirements – In subsection (2), add the words, “as applicable.” after “<825>”
- WAC 246-945-017 Prescriptions - Hospital inpatient labels - minimum requirements. – Change (2) to read, ... “must meet the labeling requirements of USP chapters <795>, <797>, <800>, or < 825> if applicable.”

## **Part 2, general licensing covering WAC 245-945-145 through WAC 246-945-255**

**MOTION:** Teri Ferreira moved to approve the non-substantive changes recorded below.  
Second by Steve Anderson. **Motion carried.** 12-0

- General licensing – Update references to the fee rules with XXX with new 2-year renewal periods. Current fix will reference WAC 246-907
- WAC 246-945-215 Pharmacy technician education and training programs – Change section (4) to read, “Except for the programs listed in 246-945-215 (1), pharmacy technician training program must renew every five years.” And, add a section (5) to read, “Any substantive changes to the program or change in program director must be reported to the commission within thirty calendar days.
- WAC 246-945-220 Pharmacy Technician - continuing education – Change subsection (1) to read, “As part of the process to renew a Pharmacy Technician license, a Pharmacy Technician shall complete continuing pharmacy education (CPE) in compliance with this section.”

Chris Gerard, AAG, noted that WAC references in WAC 246-945-230, currently showing XXX need to be changed to the actual number. These are found in (2)(b), (3)(b), (3)(c), and (3)(f).

## **Part 3, professional standards covering WAC 245-945-305 through WAC 246-945-370**

**MOTION:** Steve Anderson moved to approve the non-substantive changes recorded below. Second by Teri Ferreira. **Motion carried.** 12-0

- WAC 236-945-332 Continuity of care – Change subsection (2)(c) to read, “Record the prescription or patient record as an “emergency” prescription.”
- WAC 246-945-355 Monitoring of drug therapy by pharmacist – Strike the word “be” in the second sentence. The sentence will read, “Monitoring of drug therapy includes, but not limited to, the evaluation of...”

**Part 4, operational standards covering WAC 245-945-405 through WAC 246-945-600**

In a comment, WSHA posed several questions concerning WAC 246-945-430 Pharmacies storing, dispensing and delivering drugs to patients without a pharmacist on-site. Their questions are:

- Would the Commission consider quarterly inspections instead of monthly?
- Do audio and video communication recordings need to be retained for two years, per WAC 246-945-020?
- Are there requirements in other areas of state statute that require facilities to post a notification about visual surveillance? If so, it would be helpful to include a reference to those in the proposed WAC’s addressing surveillance and security.
- Does this apply to Washington State pharmacies who supervise facilities located out of state?
- Does this apply to Washington State facilities who are supervised by out of state pharmacies?
- Is there any conflict between this section and state afterhours dispensing laws, or with 42 CFR 48.25.b- Condition of Participation?

The Commission recognized that the questions warrant review. It was suggested that public education be provided on this rule.

**MOTION:** Bonnie Bush moved that the proposed rule move forward as written rather than hold it back. Second by Craig Richie. **Motion carried.** Approved 9/Abstentions 3 (Tim Lynch, Terri Ferreira, Ken Kenyon)

**MOTION:** Teri Ferreira moved to approve the non-substantive changes recorded below. Bonnie Bush second. **Motion carried.** 12-0

- WAC 246-945-410 Facility standards – Change (8)(c) to read, “The medication delivery system is being used to provide access to medications on override and only a quantity sufficient to meet the immediate need of the patient is removed; or”
- WAC 246-945-415 Dispensing and delivery of prescription drugs – In subsection (4), and in subsection (4)(a), correct “(1)(a)” to read (2)(a).
- WAC 246-945-490 Nuclear pharmacies – In subsection (3) and subsection (4), strike “<800> and”.

The Commission considered the general comments received. General comments were included for reference and completeness of record. They included no recommendations, and no action was required.

The Commission reviewed the verbal comments received during the public comment period of the hearing. Recommendations had been addressed earlier in the Commission's review. No additional actions were required. Walgreens Pharmacies asked to be on record as being in support of the proposed rules.

Chair, Tim Lynch invited final comments. There were no final comments.

**FINAL MOTION:** Terri Ferreira moved to adopt the proposed new chapter of rules with the approved non-substantive changes. Second by Steve Anderson. **Motion carried unanimously.** 12-0

**For the record – for future meetings:**

**The following are substantive recommendations the Commission identified to be considered after the new rules are in effect:**

- WSHA's recommendations for WAC 246-945-233 Hospital pharmacy associated clinics. Requested is to clarify whether locations within the four walls of the hospital could be licensed as HPACs, in contrast with clinics existing with a different physical address. Also requested is standardizing the licensing process for hospice pharmacies that are located on hospital campuses, instead of treating them separately under WAC rules governing long-term care.
- CVS' recommendation of language changes in WAC 246-945-317 Tech Check Tech.
- Washington Association of Nurse Anesthetists' recommendation regarding knowing the intent of the prescriber in WAC 246-945-335 Prescription Adaptation.
- Walgreens' recommendation for WAC 246-945-410 Facility standards. Requested is to add the phrase "...” except in the case of an emergency” at the end of the section.
- WSHA's questions concerning WAC 246-945-430 Pharmacies storing, dispensing and delivering drugs to patients without a pharmacist on-site. (See Part 4 record above.)
- CVS' recommendation of language change in WAC 246-945-485 Destruction or Return of Drugs and Devices.

**Other comment responses to be considered:**

- Creating an FAQ document to be posted on the website to provide clarification for D Downing's question on WAC 246-945-012 Prescription refills.
- Creating an FAQ on pharmacist discretion in response to Lorri Walmsley's (Walgreens) comment on WAC 246-945-345 Prescription transfers.
- Providing public education to address WSHA's recommendation for WAC 246-945-430 Pharmacies storing, dispensing and delivering drugs to patients without a pharmacist on-site.

**2. Conclusion of Public Hearing**

Chair, Tim Lynch explained that the Notice of Adoption will be filed with the Code Reviser, and the rules will be effective on July 1, 2020.

The hearing concluded at 4:32 p.m.

**3. Next Steps if time permits**

No next steps were taken.

**4. Adjournment**

There being no further business, the Commission meeting adjourned at 4:32 p.m.

*Respectfully submitted by:*

*Approval May 29, 2020*

A handwritten signature in black ink, appearing to read "Tim Lynch", is centered on the page.

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