STATE OF WASHINGTON
Pharmacy Quality Assurance Commission
PO Box 47852 – Olympia, Washington 98504-7852
Tel: 360-236-4030 – 711 Washington Relay Service

Pharmacy Quality Assurance Commission Special Meeting
August 5, 2022 - Minutes

Convene: Chair, Teri Ferreira called the meeting to order August 5, 2022, 12:08 p.m.

Commission Members:
Teri Ferreira, RPh, Chair
Jerrie Allard, Public Member, Vice Chair
Bonnie Bush, Public Member
Uyen Thorstensen, CPhT
Hawkins DeFrance, Nuclear Pharmacist
William Hayes, PharmD, CCHP
Craig Ritchie, RPh, JD
Matthew Ray, PharmD
Ken Kenyon, PharmD, BCPS

Staff:
Marlee O'Neill, Executive Director
Lindsay Trant, Deputy Director
Christopher Gerard, AAG
Joshua Munroe, Legislative and Rules Consultant
Taifa "Nomi" Peaks, Pharmacist Consultant
Haleigh Mauldin, Program Consultant
Amy L Robertson, Communications Coordinator and Program Support

Commission Members Absent:
Patrick Gallaher, BS, BPharm, MBA, MPH
Judy Guenther, Public Member
Helen H. Jung, PharmD, MBA
Tim Lynch, PharmD, MS, FABC, FASHP
Ann Wolken, PharmD, RPh

1. Call to Order Teri Ferreira, Chair.

1.1 Meeting Agenda Approval – August 5, 2022

MOTION: Craig Ritchie moved to approve the special meeting agenda for August 5, 2022. Ken Kenyon, second. Motion carries, 9:0.

2. New Business

2.1 Ancillary Utilization Plans Approval – Multicare AUP

MOTION: William Hayes moved to approve AUP-Multicare. Ken Kenyon, second. Motion carries, 9:0.

3. Rules and Legislative Updates

3.1 Uniform Facilities Enforcement Framework (UFEF) - Draft Bill Language

Marlee O'Neill reviewed the history of the UFEF draft bill language. Staff will send out GovDelivery message for written feedback from stakeholders no later than August 19. Another special meeting will be held August 24 to review the feedback.

Christopher Gerard continued the discussion and presented the overall objectives and framework of the language in the UFEF.

Overall Objectives

- Applies to Non-UDA License Holders Only
- Uniform Enforcement
- Enhance Enforcement Options
- Clarify Secretary Authority for Unlicensed Cases
- Clarify Enforcement Procedure

UFEF Framework

- Section 13 and 14 – Commission's Powers and Duties, and Definitions
- Section 15 and 16 – Addresses Notice and Procedural Requirements for Non-UDA Enforcement
- Section 17 – Addresses the Types of Non-UDA Enforcement Action, Including Suspension, Revocation, Modification, Imposition of Reasonable Conditions, Stop Service, and Civil Fines.
- Sections 18 – 33 – Incorporates Sections 15 through 17 into a number of other statutes that the Commission has licensing and enforcement authority within. Also clarifies that the Secretary of Health will have enforcement authority over entities that are unlicensed.

Commissioner discussion:

- Commissioners Craig Ritchie and Ken Kenyon would like to see a provision added that would allow the Commission to take enforcement action against a nonresident pharmacy who has been subject to an enforcement action by another state.
- The definitions need clarification and would like to attempt to hold facility owners responsible.
- Have some ability to take action against a non-licensed person if their facility has a deficiency.
- The civil monetary fine is huge step forward. However, we need to ensure we are not disproportionately having a greater impact on our in-state facilities and look at how we can enhance compliance/discipline on the out-of-state facilities.
- Want to ensure first priority is compliance and not simply taking action or fining an entity because of action in another state but that we are taking action that ensures protection of Washington patients.

Stakeholder Mary Storace, Washington State Hospital Association – appreciates the time the commission is spending on this matter.

3.2 Rescinding of Governor's Proclamations and Decision on CE Requirement

Lindsay relayed that Governor Inslee announced he will rescind the following effective as of October 27th, 2022: Proclamations 20-52.10 (which incorporates 20-06, 20-10, 20-16, 20-17, and 20-18), 20-24.3, 20-32.11, 20-36.10, 20-59.8, 20-65.5, 20-66.5 and 20-74.3. The most relevant to the commission are 20-32.11 and 20-36.10 regarding CE requirements, ancillary utilization plans, manufacture of hand sanitizer, and storage of vaccines and COVID-19 treatments outside of a pharmacy.

MOTION: Commissioner Jerrie Allard moved to approve staff sending a GovDelivery to stakeholders stating, "the commission encourages licensees to continue with their CE

requirements. However, the commission will not take enforcement action and\or conduct audits on CE requirements until one full renewal cycle after Oct 27, 2022, the anticipated date on which the governor will rescind proclamation 20-32." Hawkins DeFrance, second. Motion carries, 9:0.

4. Open forum – no discussion.

5. Summary of meeting action items.

- 2.1 – carry out the AUP approval
- 3.1 – incorporate feedback from today into the UFEF draft language and send out GovDelivery soliciting feedback from licensees by August 19 in preparation for the special meeting on August 24.
- 3.2 –send a GovDelivery stating that the commission encourages earning CE, but not take enforcement action and the department will not conduct CE audits until one full cycle after October 27, 2022 (with examples) when the governor's recission of 20-32 is effective.

Business Meeting Adjourned. 1:42 p.m.

STATE OF WASHINGTON
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Pharmacy Quality Assurance Commission Special Meeting
August 24, 2022 - Minutes

Convene: Chair, Teri Ferreira called the meeting to order August 24, 2022, 12:07 p.m.

Commission Members:
Teri Ferreira, RPh, Chair
Jerrie Allard, Public Member, Vice Chair
Bonnie Bush, Public Member
Uyen Thorstensen, CPhT
Hawkins DeFrance, Nuclear Pharmacist
William Hayes, PharmD, CCHP
Patrick Gallaher, BS, BPharm, MBA, MPH
Judy Guenther, Public Member
Helen H. Jung, PharmD, MBA
Matthew Ray, PharmD
Ken Kenyon, PharmD, BCPS
Ann Wolken, PharmD, RPh

Staff:
Marlee O'Neill, Executive Director
Lindsay Trant-Sinclair, Deputy Director
Christopher Gerard, AAG
Joshua Munroe, Legislative and Rules Consultant
Amy L Robertson, Communications Coordinator and Program Support

Commission Members Absent:
Tim Lynch, PharmD, MS, FABC, FASHP
Craig Ritchie, RPh, JD

1. Call to Order Teri Ferreira, Chair.

1.1 Meeting Agenda Approval – August 24, 2022

MOTION: Ken Kenyon moved to approve the special meeting agenda for August 24, 2022. William Hayes, second. Motion carries, 12:0.

2. Rules and Legislative Updates

2.1 Uniform Facilities Enforcement Framework - Draft Bill Language

Marlee O'Neill reminded the commission, the goal of these enforcement tools is to provide a progressive set of tools as an alternative to the commission's current options which are limited to suspending or revoking an entity's license or denying an entity's application. While this adds more enforcement options, it is important to note that the goal here is to provide less severe options to help entities come into compliance. This applies only to *entities* the commission regulates. The commission is not proposing any changes to the disciplinary process for *people* that it regulates.

Christopher Gerard, AAG, reviewed changes made to the language of the UFEF.

- Section 13 – new – clarifies the commission has the authority to allow the Secretary of Health to appoint *pro tempore* members to disciplinary cases.
- Section 15 – There are two changes: (1) non-substantive changes for clarity, and (2) creating authority for the Commission to accept the surrender of a license from a facility.
- Section 17 – Additions made to clarify overall intent, particularly on the commission's ability to impose conditions immediately if the violations amount to immediate jeopardy.
- Section 18 – new – provides mechanism for a suspended licensee to request reinstatement.
- Section numbers were updated.

Teri Ferreira reviewed the three comments submitted by WSHA during the comment period for this item. The commission addressed WSHA's concerns and agreed with the proposed responses staff drafted.

Discussion of commissioners and stakeholders centered around type, cost, multiplicity of infractions and how to fine in a fair manner. During the rulemaking process, the commission will develop a fining matrix with input from stakeholders.

MOTION: Ken Kenyon moved to approve the comments the commission has provided to those that have submitted commentary on these proposed changes to the rules. Patrick Gallaher, second. Motion carries, 12:0.

Next Steps: Lindsay Trant-Sinclair, Deputy Director

- The deadline to submit the full bill to the Code Revisor is August 26, 2022. (We have been discussing only the pharmacy piece.)
- The pharmacy part will need to go into "bill language" reviewed by the department.
- Goes to the Office of Financial Management and the Governor's Office for review.
- Pharmacy staff will provide updates as needed.

MOTION: Ken Kenyon moved to approve the August 24, 2022 updated draft language for Uniform Facilities Enforcement Framework with changes discussed in today's meeting. Hawkins DeFrance, second. Motion carries, 12:0.

3. Open forum

- David Streeter, Washington State Hospital Association, thanked the commission for extending the comment deadline as well as considering its comments.

4. Summary of meeting action items.

- Make the changes as discussed
- Draft rule language to the Code Revisor as directed by the department
- Bring this back to the commission regularly

Business Meeting Adjourned. 12:55 p.m.

STATE OF WASHINGTON
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Pharmacy Quality Assurance Commission Special Meeting
September 22, 2022 - Minutes

Convene: Vice Chair, Jerrie Allard called the meeting to order September 22, 2022, 9:03 a.m.

Commission Members:
Jerrie Allard, Public Member, Vice Chair
Bonnie Bush, Public Member
Uyen Thorstensen, CPhT
Hawkins DeFrance, Nuclear Pharmacist
William Hayes, PharmD, CCHP
Craig Ritchie, RPh, JD
Patrick Gallaher, BS, BPharm, MBA, MPH
Judy Guenther, Public Member
Matthew Ray, PharmD
Ken Kenyon, PharmD, BCPS
Ann Wolken, PharmD, RPh

Commission Members Absent:
Tim Lynch, PharmD, MS, FABC, FASHP
Teri Ferreira, RPh, Chair

Staff:
Shawna Fox, OHP Office Director
Marlee O'Neill, Executive Director
Lindsay Trant-Sinclair, Deputy Director
Christopher Gerard, AAG
Hope Kilbourne, Policy Analyst
Irina Tiginyanu, Pharmacy Technician Consultant
Joshua Munroe, Legislative and Rules Consultant
Taifa "Nomi" Peaks, Pharmacist Consultant
Haleigh Mauldin, Program Consultant
Joanne Miller, Program Manager
Amy L Robertson, Communications Coordinator and Program Support

Inspectors:
Scott Craig
Stephanie Martin
Crystal Phipps

1. Call to Order Jerrie Allard, Vice Chair.

1.1 Meeting Agenda Approval – September 22, 2022

MOTION: Bonnie Bush moved to approve the business meeting agenda for September 22, 2022. Hawkins DeFrance, second. Motion carries, 11:0.

1.2 Meeting Minutes Approval – July 14, 2022

MOTION: Craig Ritchie moved to approve the business meeting agenda for July 14, 2022. Hawkins DeFrance, second. Motion carries, 11:0.

1.3 Meeting Minutes Approval – July 15, 2022

MOTION: Craig Ritchie moved to approve the special meeting agenda for July 15, 2022 as amended adding Jerrie Allard as in attendance. Hawkins DeFrance, second. Motion carries, 12:0.

2. Consent Agenda.

2.1 National Precursor Log Exchange Monthly Dashboard-July- August 2022
2.2 Pharmaceutical Firms Application Report
June 29, 2022, thru September 15, 2022
2.3 Ancillary Utilization Plans Approval
- **2.3.1** Cascade General Hospital Pharmacy
- **2.3.2** Community Healthcare
- **2.3.3** Coulee Medical Center
- **2.3.4** Credena Health
- **2.3.5** Harborview Hobson
- **2.3.6** Harborview LTC
- **2.3.7** Madrona Health
- **2.3.8** Othello Specialty
- **2.3.9** PeaceHealth
- **2.3.10** Professional Pharmacy Royal City
- **2.3.11** Professional Pharmacy Waterville
- **2.3.12** Seattle Children's Hospital
- **2.3.13** West Valley Clinic Pharmacy
- **2.3.14** Whidbey Health
- **2.3.15** Yokes Foods

2.4 Pharmacy Technician Training Program Approval
- **2.4.1** Island Health
- **2.4.2** Mcleary, Elma Health Mart, Huttula Enterprises
- **2.4.3** Yakama HIS
- **2.4.4** Valley Drug

MOTION: Craig Ritchie moved to approve the consent agenda excluding the items pulled for discussion in 2.5. Hawkins DeFrance, second. Motion carries, 12:0.

2.5 Regular Agenda/Items Pulled from 2.3 and 2.4.

Pulled by Ann Woken:

2.3.2 **Community Healthcare** – remove "and the general pharmacy ancillary role" at the beginning of the AUP.

Pulled by William Hayes:

2.3.7 **Madrona Health**
2.4.2 **Othello Specialty**
2.4.3 **PeaceHealth**
All have old references to WAC 246-901, 246-030. Recommend approval contingent upon removal or update of that citation(s).

2.3.10 **Professional Pharmacy Royal City** – the SBAR cites contingent approval upon removal of WAC citation and reference #14 indicating reference to cassette filling. Irina Tiginyanu informed the commission that the individual did specify they did unit dose filling, and that language is not pertaining to that location.

2.3.11 **Professional Pharmacy Waterville**
2.3.13 **West Valley Clinic Pharmacy**
WAC citations are out-of-date. Recommend approval contingent upon removal or update of those WACs.

2.4.1 Island Health – SBAR indicates Irina recommends approval contingent upon submission of AUP.

MOTION: Jerrie Allard moved to approve the recommended changes: 2.3.2, 2.3.7, 2.3.8, 2.3.9, 2.3.10, 2.3.11, 2.3.13, and 2.4.1. William Hayes, second. Motion carries, 12:0.

3. Old Business.

3.1 Office of Customer Service Action Plan Update – Blake Maresh, Director for the Office of Customer Service at DOH, provided an update on the Office of Customer Service Action Plan. The customer service center (CSC) manager position as well as most of the grant funded positions have been filled. However, there is significant turnover. Strategic planning is ongoing to rebuild OCS from the ground up. Average processing for credentials is nine days (down from 14). Intake processing of applications is down to 17.7 days.

3.2 Washington Recovery and Assistance Program for Pharmacy – William Rhodes, Washington Recovery and Assistance Program for Pharmacy provided an overview/update on WRAPP (the commission's approved substance use recovery, assistance, and monitoring program under RCW 18.130.175.

3.3 Overdose Data to Action (OD2A) Program at DOH – Anjali Shankar and Carolyn House-Higgins provided information on the OD2A program and how the program may be helpful to pharmacy professionals through surveillance to gather information and prevention of overdose data The funding for this program provides resource links to obtain care. The program itself does not provide or fund treatment but assists in navigation and access to treatment areas.

Stakeholders Jenny Arnold (WSPA) and Dawn Ipsen expressed concern over cost as well as availability of naloxone to schools and the general public.

3.4 Presentation on the Disciplinary Hearing Process – Roman Dixon, Chief Health Law Judge at the Department, provided an overview of the hearing process and the commissioners' role when serving on a hearing panel.

4. New Business.

4.1 Humane Society of Cowlitz County Euthanasia Training Program Approval – The commission has received a request from Humane Society of Cowlitz County for approval of their Euthanasia training program. Background is provided in the SBAR. Joanne Miller informed the commission all required information including course outline, exam sample, certificate of completion of the program, and that the training records are held indefinitely.

MOTION: Craig Ritchie moved to approve the Humane Society of Cowlitz County Euthanasia Training Program. Bonnie Bush, second. Motion carries, 12:0.

5. Rules and Legislative Updates. ***Information/Action***

5.1 ESSB 5229 – Rulemaking Authorization to Incorporate the Secretary's Rules on Health Equity CE.

MOTION: Craig Ritchie moved the commission authorize standard rulemaking to consider adding a health equity CE requirement in its rules informed by the Secretary's model rules on health equity CE. William Hayes, second. Motion carries, 12:0.

Stakeholder Jenney Arnold (WSPA) informed the commission WSPA is committed to partnering to offer CE in a multitude of CEs that meet this requirement for our profession.

5.2 Emergency Rule Refile Request – Emergency Oral Prescription for Schedule II, WSR 22-13-180.

MOTION: Craig Ritchie moved to refile the Emergency Rule Refile Request – Emergency Oral Prescription for Schedule II, WSR 22-13-180 and give staff authority to withdraw the filing if the DEA changes its rule. Bonnie Bush, second. Motion carries, 12:0.

5.3 Emergency Rule Refile Request – Medication Assistance

MOTION: Craig Ritchie moved to approve the staff to refile emergency rules for medication assistance. William Hayes, second. Motion carries, 12:0.

5.4 Amend the Scope of the Rulemaking Authorized on WAC 246-945-585 to Consider Changing the Suspicious Order Requirement *(Follow up from Facility Subcommittee)*

MOTION: Craig Ritchie moved that the commission expand the scope of the previously authorized standard rulemaking on WAC 246-945-585 to include revisiting the suspicious order reporting requirement and to task the facility subcommittee with the initial work in preparing proposed rule language. Hawkins DeFrance, second. Motion carries, 12:0.

6. Panel Review- Study Plan(s).

MOTION: William Hayes moved to approve Matthew Ray, Craig Ritchie (chair), and Bonnie Bush as the panel reviewing and approving/denying the study plans. Ken Kenyon, second. Motion carries, 12:0.

Matthew Ray recused himself from PHRM.PH.61066462 as there is a conflict of interest.

MOTION: Judy Guenther moved to appoint William Hayes (in place of Matthew Ray), Craig Ritchie (chair), and Bonnie Bush as the panel reviewing and approving/denying the study plans. Hawkins DeFrance, second. Motion carries, 12:0.

6.1 PHRM.PH.61163629

MOTION: Craig Ritchie moved to approve the study plan for PHRM.PH.61163629. Matthew Ray, second. Motion carries, 3:0.

6.2 PHRM.PH.61066462

MOTION: Judy Guenther moved to approve the study plan for PHRM.PH.61066462. William Hayes, second. Motion carries, 3:0.

7. Summary of Meeting Action Items.

- **1.2 / 1.3 – July Meeting Minutes** – Staff will post the approved minutes to the commission website and confirm Jerrie Allard is marked as present on July 15, 2002.

- **2.3 / 2.4 – AUPs / Pharmacy Technician Training Programs** – Staff will follow-up with AUPs and training programs with contingency approvals as directed as well as the AUPs that were approved.
- **4.1 – Humane Society of Cowlitz County Euthanasia Training Program** – Staff will notify the Humane Society of Cowlitz County the training program was approved.
- **5.1 – ESSB 5229 – Rulemaking Authorization to Incorporate the Secretary's Rules on Health Equity CE** – Staff will file CR101 authorizing standard rulemaking to consider adding a health equity CE requirement into the rules as informed by the secretary's model rules on health quality.
- **5.2 – Emergency Rule Refile Request – Emergency Oral Prescription for Schedule II, WSR 22-13-180 –** Staff will file emergency rules and rescind emergency rules if the DEA repeals their policy on emergency oral prescriptions for Schedule II during COVID.
- **5.3 – Emergency Rule Refile Request – Medication Assistance** – Staff will refile emergency rules on medication assistance.
- **5.4 – Amend the Scope of the Rulemaking Authorized on WAC 246-945-585 to Consider Changing the Suspicious Order Requirement** – Staff will file CR101 to expand the scope to consider amending both the zero order report and suspicious order reports in WAC 246-945-585. Staff will work with the facilities subcommittee on developing draft rules.
- **6.1 / 6.2 – Study Plans approved** – staff will notify credentialling that the candidate's study plans have been approved.

Business Meeting Adjourned. 1:57 p.m.

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Pharmacy Quality Assurance Commission Special Meeting
September 23, 2022 - Minutes

Convene: Chair, Teri Ferreira called the meeting to order September 23, 2022, 9:06 a.m.

Commission Members:
Teri Ferreira, RPh, Chair
Jerrie Allard, Public Member, Vice Chair
Bonnie Bush, Public Member
Tim Lynch, PharmD, MS, FABC, FASHP
Uyen Thorstensen, CPhT
William Hayes, PharmD, CCHP
Craig Ritchie, RPh, JD
Patrick Gallaher, BS, BPharm, MBA, MPH
Judy Guenther, Public Member
Matthew Ray, PharmD
Ken Kenyon, PharmD, BCPS
Ann Wolken, PharmD, RPh

Commission Members Absent:
Hawkins DeFrance, PharmD

Staff:
Marlee O'Neill, Executive Director
Lindsay Trant-Sinclair, Deputy Director
Christopher Gerard, AAG
Hope Kilbourne, Policy Analyst
Joshua Munroe, Legislative and Rules Consultant
Taifa "Nomi" Peaks, Pharmacist Consultant
Haleigh Mauldin, Program Consultant
Joanne Miller, Program Manager
Amy L Robertson, Communications Coordinator and Program Support

Inspectors:
Scott Craig
Stephanie Martin
Crystal Phipps

1. **Call to Order**

1.1 Meeting Agenda Approval – September 23, 2022

MOTION: Craig Ritchie moved to approve amended business meeting agenda adding *2.8 Subcommittee assignments* (replace Kat Wolf-Khachatourian as representative on the Total Cost of Insulin Workgroup) for September 23, 2022. Tim Lynch, second. Motion carries, 12:0.

2. Old Business

2.1 Sample Ancillary Utilization Plan *(Follow up from Pharmacy Practice Subcommittee)*

Taifa "Nomi" Peaks, Pharmacist Consultant, presented a brief review of past comments/ suggestions, how these comments/suggestions were applied to the form(s), and asked for additional feedback/instructions.

The commission tasked the subcommittee to make these following edits and discuss the following as possible changes:

- Remove the column that says *Reviewed by Responsible Pharmacy Manager*.
- Other Pharmacy Functions: gather feedback related to the function of cassettes/canisters.
- Add spot for pharmacy name and license number whether on the form or by using an addendum.
- Prescription Intake: add "or drug name."

- Add to assistant: “Handles calls from prescriber’s office authorizing refills, provided no changes in the prescriptions are involved.”
- Remove: “Pharmacist initials on the prescription label.” (page 9)

2.2 Pharmacy Assistants Scope of Practice (*Follow up from Pharmacy Practice Subcommittee)*

Taifa “Nomi” Peaks, Pharmacist Consultant, reviewed highlights of the Pharmacy Practice Subcommittee meeting. Specifically, the subcommittee was tasked with examining the guidance document, DOH 690-356 (Access to Drugs Stored Outside of the Pharmacy), to determine if modifications to the document’s current language were needed in order to address the question, “May assistants stock an ADDD?” The subcommittee was also tasked with engaging in stakeholdering to consider the viewpoints of those in support of, and those opposed to, pharmacy assistants retrieving (also called “pulling”) medications from pharmacy shelves for filling prescriptions and for stocking outside of a pharmacy. The subcommittee did not recommend making changes to DOH 690-356 because the document refers to unlicensed employees of healthcare facilities, and pharmacy assistants are licensed pharmacy personnel. The comments offered by stakeholders during the subcommittee meeting were compiled and shared with the full commission in an SBAR. During the discussion, commissioners and stakeholders expressed concern over patient safety and proper training for assistants. The commission also asked the pharmacy practice subcommittee to review the following:

- If pulling drugs should be part of a pharmacy assistant’s scope of practice.
- Defining whether “stocking” for assistants means just shelves or includes other things such as stocking an ADDD, etc.
- Related to prescription processing, does the definition of “obtain” encompass medication retrieval?

2.3 Uniform Facility Enforcement Framework (UFEF) Z-draft

Marlee O’Neill, Executive Director, reviewed the minor changes from the August 24, 2022 version to the draft Z-draft. Both changes were requested by the Code Revisor’s office:

1. Section 34(1) (page 91, line 6) – the last sentence now states: “**The Commission** ~~and~~ may deny the petition or may order reinstatement **of the licensee’s license. The Commission may** ~~and~~ impose terms and conditions ~~issue an~~ **in the** order of reinstatement.”

2. Section 34 (page 97, line 22) – removed RCW reference and redirected to Section 31 and 33.

Christopher Gerard also presented some potential edits to the draft Z-draft for consideration by the Commission.

3. Page 85, line 6 and line 17 – remove “corrective”.

4. Page 85, line 14 – definition: (36) "License," "licensing," and "licensure" shall be deemed equivalent to the terms “approval”, “credential”, ~~“licensure,”~~ "certificate," "certification," “permit”, ~~and~~ "registration", **and an “exemption” issued under chapter 69.50 RCW.**

5. PAGE 85, line 21, (38) “Statement of deficiency” means a written statement of the deficiencies ~~completed~~ **prepared** by the commission, or its designee, identifying one or more

violations of law. The report clearly identifies the specific law or rule that has been violated along with a description of the reasons for noncompliance.

6. Page 86, starting at line 1 and page 87 starting at line 9, replacing the word "their" with "its".

7. PAGE 86-87, starting at line 39 – a (6) ~~If the commission issues a written notice of revocation, suspension, or modification of a license and the licensee timely files an appeal, t~~ **The commission may accept the surrender of the licensee's license. A licensee that surrenders its license may not petition for reinstatement of their surrendered license.**

8. PAGE 90-91, starting at line 39 (page 90) – The commission may ~~only~~ take action under subsection (1) of this section against a nonresident pharmacy for failure to comply with any requirement of RCW 18.64.350 through 18.64.400, unless the nonresident pharmacy's conduct cause psychological, physical, or financial injury to a resident of this state* ~~and~~ **or** the conduct resulted in adverse action against the nonresident pharmacy by **a federal agency or** the regulatory or licensing agency in the state in which the nonresident pharmacy is located.

The commission discussed potential third-party payor language and wanting to ensure it has authority to take enforcement action against non-resident pharmacies.

MOTION: Craig Ritchie moved to approve the proposed changes and proceed with third party payor language and give the commission as much authority as possible around non-resident pharmacies . Bonnie Bush, second. Motion carries, 12:0.

2.4 Review Enforcement Discretion on USP 800

Lindsay Trant-Sinclair, Deputy Director reviewed Policy #65.3 on the enforcement of USP 800 is set to expire on September 30. The commission can consider extending its enforcement discretion on USP 800 for a period of time to be determined by the commission. The current enforcement discretion on USP 800 expires after September 30, 2022.

MOTION: Craig Ritchie moved to approve extend enforcement discretion until it is withdrawn by the commission at an open public meeting and staff will keep the commission updated at least once every three months on the status of revised USP 795 and 797. Jerrie Allard, second. Motion carries, 12:0.

2.5 Regulatory Framework for White Bagging *(Follow up from Compounding Subcommittee)*

Taifa "Nomi" Peaks, Pharmacist Consultant, presented a brief review of the SBAR on White Bagging. The commission tasked the legislative subcommittee with discussing whether legislation on this issue is something the commission should pursue. The commission also tasked the facility subcommittee with reviewing current laws and rules to see how those impact white bagging and to consider possible rulemaking.

2.6 Guidance for Prescription Drug Pick-up Lockers

Taifa "Nomi" Peaks, Pharmacist Consultant, presented a brief review of this document which serves to detail the commission's position on the topic of prescription drug pick-up lockers, with a specific examination of how the delivery of filled prescriptions of non-controlled legend drugs

to pharmacy-owned lockers does not fall under the commission's rules on drug stored outside of a pharmacy in WAC 246-945-455.

MOTION: Craig Ritchie moved to approve the guidance document for Prescription Drug Pick-up Lockers. Bonnie Bush, second. Motion carries, 12:0.

2.7 Update on Accessible Label Rulemaking

Joshua Munroe, Rules and Legislative Coordinator, informed the commission that staff developed and distributed a survey to licensed pharmacy personnel for two purposes: 1) to discover whether and how pharmacies are currently providing accessible labeling options to patients, and 2) to determine what logistic and fiscal obstacles exist for pharmacies and other facilities licensed under the commission's jurisdiction in providing accessible labeling options. The survey is open until October 16. Feedback from the survey will be shared with the commission at the November business meeting.

2.8 Updates to Subcommittee Assignments

Committee	Commission Members
Recurring	
Budget Subcommittee • HELMS	**Chair**: Patrick Gallaher **Members**: Williams Hayes, Bonnie Bush, Matthew Ray **Staff lead**: PQAC Executive Director and Finance Officer
Legislative Subcommittee • White bagging	**Chair**: William Hayes **Members**: Hawkins DeFrance; Craig Ritchie; Chair -or- Vice Chair **Staff lead**: Rules and Legislative Consultant
Strategic Planning Subcommittee	**Chair**: Jerrie Allard **Members**: Ann Wolken; Hawkins DeFrance; Chair **Staff lead:** Program Manager, Executive Director, Deputy Director
Ad Hoc	
Compounding Subcommittee • FDA MOU • Self-inspection worksheets	**Chair**: Hawkins DeFrance **Members**: Ken Kenyon, Uyen Thorstensen **Staff lead**: Pharmacist Consultant
Facility Subcommittee • HPACs committee • Suspicious orders • Facility enforcement authority • White bagging	**Chair**: Ken Kenyon **Members**: Teri Ferreira, William Hayes, Uyen Thorstensen **Staff lead**: Pharmacist Consultant
Pharmacy Practice Subcommittee • Misfill and Pharmacy Work Condition Workgroup • Sunrise review • CDTA WMC Committee (Teri) • Sample AUP review	**Chair**: Craig Ritchie **Members**: Teri Ferreira, Patrick Gallaher, Ann Wolken **Staff lead**: Pharmacist Consultant

Approved 092322

MOTION: Craig Ritchie moved to approve all the members as listed to the various subcommittees and other revisions made. Judy Guenther, second. Motion carries, 12:0.

Amended Item – Appoint New Commissioner to the Total Cost of Insulin Workgroup

MOTION: Craig Ritchie moved to appoint Tim Lynch as representative for the Pharmacy Quality Assurance Commission to the Total Cost of Insulin Cost Workgroup. Jerrie Allard, second. Motion carries, 12:0.

2.9 Governor Inslee Rescinding all Remaining COVID-19 Proclamations and the State of Emergency in Washington by October 31, 2022

Marlee O'Neill, Executive Director, and Lindsay Trant-Sinclair, Deputy Director, reviewed various decisions the commission made throughout the pandemic and next steps given the ending of the state of emergency (SOE).

- Staff will remove Plan-19 from the website but will take information or FAQs from it that remain applicable independent of the SOE and put those on the commission's website.
- In August 2020, the commission approved the use of a technical assistance letter to provide healthcare providers assistance if reported for allegedly not following or violating Governor issued proclamations related to the COVID-19 state of emergency. The Secretary's mask order will remain in effect. Staff can update the technical assistance letter so that it can still be used, on a case-by-case basis, to provide technical assistance for reports of not complying with the Secretary's mask order while it is in effect.
- In October 2020, the commission approved the use of virtual inspections when: (i) the inspector and licensee agree to a virtual inspection, (ii) the inspector makes this request to the inspector supervisor or designee to conduct a virtual inspection due to unavoidable circumstances (COVID-19, PPE shortages), and (iii) the inspector supervisor or designee approves the virtual inspection. The inspectors are using this option very infrequently now. The motion was tied to "unavoidable circumstances" and not specifically to COVID or the state of emergency. We would like to continue to have this option available when there are "unavoidable circumstances."
- Yesterday, the commission reauthorized refiling emergency rules on dispensing emergency oral Schedule II prescription drugs during the COVID-19 pandemic. The emergency rule mirrors guidance in place by the DEA. This emergency rules is necessary until the federal state of emergency ends or a similar policy announcement is made by the DEA.
- In March 2021, the commission approved joint COVID-19 safety guidance with L&I. This guidance was based on proclamation 20-24.2 which will be rescinded, effective as of October 27th. We will remove this from the commission's website effective October 27th.
- In May 2022, the commission agreed to waive the inspection report requirement for non-resident pharmacy renewals if the non-resident pharmacy provided a letter from its home state stating that the home state cannot timely complete an inspection due to COVID. This was just for the 2022 renewal cycle, so no action is needed as all non-resident pharmacies' credentials expire on May 31 of each year.
- The recission of the state of emergency in Washington will not impact the validity of the U.S. Dept of Health and Human Services' PREP Act, which authorizes pharmacists to "order and administer COVID-19 tests, including serology tests, that the Food and Drug administration has authorized." This guidance preempts any state law requirements that are different or conflict. HHS has explained that because pharmacists are covered persons

under the declaration, they may order and administer COVID-19 tests even if state law would typically require a prescription.

The commission agreed with what staff outlined and determined a FAQ related to the PREP Act was not necessary.

3 New Business

3.1 Monitoring of Drug Therapy

Marlee O'Neill, Executive Director, reviewed the SBAR, which outlined that "the monitoring of drug therapy" is within the "practice of pharmacy." RCW 18.64.011(28). The commission has further defined the definition of the "monitoring of drug therapy" in WAC 246-945-355. This rules states that "a review of the drug therapy regimen of patients by a pharmacist for the purpose of evaluating or rendering advice to the prescribing practitioner or patient regarding the patients' drug therapy. Monitoring of drug therapy includes, but is not limited to, the evaluation of the patient through history taking, physical examination, ordering, administering, or reviewing laboratory tests, imaging, and social evaluation related to an existing diagnosis and drug therapies for optimization of drug therapy."

Taken in aggregate, the commission's statute and rule do not permit pharmacists independently engaging in POC testing and health screenings related to a condition an individual has not received a diagnosis for and has not been prescribed any medication to treat, unless the pharmacist is acting pursuant to the terms of a CDTA, or other standing order or protocol developed by an interdisciplinary team that includes a prescribing practitioner.

Commissioners and stakeholders engaged in discussion around the how the rule impacts pharmacy practice. Concerns were raised by both Commissioner and stakeholders that the applicable statute and rule may be too restrictive and not reflective of current pharmacy practice.

MOTION: Tim Lynch moved that the commission staff further evaluate the monitoring of drug therapy and consider rulemaking. Craig Ritchie, second. Motion carries, 12:0.

4 Open Forum

5 Commission Member Reports. *Information/Action*

5.1 NABP District Meeting Report Out – Teri Ferreira / Jerrie Allard / Ann Wolken – reported the meeting had two very powerful presentations: 1) the impact of the pharmacist on the opioid epidemic and 2) maintaining temperature control for medications that are mailed. While informative, there were no 'take away' tools, but still a good meeting overall.

5.2 Budget Subcommittee – Patrick Gallaher – As of June 30, there is a balance $6.6 million. We are on target for the biennial projection for our fund balance.

5.3 Open discussion related to items or issues relevant to commission business/pharmacy practice.

5.3.1 Jerrie Allard commended the staff on our first successful hybrid meeting.

5.3.2 Ken Kenyon commented on Jerrie's meeting report – One thing to not forget is that Washington State is one of a handful of states that is not an "any willing provider state." One of the things we can advocate for patients is to work on Washington State to become an "any willing provider state" giving patients the freedom of choice to choose a pharmacy and how to receive their pharmaceutical care.

5.3.3 Matthew Ray asked where the six-month inspection letters are sent. Marlee O'Neill stated that they are sent to the mailing address that the entity provides the department.

6 Staff Reports *Information/Action*

6.1 Executive Director – Marlee O'Neill - Marlee provided the following report.

- We are tentatively planning to have all of the inspectors attend the January business meeting. Patrick Gallaher appreciates the inspectors will be joining to have more of a "boots on the ground" perspective.
- At the commission's direction, staff provided comment to the FDA in response to the FDA's proposed rule for National Standards for the Licensure of Wholesale Drug Distributors (and 3PLs). The letter is included in your correspondence.
- The State Auditor's Office (SAO) is conducting an audit of the Prescription Monitoring Program (PMP). The final audit report is scheduled to be released on October 4th. There will be a virtual Joint Legislative Audit and Review Committee (JLARC) hearing at 10am on October 19, 2022 to consider the audit findings and receive public testimony.

6.2 Deputy Director – Lindsay Trant-Sinclair – Lindsay provided the following report.

- The department is shifting to a new system for reviewing rules packages. This new system will replace the outdated RMS system currently used, but the implementation has resulted in some short delays. We will hold two public hearings in November.
- We will be hiring for a new Administrative Assistant 3 in the coming weeks.
- The recruitment for a new pharmacist member is finished and we are putting forth a candidate to the Governor's Office. We will have a second opening with Helen's resignation. We are also currently conducting interviews to fill the vacant public member seat.

6.3 Assistant Attorney General – Christopher Gerard – none.

7 Summary of Meeting Action Items –

Commissioners and staff will revisit action items identified during today's business meeting.

- **2.1 – Sample Ancillary Utilization Plan** – bring sample AUP back to the pharmacy practice subcommittee to review items identified.
- **2.2 – Pharmacy Assistants Scope of Practice** – Bring questions regarding pharmacist scope of practice back to pharmacy practice subcommittee for recommendations.
- **2.3 – Uniform Facility Enforcement Framework** – Staff will make the revisions and keep the commission apprised on the status of the UFEF.
- **2.4 – Review Enforcement Discretion on USP 800 –** Staff will update the policy statement on its enforcement direction on USP 800, will update website, and will update the commission regularly on the status of this matter on 795 and 797.
- **2.5 – Regulatory Framework for White Bagging** – bring this topic to legislative and facilities committees.

- **2.6 – Guidance for Prescription Drug Pick-up Lockers** –Staff will publish the guidance document on prescription drug pick-up lockers and distribute GovDelivery.
- **2.7 – Update on Accessible Label Rulemaking –** Survey – bring back results in November.
- **2.8 – Updates to Subcommittee Assignments** – Staff will update the subcommittee table.
- **2.9 – Governor Inslee Rescinding all Remaining COVID-19 Proclamations and the State of Emergency in Washington by October 31, 2022 –** Staff will review Plan 19 and maintain FAQs that remain relevant once the state of emergency ends and bring this back in November.
- **3.1 – Monitoring of Drug Therapy** – Staff will further evaluate the monitoring of drug therapy and bring this topic back at a future meeting.

Business Meeting Adjourned 2:30 pm

PROPOSED RULE MAKING

CR-102 (July 2022)
(Implements RCW 34.05.320)
Do **NOT** use for expedited rule making

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: October 04, 2022
TIME: 1:48 PM

WSR 22-20-100

Agency: Department of Health – Pharmacy Quality Assurance Commission

☒ **Original Notice**

☐ **Supplemental Notice to WSR _____**

☐ **Continuance of WSR _____**

☒ **Preproposal Statement of Inquiry was filed as WSR** 20-17-143 **; or**

☐ **Expedited Rule Making--Proposed notice was filed as WSR _____; or**

☐ **Proposal is exempt under RCW 34.05.310(4) or 34.05.330(1); or**

☐ **Proposal is exempt under RCW _____.**

Title of rule and other identifying information: (describe subject) WAC 246-945-486 (New) Return and reuse of unexpired medications – Department of corrections and WAC 246-945-488 (New) Safe donation of unexpired prescription drugs. The Pharmacy Quality Assurance Commission (commission) is proposing new sections in chapter 246-945 WAC for the implementation of Substitute Senate Bill (SSB) 6526, an act relating to the reuse and donation of unexpired prescription drugs.

Hearing location(s):

Date:	**Time:**	**Location:** (be specific)	**Comment:**
11/17/2022	9:20 a.m.	The Pharmacy Quality Assurance Commission will provide a virtual and a physical location for this hearing to promote social distancing and the safety of the citizens of Washington State. **Physical location:** Capital Region ESD 113 6005 Tyee Dr SW Tumwater, WA 98512 Lewis Room **Virtual:** Please download and import the following iCalendar (.ics) files to your calendar system. Daily: https://us02web.zoom.us/webinar/tZIsdu2hqzMuHNJhllH4KKYkCjwBU5J0e2Ps/ics?icsToken=98tyKuGurzouE9GdtB-BRpwABYj4LPPwmFxbgo13lBPpK3R4STr9FehVEIcqOojV Topic: PQAC Business Meeting 2022 To access the meeting on November 17 at 9 a.m., go to https://zoom.us/join or https://us02web.zoom.us/j/86114958466 and use the Webinar ID 861 1495 8466	

		The access options include one tap mobile: US: +12532158782,,86114958466# or +16699009128,,86114958466# Or Telephone: Dial(for higher quality, dial a number based on your current location): US: +1 253 215 8782 or +1 669 900 9128 or +1 346 248 7799 or +1 669 444 9171 or +1 386 347 5053 or +1 564 217 2000 or +1 646 558 8656 or +1 646 931 3860 or +1 301 715 8592 or +1 312 626 6799 Webinar ID: 861 1495 8466 International numbers available: https://us02web.zoom.us/u/kdLNo6unOZ	

Date of intended adoption: 11/17/2022 (Note: This is **NOT** the **effective** date)

Submit written comments to:	**Assistance for persons with disabilities:**
Name: Joshua Munroe	Contact Joshua Munroe
Address: PO Box 47582 Olympia, WA 98504-7852	Phone: 360-236-2987
Email: https://fortress.wa.gov/doh/policyreview	Fax: 360-236-2901
Fax: 360-236-2901	TTY: 711
Other: N/A	Email: PharmacyRules@doh.wa.gov
By (date) 11/03/2022	Other: N/A
	By (date) 11/10/2022

Purpose of the proposal and its anticipated effects, including any changes in existing rules: The 2020 Washington state legislature passed SSB 6526, an act relating to the reuse and donation of unexpired prescription drugs. SSB 6526 permits the Department of Corrections (DOC) pharmacy to accept returns of unit dose packages. The law also allows the commission to adopt rules to allow the safe donation of prescription drugs under chapter 69.70 RCW including, but not limited to, allowing pharmacy to pharmacy donation of unexpired prescription drug stock.

The proposed WAC 246-945-486 specifically allows the DOC pharmacy to accept for return and reuse noncontrolled unexpired legend drugs in unit dose packages, or full or partial multiple dose medication cards from the facilities it serves. The DOC pharmacy must ensure product integrity by adhering to RCW 69.70.050(1), (2), and (5).

The proposed language in WAC 246-945-488 adopts the required conditions for donated prescription drugs outlined in chapter 69.70 RCW, but also adds a requirement that participating pharmacies must submit an additional form to the commission as notification of participation in the program. They must also notify the commission when terminating participation in the program. The proposed rule also directs participating pharmacies to develop policies and procedures that facilitate compliance with the statutory requirements. The policies and procedures must also include an additional requirement to notify the prescriber when donated medications are dispensed to a patient.

In addition, WAC 246-945-488 contains measures to ensure patient safety and product integrity such as separating the donated drugs from the rest of the pharmacy's drug stock and maintaining a separate inventory. Finally, the rule also adds the clarification that practitioners, pharmacists, medical facilities, manufacturers, wholesalers, or persons to whom a prescription drug was prescribed are not required to obtain a wholesaler license when donating drugs to a pharmacy.

Reasons supporting proposal: SSB 6526 requires the commission to adopt rules allowing the DOC pharmacy to accept returns of unit dose packages or full or partial multiple dose medication cards from the facilities it serves and reuse the unexpired medication. The bill also allows the commission to adopt rules allowing the safe donation of prescription drugs under chapter 69.70 RCW including, but not limited to, allowing pharmacy to pharmacy donations of unexpired prescription

drug stock. The proposed rules improve accessibility and visibility of the drug donation program under chapter 69.70 RCW while ensuring optimal patient safety and product integrity.

Statutory authority for adoption: RCW 18.64.005; SSB 6526 (chapter 264, Laws of 2020) codified as RCW 18.64.610 and RCW 69.70.110

Statute being implemented: SSB 6526 (chapter 264, Laws of 2020) codified as RCW 18.64.610 and RCW 69.70.110

Is rule necessary because of a:

Federal Law?	☐ Yes	☒ No
Federal Court Decision?	☐ Yes	☒ No
State Court Decision?	☐ Yes	☒ No

If yes, CITATION:

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters: None

Type of proponent: ☐ Private ☐ Public ☒ Governmental
Name of proponent: (person or organization) Washington State Pharmacy Quality Assurance Commission

Name of agency personnel responsible for:

	Name	Office Location	Phone
Drafting:	Joshua Munroe	111 Israel Rd SE, Tumwater, WA 98501	360-236-2987
Implementation:	Joshua Munroe	111 Israel Rd SE, Tumwater, WA 98501	360-236-2987
Enforcement:	Marlee O'Neill	111 Israel Rd SE, Tumwater, WA 98501	360-480-9108

Is a school district fiscal impact statement required under RCW 28A.305.135? ☐ Yes ☒ No
If yes, insert statement here:

The public may obtain a copy of the school district fiscal impact statement by contacting:
Name:
Address:
Phone:
Fax:
TTY:
Email:
Other:

Is a cost-benefit analysis required under RCW 34.05.328?

☒ Yes: A preliminary cost-benefit analysis may be obtained by contacting:
Name: Joshua Munroe
Address: PO Box 47852
Olympia, WA 98504-47852
Phone: 360-236-2987
Fax: 360-236-2901
TTY: 711
Email: PharmacyRules@doh.wa.gov
Other: N/A

☐ No: Please explain:

Regulatory Fairness Act and Small Business Economic Impact Statement
Note: The Governor's Office for Regulatory Innovation and Assistance (ORIA) provides support in completing this part.

(1) Identification of exemptions:
This rule proposal, or portions of the proposal, **may be exempt** from requirements of the Regulatory Fairness Act (see chapter 19.85 RCW). For additional information on exemptions, consult the exemption guide published by ORIA. Please check the box for any applicable exemption(s):

☐ This rule proposal, or portions of the proposal, is exempt under RCW 19.85.061 because this rule making is being adopted solely to conform and/or comply with federal statute or regulations. Please cite the specific federal statute or regulation this rule is being adopted to conform or comply with, and describe the consequences to the state if the rule is not adopted.
Citation and description:

☐ This rule proposal, or portions of the proposal, is exempt because the agency has completed the pilot rule process defined by RCW 34.05.313 before filing the notice of this proposed rule.

☐ This rule proposal, or portions of the proposal, is exempt under the provisions of RCW 15.65.570(2) because it was adopted by a referendum.

☐ This rule proposal, or portions of the proposal, is exempt under RCW 19.85.025(3). Check all that apply:

- ☐ RCW 34.05.310 (4)(b) (Internal government operations)
- ☐ RCW 34.05.310 (4)(c) (Incorporation by reference)
- ☐ RCW 34.05.310 (4)(d) (Correct or clarify language)
- ☐ RCW 34.05.310 (4)(e) (Dictated by statute)
- ☐ RCW 34.05.310 (4)(f) (Set or adjust fees)
- ☐ RCW 34.05.310 (4)(g) ((i) Relating to agency hearings; or (ii) process requirements for applying to an agency for a license or permit)

☐ This rule proposal, or portions of the proposal, is exempt under RCW 19.85.025(4) (does not affect small businesses).

☐ This rule proposal, or portions of the proposal, is exempt under RCW _____.

☐ Explanation of how the above exemption(s) applies to the proposed rule:

(2) Scope of exemptions: *Check one.*

☐ The rule proposal is fully exempt *(skip section 3)*. Exemptions identified above apply to all portions of the rule proposal.

☐ The rule proposal is partially exempt *(complete section 3)*. The exemptions identified above apply to portions of the rule proposal, but less than the entire rule proposal. Provide details here (consider using this template from ORIA):

☒ The rule proposal is not exempt *(complete section 3)*. No exemptions were identified above.

(3) Small business economic impact statement: *Complete this section if any portion is not exempt.*

If any portion of the proposed rule is **not exempt**, does it impose more-than-minor costs (as defined by RCW 19.85.020(2)) on businesses?

☒ No Briefly summarize the agency's minor cost analysis and how the agency determined the proposed rule did not impose more-than-minor costs.

The proposed rule does not require changes to a licensee's or a pharmacy's existing practices or infrastructure. For pharmacies that choose to participate in the prescription donation program, costs are limited to one-time costs—procuring additional shelving/storage, time taken creating policies and procedures, and time taken to fill out the necessary registration form—and the recurring cost of maintaining a separate inventory for donated items. The agency estimates that the probable one-time cost to comply with the optional program could be as high as $733.50 which is significantly less than the minor cost threshold of either 1% of average annual payroll ($6,639.73) or .3% of average annual gross business income ($53,119.28). The agency determined that the requirements to comply with the optional program did not impose more-than-minor costs on small businesses.

☐ Yes Calculations show the rule proposal likely imposes more-than-minor cost to businesses and a small business economic impact statement is required. Insert the required small business economic impact statement here:

The public may obtain a copy of the small business economic impact statement or the detailed cost calculations by contacting:

Name: Joshua Munroe
Address: PO Box 47852
Olympia, WA 98504-7852
Phone: 360-236-2987
Fax: 360-236-2901
TTY: 711
Email: PharmacyRules@doh.wa.gov
Other: N/A

Date: October 4, 2022	**Signature:** 
Name: Teri Ferreira, RPh	
Title: Pharmacy Quality Assurance Chair	

NEW SECTION

WAC 246-945-486 Return and reuse of unexpired medications—Department of corrections. (1) For the purposes of this section, the term "facilities" includes all facilities served by the Washington state department of corrections pharmacy.

(2) The Washington state department of corrections pharmacy may accept for return and reuse noncontrolled legend drugs in unit dose packages, or full or partial multiple dose medication cards from the facilities it serves, if product integrity can be assured and the Washington state department of corrections pharmacy complies with RCW 69.70.050 (1), (2), and (5).

NEW SECTION

WAC 246-945-488 Safe donation of unexpired prescription drugs. (1) For the purposes of this section, the definitions in RCW 69.70.010 apply.

(2) A pharmacy that accepts, distributes, or dispenses prescription drugs and supplies under WAC 246-945-485 (1)(b) that are donated shall:

(a) Comply with the requirements in RCW 69.70.020, 69.70.030, 69.70.040, and 69.70.050, when applicable;

(b) Complete and return an attestation form developed and supplied by the commission attesting to participation in the drug donation program;

(c) Notify the commission in writing if it is no longer accepting donated prescription drugs and supplies. This notification must occur within thirty calendar days of the pharmacy no longer accepting donated prescription drugs and supplies;

(d) Not accept donations of prescription drugs and supplies via a drop box;

(e) Ensure that prescription drugs and supplies donated by the person to whom the prescription drug was prescribed or the person's representative are accompanied by the department's drug donation form in accordance with RCW 69.70.020(2);

(f) Ensure clear separation of the pharmacy's donated prescription drug stock from the rest of the pharmacy's drug stock;

(g) Maintain a separate inventory of all prescription drugs and supplies donated to the pharmacy; and

(h) Develop and implement policies and procedures addressing:

(i) When prescription drugs or supplies may be accepted and dispensed. The policy and procedure shall require a pharmacist to inspect the donated prescription drugs and supplies and to notify the prescriber when delivering donated prescription drugs and supplies to a patient; and

(ii) How the pharmacy will respond when it is informed of a recall for donated prescription drugs and supplies.

(3) Practitioners, pharmacists, medical facilities, drug manufacturers, drug wholesalers, persons to whom a prescription drug was prescribed, or the person's representative, are not required to obtain a wholesaler license when donating prescription drugs to a pharmacy.

PROPOSED RULE MAKING

CR-102 (July 2022)
(Implements RCW 34.05.320)
Do **NOT** use for expedited rule making

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STATE OF WASHINGTON
FILED

DATE: October 04, 2022
TIME: 2:03 PM

WSR 22-20-101

Agency: Department of Health – Pharmacy Quality Assurance Commission

☒ **Original Notice**
☐ **Supplemental Notice to WSR**
☐ **Continuance of WSR**

☒ **Preproposal Statement of Inquiry was filed as WSR** 21-09-063 **; or**
☐ **Expedited Rule Making--Proposed notice was filed as WSR; or**
☐ **Proposal is exempt under RCW 34.05.310(4) or 34.05.330(1); or**
☐ **Proposal is exempt under RCW**

Title of rule and other identifying information: (describe subject)

WAC 246-945-171 (New) Retired Active Pharmacist License Status. The Pharmacy Quality Assurance Commission (commission) is proposing adding a new section in chapter 246-945 WAC to allow retired pharmacists to apply for a retired active pharmacist license status and practice pharmacy under certain conditions.

Hearing location(s):			
Date:	**Time:**	**Location:** (be specific)	**Comment:**

11/17/2022	10:30am	The Pharmacy Quality Assurance Commission will provide a virtual and a physical location for this hearing to promote social distancing and the safety of the citizens of Washington State. Physical location: Capital Region ESD 113 6005 Tyee Dr SW Tumwater, WA 98512 Lewis Room Virtual: Please download and import the following iCalendar (.ics) files to your calendar system. Daily: https://us02web.zoom.us/webinar/tZIsdu2hqzMuHNJhllH4KKYkCjwBU5J0e2Ps/ics?icsToken=98tyKuGurzouE9GdtB-BRpwABYj4LPPwmFxbgo13lBPpK3R4STr9FehVEIcqOojV Topic: PQAC Business Meeting 2022 To access the meeting on November 17 at 9 a.m., go to https://zoom.us/join or https://us02web.zoom.us/j/86114958466 and use the Webinar ID 861 1495 8466 Other access options include one tap mobile: US: +12532158782,,86114958466# or +16699009128,,86114958466# Or Telephone: Dial(for higher quality, dial a number based on your current location): US: +1 253 215 8782 or +1 669 900 9128 or +1 346 248 7799 or +1 669 444 9171 or +1 386 347 5053 or +1 564 217 2000 or +1 646 558 8656 or +1 646 931 3860 or +1 301 715 8592 or +1 312 626 6799 Webinar ID: 861 1495 8466 International numbers available: https://us02web.zoom.us/u/kdLNo6unOZ	

Date of intended adoption: 11/17/2022 (Note: This is **NOT** the **effective** date)

Submit written comments to:	**Assistance for persons with disabilities:**
Name: Joshua Munroe	Contact Joshua Munroe
Address: PO Box 47852 Olympia, WA 98504-7852	Phone: 360-236-2987

Email: https://fortress.wa.gov/doh/policyreview Fax: 360-236-2901 Other: N/A By (date) 11/3/2022	Fax: 360-236-2901 TTY: 711 Email: PharmacyRules@doh.wa.gov Other: N/A By (date) 11/10/2022

Purpose of the proposal and its anticipated effects, including any changes in existing rules:
On March 26, 2020, Governor Inslee signed proclamation 20-32 to help increase the number of healthcare workers available to meet the needs of patients during the coronavirus disease 2019 (COVID-19) pandemic. This proclamation included a provision that allows a pharmacist with a retired active pharmacist license status to practice pharmacy. Specifically, the proclamation waived "shall not be authorized to practice pharmacy and" from WAC 246-863-080(2) Retired pharmacist license. In other words, the proclamation amended WAC 246-863-080(2) to read: "The holder of a retired pharmacist license… need not comply with the continuing education requirements of chapter 246-861 WAC."

However, the commission recently updated and consolidated all rules under its authority into one new chapter (chapter 246-945 WAC). In this rewrite process, WAC 246-863-080 and the retired active pharmacist license was removed, effective July 1, 2020, as the retired active pharmacist status at the time did not allow for the practice of pharmacy in any capacity and was deemed unnecessary.

The novel coronavirus COVID-19 pandemic illustrated the need for additional qualified and licensed personnel in intermittent and emergency settings, and the commission chose to reinstate the retired active pharmacist license status. However, the interaction between the old rule language and proclamation 20-32 prompted the commission to approve new rule language to both accommodate the proclamation language and update the retired active pharmacist licensing requirements and fees.

In order to allow retired pharmacists to assist with the COVID-19 response with pharmacy services such as vaccine administration while permanent rulemaking was ongoing, the commission adopted an emergency rule on February 1, 2021 under WSR 21-04-116, temporarily creating a retired active pharmacy license status in the new chapter. This emergency rule has been continuously adopted to retain the licensure statutes until permanent rules could be adopted. Permanent rules are required to keep the retired active pharmacist license status in place. The proposed rule differs from the emergency rules in that it includes updated references to license application fees, license renewal fees, and the license renewal period in rule. The proposed language also adds a reference to continuing education requirements for licensees.

Governor Inslee announced on July 29, 2022 that multiple proclamations will be rescinded on October 27, 2022 including proclamation 20-32. However, should relevant proclamations be rescinded or the state of emergency end, this permanent rule will continue to provide guidance for prospective and current licensees should another state of emergency be declared in the future.

Reasons supporting proposal:
Additional qualified, experienced, and licensed personnel is needed to address public health needs during the state of emergency declared under Governor Inslee's proclamation 20-05. The retired active pharmacist license status created under proposed rule WAC 246-945-171 will help make available more health care providers during other states of emergency.

Statutory authority for adoption: RCW 16.64.005; RCW 18.64.205

Statute being implemented: RCW 18.64.205

Is rule necessary because of a:

Federal Law?	☐ Yes	☒ No
Federal Court Decision?	☐ Yes	☒ No
State Court Decision?	☐ Yes	☒ No

If yes, CITATION:

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters: None

Type of proponent: ☐ Private ☐ Public ☒ Governmental
Name of proponent: (person or organization) Pharmacy Quality Assurance Commission

Name of agency personnel responsible for:

	Name	Office Location	Phone
Drafting:	Joshua Munroe	111 Israel Rd SE Tumwater, WA 98501	360-236-2987
Implementation:	Joshua Munroe	111 Israel Rd SE Tumwater, WA 98501	360-236-2987

Enforcement:	Joshua Munroe	111 Israel Rd SE Tumwater, WA 98501	360-2362987

Is a school district fiscal impact statement required under RCW 28A.305.135? ☐ Yes ☒ No

If yes, insert statement here:

The public may obtain a copy of the school district fiscal impact statement by contacting:

Name:
Address:
Phone:
Fax:
TTY:
Email:
Other:

Is a cost-benefit analysis required under RCW 34.05.328?

☒ Yes: A preliminary cost-benefit analysis may be obtained by contacting:

Name: Joshua Munroe
Address: PO Box 47852 Olympia, WA 98504-7852
Phone: 360-236-2987
Fax: 360-236-2901
TTY: 711
Email: PharmacyRules@doh.wa.gov
Other: N/A

☐ No: Please explain:

Regulatory Fairness Act and Small Business Economic Impact Statement

Note: The Governor's Office for Regulatory Innovation and Assistance (ORIA) provides support in completing this part.

(1) Identification of exemptions:

This rule proposal, or portions of the proposal, **may be exempt** from requirements of the Regulatory Fairness Act (see chapter 19.85 RCW). For additional information on exemptions, consult the exemption guide published by ORIA. Please check the box for any applicable exemption(s):

☐ This rule proposal, or portions of the proposal, is exempt under RCW 19.85.061 because this rule making is being adopted solely to conform and/or comply with federal statute or regulations. Please cite the specific federal statute or regulation this rule is being adopted to conform or comply with, and describe the consequences to the state if the rule is not adopted.

Citation and description:

☐ This rule proposal, or portions of the proposal, is exempt because the agency has completed the pilot rule process defined by RCW 34.05.313 before filing the notice of this proposed rule.

☐ This rule proposal, or portions of the proposal, is exempt under the provisions of RCW 15.65.570(2) because it was adopted by a referendum.

This rule proposal, or portions of the proposal, is exempt under RCW 19.85.025(3). Check all that apply:

☐ RCW 34.05.310 (4)(b) (Internal government operations)

☐ RCW 34.05.310 (4)(c) (Incorporation by reference)

☐ RCW 34.05.310 (4)(d) (Correct or clarify language)

☐ RCW 34.05.310 (4)(e) (Dictated by statute)

☐ RCW 34.05.310 (4)(f) (Set or adjust fees)

☐ RCW 34.05.310 (4)(g) ((i) Relating to agency hearings; or (ii) process requirements for applying to an agency for a license or permit)

☒ This rule proposal, or portions of the proposal, is exempt under RCW 19.85.025(4) (does not affect small businesses).

☐ This rule proposal, or portions of the proposal, is exempt under RCW

☐ Explanation of how the above exemption(s) applies to the proposed rule:

(2) Scope of exemptions: *Check one.*

☒ The rule proposal is fully exempt *(skip section 3)*. Exemptions identified above apply to all portions of the rule proposal.

☐ The rule proposal is partially exempt *(complete section 3)*. The exemptions identified above apply to portions of the rule proposal, but less than the entire rule proposal. Provide details here (consider using this template from ORIA):
☐ The rule proposal is not exempt *(complete section 3)*. No exemptions were identified above.

(3) Small business economic impact statement: *Complete this section if any portion is not exempt.*

If any portion of the proposed rule is **not exempt**, does it impose more-than-minor costs (as defined by RCW 19.85.020(2)) on businesses?

☐ No Briefly summarize the agency's minor cost analysis and how the agency determined the proposed rule did not impose more-than-minor costs.

☐ Yes Calculations show the rule proposal likely imposes more-than-minor cost to businesses and a small business economic impact statement is required. Insert the required small business economic impact statement here:

The public may obtain a copy of the small business economic impact statement or the detailed cost calculations by contacting:

Name:
Address:
Phone:
Fax:
TTY:
Email:
Other:

Date: October 4, 2022 **Name:** Teri Ferreira, Rph **Title:** Pharmacy Quality Assurance Commission Chair	**Signature:** 

NEW SECTION

WAC 246-945-171 Retired active pharmacist license status. (1) A pharmacist may apply for a retired active pharmacist license status if they:

(a) Hold an active pharmacist license issued by the commission under chapter 18.64 RCW that is in good standing;

(b) Submit an application on a form provided by the commission; and

(c) Pay the retired credential status application fee as specified in WAC 246-945-990.

(2) A pharmacist with a retired active pharmacist license status shall practice only in emergent or intermittent circumstances.

(a) "Emergent" includes, but is not limited to, earthquakes, floods, times of declared war or other states of emergency.

(b) "Intermittent" means no more than a total of ninety days each year in Washington state.

(3) A pharmacist with a retired active pharmacist license status must meet the continuing education requirements in WAC 246-945-178.

(4) A pharmacist with a retired active pharmacist license status must renew their license every two years in compliance with WAC 246-12-130 and pay the retired active credential status renewal fee set in WAC 246-945-990.

(5) A pharmacist with a retired active pharmacist license status must meet the requirements in WAC 246-12-140 to return their license to active status and pay the active renewal fee set in WAC 246-945-990.

FROM THE WASHINGTON STATE

PHARMACY QUALITY ASSURANCE COMMISSION

DESIGNATION OF PRESIDING OFFICER FOR BRIEF ADJUDICATIVE PROCEEDINGS

We, a quorum of the Pharmacy Quality Assurance Commission, do hereby delegate to Marc Defreyn, Office Director, Office of Investigative and Legal Services, Bill Kellington, Supervising Staff Attorney, Office of Investigative and Legal Services, and Ashley Maxwell, Supervising Staff Attorney, Office of Investigative and Legal Services under Chap. 34.05 RCW, RCW 18.64.005(4) and WAC 246-11-430(1) to serve as a presiding officer to perform the duties necessary to conduct Brief Adjudicative Proceedings on behalf of the Pharmacy Quality Assurance Commission.

These delegations shall remain in effect as long as Mr. Defreyn, Mr. Kellington, or Ms. Maxwell serve in their current capacities or until earlier revoked or withdrawn by the undersigned or my designee.

Dated this _____ day of _____, 2022.

_____

Teri Ferreira, RPh, Chair
Washington State Pharmacy Quality Assurance Commission

PQAC Happenings - meetings, agendas, and surveys!

Washington State Department of Health sent this bulletin at 09/28/2022 04:25 PM PDT

View this as a web page

- Agenda, Legislative Subcommittee Meeting, Friday, 7 October
- USP 800 Enforcement Discretion Extended
- Prescription Drug Pick-up Locker Guidance
- PQAC Accessible Labeling Survey NOW LIVE!

Agenda, Legislative Subcommittee Meeting, Friday, 7 October

Join the PQAC legislative subcommittee to further discuss potential legislative priorities for the 2024 legislative session.

Join by Zoom Webinar: https://us02web.zoom.us/j/82317153848
Or **One tap mobile**: US: +12532158782,,82317153848# or +13462487799,,82317153848#
Or **Telephone**: US: +1 253 215 8782 or +1 346 248 7799 or +1 669 444 9171
Webinar ID: 823 1715 3848
or join us at: Tumwater Timberland Library 7023 New Market St SW, Tumwater

- Agenda

(Meeting times/locations subject to change – No registration required.)
Upcoming meetings...

Date and Location	Activity
Fridays (monthly) – Noon – 1 p.m. **October 7** Zoom *and* Tumwater Timberland Library November 4 and December 2, Zoom/TBD	**2022 Legislative updates** Webinar ID: 823 1715 3848
November 17– 9 a.m. - 3 p.m. **Zoom and location TBD**	**Business meeting** Webinar ID: 861 1495 8466

USP 800 Enforcement Discretion Extended

At the business meeting on September 23, 2022, the Pharmacy Quality Assurance Commission (commission) decided to extend its enforcement discretion regarding USP 800 until it is officially withdrawn during an open public meeting. The commission's previous policy on the enforcement of USP 800 was set to expire on September 30, 2022, but will be updated to reflect the new position. When available, the updated policy will be posted here.

Prescription Drug Pick-up Locker Guidance

Also at the September 23 business meeting, the commission approved the guidance document, *Pharmacy Lockers for Filled Prescription Pick-up,* to assist licensees and stakeholders in understanding the commission's interpretation of its laws and rules to permit pharmacies to use pharmacy-owned lockers to deliver filled prescriptions for non-controlled drugs. The document will also be available soon on the Pharmacy Commission's webpage.

PQAC Accessible Labeling Survey NOW LIVE!

2022 PQAC Pharmacy Survey – Accessible Labeling

A quick reminder - your participation in this survey is vital! Simply click 2022 PQAC Pharmacy Survey – Accessible Labeling! The data collected from this survey will be a valuable resource that will help the commission develop stronger and more accurate rules for pharmacies to provide translated and visually accessible prescription information to patients.

All surveys must be completed and submitted no later than **Sunday, October 16, 2022 at 11:59 p.m.** Please address any inquiries or comments to Joshua Munroe, Rules and

11:59 p.m. Please address any inquiries or comments to Joshua Munroe, Rules and Legislative Consultant, at PharmacyRules@doh.wa.gov.

If you would like to know more, please visit our website or view our recent bulletin.

SAFETY. **QUALITY.** **INNOVATION.**

To request this document in another format, call 1-800-525-0127. Deaf or hard of hearing customers, please call 711 (Washington Relay) or email civil.rights@doh.wa.gov

Frequently Asked Questions

Can pharmacy technicians engage in remote medication order processing or perform order entry from a remote location?

Yes, but pharmacists should ensure ancillary personnel or interns are supervised in a manner that meets the Pharmacy Commission's definition of "immediate supervision". Immediate supervision is defined in WAC 246-945-001(44). This includes the ability of pharmacists to employ technological means for the supervision of ancillary personnel or interns remotely. Pharmacists are encouraged to review WAC 246-945-001(44) in its entirety when remotely supervising ancillary personnel or interns.

Does the Uniform Controlled Substances Act (RCW 69.50) restrict the quantity of controlled substances that may be prescribed?

The Uniform Controlled Substances Act (UCSA), RCW 69.50, does not limit the quantity of controlled substances (including those drugs listed in Schedule II) that may be prescribed. However, prescribers, and pharmacists, should be aware of specific prescribing laws that may apply to their profession. For example, a number of prescribing boards and commissions have specific laws and rules applicable to prescriptions for opioids. The USCA does prohibit refills for a drug listed in Schedule II (see RCW 69.50.308(d)). The USCA also prohibits filling of a prescription for a drug listed in Schedule II more than six months after the date the prescription was issued (see RCW 69.50.308(d)). The USCA prohibits more than five refills of a prescription for a drug listed in Schedule III, IV, or V (see RCW 69.50.308(g)). In addition, the USCA prohibits filling or refilling of a prescription for a drug listed in Schedule III, IV, or V, more than six months after the date issued by the prescriber (see RCW 69.50.308(g)).

Note: The Pharmacy Commission cannot guarantee that prescriptions of controlled substances for any quantity will be covered by a patient's prescription drug benefit.

Can a prescription for a substance included in Schedule II be dispensed upon the oral prescription of a practitioner?

A substance included in Schedule II may be dispensed upon the oral prescription of a prescriber in an emergency (RCW 69.50.308(c)). Further guidance can be found in WAC 246-945-010(6).

Can a pharmacy use transportation network companies (TNCs) such as Uber, Lyft, or Postmates to deliver a patient's prescription medication?

Possibly--Under Washington law, a TNC could transport a patient's prescription medication if they are a "common carrier" or "contract carrier" (see RCW 69.41.030(1) and RCW 60.50.302(c)(2)). If a TNC is a "common carrier" or "contract carrier" the TNC would have to obtain a permit from the Washington State Utilities and Transportation Commission (UTC) unless they are exempt. Pharmacies should contact the UTC to verify the status of a "common carrier" or "contract carrier". Pharmacies should consider other applicable laws and other regulators e.g. United States Drug Enforcement Administration, before using TNCs to deliver a patient's prescription medications. For example, the DEA has stated registrants are responsible for selecting common or contract carriers that will provide adequate security against in-transit losses or thefts.

RULE-MAKING ORDER
EMERGENCY RULE ONLY

CR-103E (December 2017)
(Implements RCW 34.05.350 and 34.05.360)

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: September 23, 2022
TIME: 8:57 AM

WSR 22-20-023

Agency: Department of Health - Pharmacy Quality Assurance Commission

Effective date of rule:

Emergency Rules

☒ Immediately upon filing.

☐ Later (specify)

Any other findings required by other provisions of law as precondition to adoption or effectiveness of rule?

☐ Yes ☒ No If Yes, explain:

Purpose: WAC 246-945-171 Retired active pharmacist license status, establishing a new section of rule. This emergency rule will extend WSR 22-12-066 filed on May 27, 2022 without change. On March 26, 2020, Governor Inslee signed Proclamation 20-32 to help increase the number of healthcare workers available to meet the needs of patients during the coronavirus disease 2019 (COVID-19) pandemic. This proclamation included a provision that allows a pharmacist with a retired active pharmacist license status to practice pharmacy. Specifically, the proclamation amended WAC 246-863-080(2), which was effective at that time, to allow holders of a retired active pharmacist license status to practice pharmacy while the proclamation remains in effect.

The Pharmacy Quality Assurance Commission (commission) updated and consolidated all rules under its authority into one new chapter (chapter 246-945 WAC), effective July 1, 2020. In this rewrite process the requirements from WAC 246-863-080 and the retired active pharmacist license status were repealed. Beginning July 1, 2020 chapter 246-945 WAC took effect and the commission no longer enforces WAC 246-863-080. In order to allow retired pharmacists to assist with the COVID response with pharmacy services such as vaccine administration, the commission is reinstating the retired active pharmacist license in rule. This emergency rule will reinstate the retired active pharmacist credential and allow a pharmacist to apply for a retired active pharmacist license status. The holder of a retired active pharmacist license is allowed to practice during emergent or intermittent circumstances and assist with the COVID-19 response. This emergency rule also establishes the criteria for returning to active status.

Citation of rules affected by this order:

New: WAC 246-945-171
Repealed: None
Amended: None
Suspended: None

Statutory authority for adoption: RCW 18.64.005 and RCW 18.64.205

Other authority:

EMERGENCY RULE

Under RCW 34.05.350 the agency for good cause finds:

☒ That immediate adoption, amendment, or repeal of a rule is necessary for the preservation of the public health, safety, or general welfare, and that observing the time requirements of notice and opportunity to comment upon adoption of a permanent rule would be contrary to the public interest.

☐ That state or federal law or federal rule or a federal deadline for state receipt of federal funds requires immediate adoption of a rule.

Reasons for this finding: The immediate adoption of WAC 246-945-171 is necessary for the preservation of public health, safety, and general welfare. This rule allows retired pharmacists to assist in the response during public health emergencies such as the COVID-19 pandemic. This emergency rule allows retired pharmacists to help meet the needs of patients during the COVID-19 pandemic through performing pharmacy services such as vaccine administration. Observing the time requirements of notice and opportunity to comment upon adoption of a permanent rule would be contrary to the public interest.

The commission authorized permanent rules and the CR-101 (WSR 21-09-063) was filed April 19, 2021, but will not be completed by the time the current emergency rules expire. Proposed rule language for a permanent rule was recently approved by the commission and the CR-102 should be filed soon.

Note: If any category is left blank, it will be calculated as zero. No descriptive text.

Count by whole WAC sections only, from the WAC number through the history note. A section may be counted in more than one category.

The number of sections adopted in order to comply with:

Federal statute:	New	0	Amended	0	Repealed	0
Federal rules or standards:	New	0	Amended	0	Repealed	0
Recently enacted state statutes:	New	0	Amended	0	Repealed	0

The number of sections adopted at the request of a nongovernmental entity:

	New	0	Amended	0	Repealed	0

The number of sections adopted on the agency's own initiative:

	New	1	Amended	0	Repealed	0

The number of sections adopted in order to clarify, streamline, or reform agency procedures:

	New	0	Amended	0	Repealed	0

The number of sections adopted using:

Negotiated rule making:	New	0	Amended	0	Repealed	0
Pilot rule making:	New	0	Amended	0	Repealed	0
Other alternative rule making:	New	1	Amended	0	Repealed	0

Date Adopted: September 23, 2022	**Signature:** 
Name: Teri Ferreira,RPH	
Title: Pharmacy Quality Assurance Chair	

NEW SECTION

WAC 246-945-171 Retired active pharmacist license status. (1) A pharmacist may apply for a retired active pharmacist license status if they:

(a) Hold an active pharmacist license issued by the commission under chapter 18.64 RCW that is in good standing;

(b) Submit an application on a form provided by the commission; and

(c) Pay the retired credential application fee as specified in WAC 246-907-030.

(2) A pharmacist with a retired active pharmacist license status shall practice only in emergent or intermittent circumstances.

(a) "Emergent" includes, but is not limited to, earthquakes, floods, times of declared war or other states of emergency.

(b) "Intermittent" means no more than a total of ninety days each year in Washington state.

(3) A pharmacist with a retired active pharmacist license status must renew every year, comply with WAC 246-12-130 and pay the retired credential renewal fee in WAC 246-907-030.

(4) To return to active status, a retired active pharmacist must comply with WAC 246-12-140 and pay the pharmacist license renewal fee in WAC 246-907-030.

8.4

WAC 246-945-040 Uniform Controlled Substance Act. (1) The commission adopts and incorporates Title 21 of the C.F.R. in effect as of November 17, 2022 by reference. The following sections do not apply: [insert sections identified by review]. Any inconsistencies between 21 C.F.R. Sec. 1300 through 1321 and this chapter should be resolved in favor of this chapter. Nothing in this chapter applies to the production, processing, distribution, or possession of marijuana as authorized and regulated by the Washington state liquor and cannabis board.

(2) Copies of the reference material listed in subsection (1) of this section are available for public inspection at the commission's office at Department of Health, Town Center 2, 111 Israel Road S.E., Tumwater, WA 98501. Requesters may also access copies at: https://www.ecfr.gov/current/title-21.

(3) Registration. A separate registration is required for each place of business, as defined in 21 C.F.R. Sec. 1301.12, where controlled substances are manufactured, distributed, or dispensed. Application for registration must be made on forms supplied by the commission, and all requested information must be supplied unless the information is not applicable, which must

be indicated by the applicant. An applicant for registration must hold the appropriate license provided for in chapter 18.64 RCW.

(4) Recordkeeping and Inventory. Every registrant shall keep and maintain inventory records required by 21 C.F.R. Sec. 1304.04. Registrants are also required to keep a record of receipt and distribution of controlled substances. Records shall include:

(a) Invoices, orders, receipts, or any other document regardless of how titled, establishing the date, supplier, and quantity of drug received, and the name of the drug;

(b) Distribution records, including invoices, or any other document regardless of how titled from wholesalers, manufacturers, or any other entity to which the substances were distributed and prescriptions records for dispensers;

(c) In the event of a significant loss or theft, two copies of DEA 106 (report of theft or loss of controlled substances) must be transmitted to the federal authorities and a copy must be sent to the commission;

(d) For transfers of controlled substances from one dispenser to another, a record of the transfer must be made at the time of transfer indicating the drug, quantity, date of transfer, who it was transferred to, and from whom. Records must be retained by both the transferee and the transferor. These transfers can only be made in emergencies pursuant to 21 C.F.R. Sec. 1307.11.

(5) Credential holders and pharmaceutical firms shall maintain records for Schedule II drugs separately from all other records.

(6) Credential holders and pharmaceutical firms may maintain records for Schedule III, IV, and V drugs either separately or in a form that is readily retrievable from the business records of the registrant.

(7) A federal order form is required for each distribution of a Schedule I or II controlled substance. Credential holders and pharmaceutical firms must keep and make readily available these forms and other records to the commission or its designee. [Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470,

18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-040, filed 6/1/20, effective 7/1/20.]

2022 Accessible Labeling Survey

Pharmacy Quality Assurance Commission

November 17, 2022

Accessible Labeling Rulemaking

Two pillars

- Translated prescription information
- Visually accessible prescription information

Preproposal Statement of Inquiry (CR-101)

- WSR 22-09-065 (filed April 19, 2022)

Listening sessions/public meetings

- Affected groups
  - Patients/individuals
  - Pharmacists/pharmacy personnel

Accessible Labeling Survey

Commission Approved: July 2022

Goals:

- Assess current practices in providing accessible labeling options
- Identify licensee barriers to providing accessible labeling services
- Collect estimated cost data for accessible labeling services

Survey basics

- Target population: Professionals licensed under the commission (pharmacists, pharmacy technicians, pharmacy assistants, etc.)
- Number of questions: 25 (mix of single-response, multiple-response, and long-form response entry)

Accessible Labeling Survey (cont.)

Survey active:

- 9/21/2022 – 10/16/2022

Responses:

- 294 people started
- n = 147

Who Participated?

(147 Respondents)

Pharmacists:	87.1%	(128)
Pharmacy Technicians:	7.5%	(11)
Pharmacy Interns:	0.6%	(1)
Retired Pharmacy Personnel:	0.6%	(1)
Other:	4.1%	(6)

Represented Workplaces

(147 Respondents)

Retail Pharmacy:	**47.6%**	**(70)**
• Independent:	30.6%	(45)
• Chain:	12.2%	(18)
• Supermarket:	4.8%	(7)
Ambulatory Care Clinic:	**15.6%**	**(23)**
Hospital/Institutional Pharmacy:	**12.9%**	**(19)**
• Acute Care Hospital:	8.2%	(12)
• Other Health System Pharmacy:	2.0%	(3)
• Psychiatric Hospital:	1.4%	(2)
• Rural/Critical Access Hospital:	1.4%	(2)

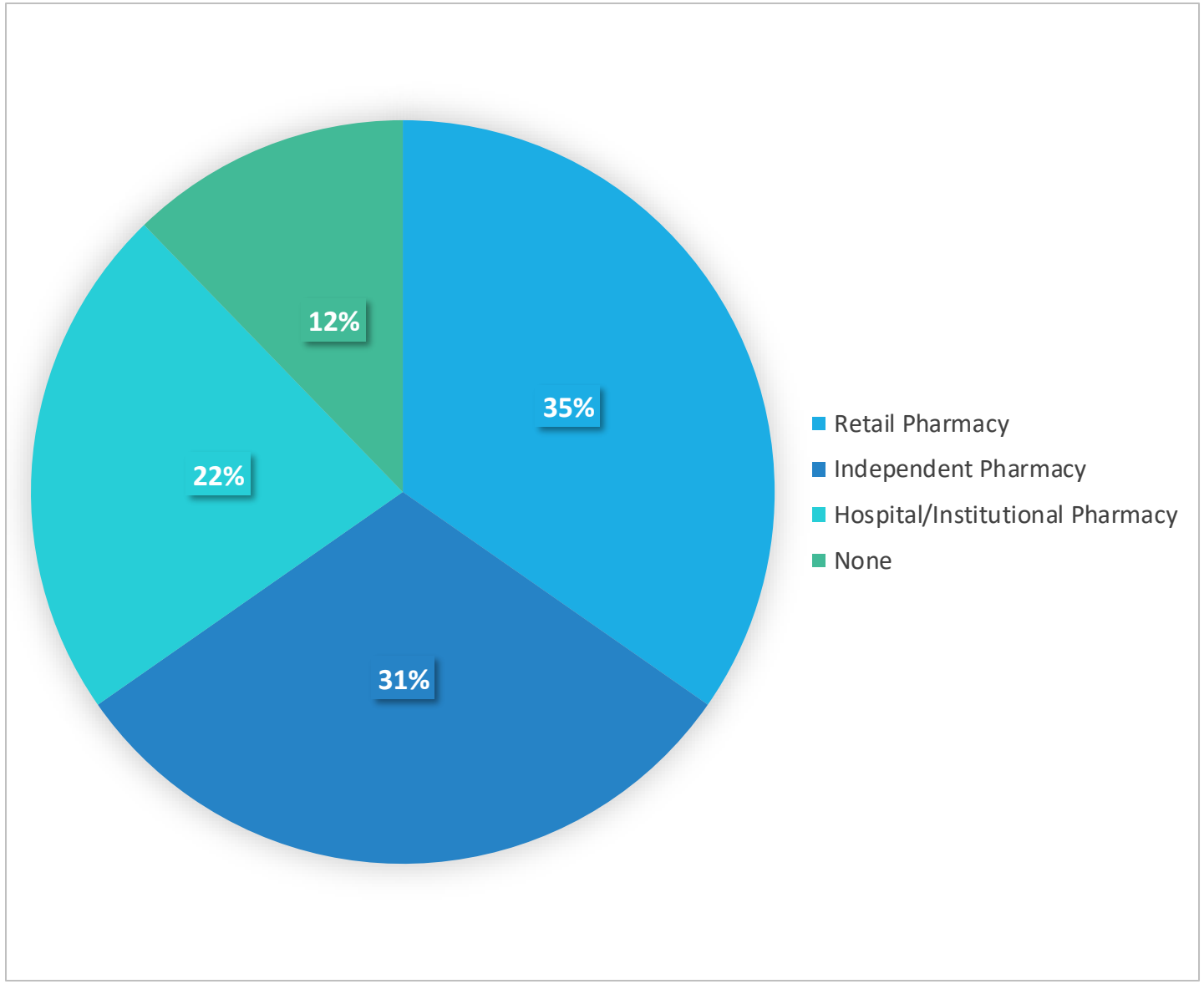
Represented Workplaces
(cont.)

Other:	5.4%	(8)
Long Term Care Pharmacy:	4.1%	(6)
Compounding Pharmacy:	2.7%	(4)
Mail-order Pharmacy:	2.7%	(4)
Academica:	2.0%	(3)
Government/Federal Pharmacy:	2.0%	(3)
Specialty Pharmacy:	2.0%	(3)
Home Health Care:	0.7%	(1)
Medical Communications/Drug Information:	0.7%	(1)
Nuclear Pharmacy:	0.7%	(1)
Pharmacy Law/Regulatory Affairs/Public Policy:	0.7%	(1)

Workplace Classification

(147 respondents)

- Retail Pharmacy: **51**
- Independent Pharmacy: **45**
- Hospital/Institutional Pharmacy: **33**
- None: **18**

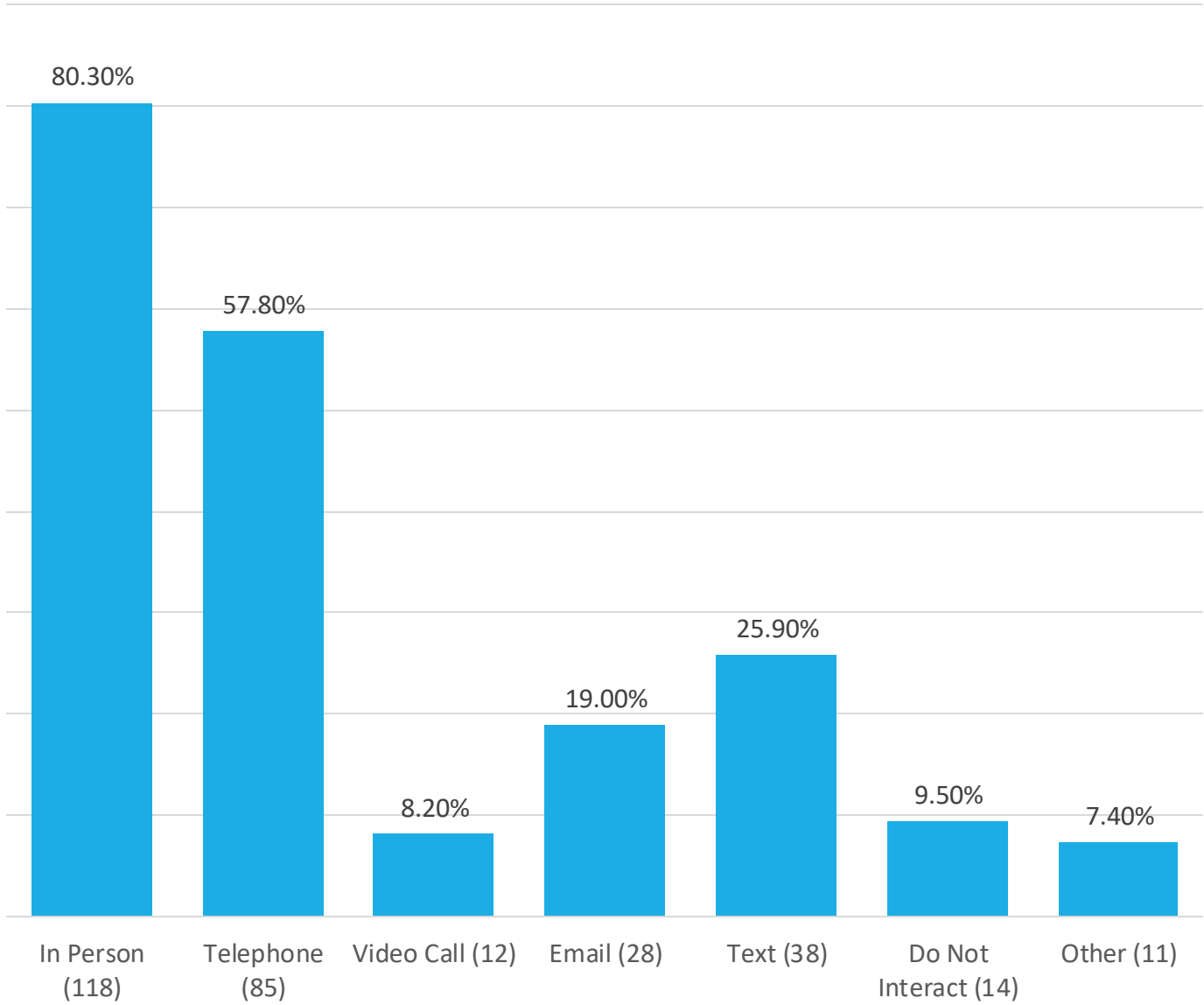


Prescription Workload

1-100 prescriptions a day:	20
101-200 prescriptions a day:	32
More than 200 prescriptions/day:	77
None:	17
N/A:	1

Patient Interaction Methods

(147 Respondents)



Unit 1 – Translated Prescription Information

Translating Prescription Info

63.0% of respondents provide translation services (92 out of 146 applicable respondents)

Who does not translate?

- Compounding and nuclear pharmacies (4 out of 4)
- About a quarter of ambulatory care clinics (6/23)
- Two out of three government/federal pharmacies (2/3)
- Nearly half of hospital/institutional pharmacies (9/19)
- Two-thirds of long-term care pharmacies (4/6)
- A third of retail pharmacies (23/70)
  - 5/18 Chain
  - 14/45 Independent
  - 4/7 Supermarkets

Translating Prescription Info

(92 Respondents)

Reported Request Frequency

• Less than once a month: of the 92 who offer translation services	34.8%	(32)
• One to three times a month:	18.5%	(17)
• One to seven times a week:	22.8%	(21)
• More than once a day:	22.8%	(21)

Translation Methods

• Printed Directions of Use:	71.7%	(66)
• Other Printed Warnings:	56.5%	(52)
• Prescription Container Label:	62.0%	(57)
• Prescription Reader:	8.7%	(8)
• Certified Health Care Translator:	46.7%	(43)
• Staff Consultant/Translator:	43.4%	(40)

Third-Party Translation Providers

54.7% of those providing translation services use Third-party providers (50/92)

40.2% require translator/interpreter in the workplace (37/92)

Which providers used?	• Pioneer Rx, Epic, FDB, RxTran, Rx30, Google Translate, McKesson, Liberty, Computer Rx, Carenotes, Envision America, Medispan, MedAction, EPS, Pacific Interpreters
Startup Costs*	• $100 (unknown) - $100,000 (Epic)
Recurring Costs	• $10/prescription (Computer Rx) - $50,000/year (Epic)

***These are self-reported costs**

Communicating Translation Services

(92 Respondents)

Signage		
• Translated:	43.5%	(40)
• Large-print:	16.3%	(15)
• Non-accessible:	47.8%	(44)
Verbal:	60.9%	(56)
Website		
• Translated:	28.3%	(26)
• Large-print:	13.0%	(12)
• Audio prompts:	5.4%	(5)
• Non-accessible:	58.7%	(54)
Web/Print Ads		
• Translated:	35.9%	(33)
• Large-print:	15.2%	(14)
• Audio prompts:	9.8%	(9)
• Non-accessible:	45.7%	(42)
No Notifications:	7.6%	(7)
Other:	5.4%	(5)

Reported Barriers to Providing Translation Services

(104 Respondents)

Cost of Translation: 55.8% (58 out of 104 respondents who reported some form of implementation barrier)*

Technology/Hardware Limitations: 71.2% (74/104)

Not Required by Statute/Regulation: 14.4% (15/104)

Other: 25.0% (26/104)

Software/Hardware Cost Estimates**

- $200 - $100,000
- One response: “Cost would be more than what our typical profits are for a prescription so it is cost prohibitive”

***These options are not mutually exclusive**

****These are self-reported/perceived one-time costs**

Languages

(Respondents listing at least one language they translate: 85)

Top 3 Requested:

Spanish
Russian
Vietnamese

17 Most Requested

- Spanish – 78
- Russian – 30
- Vietnamese – 30
- Chinese (Cantonese) – 23
- Chinese (Mandarin) – 23
- Korean – 23
- Tagalog – 18
- Farsi (Persian) – 15
- Japanese – 14
- Ukrainian – 14
- Cambodian – 13
- Arabic – 12
- Somali – 11
- Amharic – 10
- French – 8
- Lao – 8
- Romanian – 8

Additional

- Chuukese (Chuuk) – 7
- German – 7
- Hindi – 7
- Swahili – 7
- Burmese – 6
- Hmong – 6
- Portuguese – 6
- Punjabi – 6
- Samoan – 6
- Tigrinya – 6
- Nepali – 5
- Oromo (Afaan Oromo) – 5
- Karen – 4
- Marshallese – 4
- Mixteco Bajo – 4
- Thai – 4
- Urdu – 4
- Tamil – 3
- Telugu – 3
- Other – 4

Unit 2 – Visually Accessible Prescription Information

Visually Accessible Prescription Info

21.9% of respondents provide options for visually accessible prescription information (32 out of 147 respondents)

Reported Request Frequency

- Less than once a month: 78.1% (25 of the 32 providing visually accessible prescription information)
- One to three times a month: 6.3% (2/32)
- One to seven times a week: 6.3% (2/32)
- More than once a day: 9.4% (3/32)

Visually Accessible Info Options

(32 Respondents)

Large-print*

- Directions of Use: 78.1% (25)
- Auxiliary Warnings: 40.6% (13)

Braille

- Directions of Use: 12.5% (4)
- Auxiliary Warnings: 9.4% (3)

Prescription Reader (Audio): 40.6% (13)

Staff Consultant: 25.0% (8)

Other: 0%

*These options are not mutually exclusive

Employed Visually Accessible Resources

(32 Respondents)

Third-party Vendor:	25.0%	(8)
Internal Label Printing:	50.0%	(16)
Staff Consultant:	15.6%	(5)
Mail Service from Other Pharmacy:	9.4%	(3)
Other:	9.4%	(3)

Visually Accessible Cost Estimates

Only two reported cost estimates (out of 32) from respondents who use software/hardware to provide visually accessible prescription information

Start-up costs

$1,099, $10,000

Recurring costs

$900, $1,000

Notification Methods for Visually Accessible Services

(26 Respondents)

Signage*

- Pharmacy Wall: 38.5% (10)
  (of the 26 who reported using some form of notification method)
- Pharmacy Counter: 30.8% (8)
- Pharmacy Wall (Braille): 15.4% (4)
- Pharmacy Counter (Braille): 11.5% (3)

Verbal: 61.5% (16)

Pharmacy Website: 42.3% (11)

Web/Print Ad: 26.9% (7)

Other: 0%

***These options are not mutually exclusive**

Reported Barriers to Providing Visually Accessible Services

(119 Respondents)

Software/Hardware Costs: (of the 119 respondents who listed some form of implementation barrier*)	61.3% (73)
Technology/Printing Limitations:	77.3% (92)
Not Required by Statute:	16.8% (20)
Other:	17.6% (21)

Predicted costs range:

$2,000 (w/ ongoing subscription) to $20,000 (for first year)

***These options are not mutually exclusive**

Thank you!

Questions?

PharmacyRules@doh.wa.gov

Accessible Label Rule References

Translated Labels

California

- CA Law 4076.6 - California
  - 4076.6(a) – Dispenser shall provide translated directions for use on patient request
    - Printed on container label
  - 4076.6(b) – Dispensers may use translations provided by the board of pharmacy
  - 4076.6(c) – Dispenser don't need to use languages beyond those that the board provides
  - 4076.6(d) – Dispensers may use their own translation services to comply with the section
  - 4076.6(e) – Dispensers are responsible for the accuracy of English-language directions for use provided to the patient
  - 4076.6(f) – Veterinarians are not considered dispensers for this section

New York

- NY Law 6829 – New York
  - 6829(1) – Definitions provided for:
    - 6829(1)(a): "Covered pharmacy"
    - 6829(1)(b): "Limited English proficient individual"
    - 6829(1)(c): "Translation"
    - 6829(1)(d): "Competent oral interpretation"
    - 6829(1)(e): "Pharmacy primary languages"
    - 6829(1)(f): "Mail order pharmacy"
  - 6829(2)(a) – Pharmacies must provide free, competent oral interpretation services on patient request
  - 6829(2)(b) – Pharmacies must printed translated medication labels, warning labels, and other written material on patient request
  - 6829(2)(c) – Pharmacies may use staff or third-party contractors to provide translations
  - 6829(3) – Signage advertising translation services must be conspicuously posted
  - 6829(4) – The pharmacy commission is responsible for rulemaking in order to establish translation services
    - 6829(4)(a): Rules must state how to determine if patient is LEP
    - 6829(4)(b): Determine which languages are considered
    - 6829(4)(c): Manner and circumstances by which oral interpretation services are provided
    - 6829(4)(d): Which information is eligible for oral interpretation
    - 6829(4)(e): Anticipate how service is utilized, which resources used and what costs are incurred
    - 6829(4)(f): Establish compliance/monitoring standards
  - 6829(5) – Covered pharmacies are not liable for injuries resulting from third-party contractor translations

    - 6829(6) – Must establish a process by which pharmacies may apply to receive a waiver from compliance
    - 6829 (7) – Commissioner must coordinate with the commissioner of health to "effectuate" requirements of the section
- NY Rule Section 63.11 – Interpretation and translation requirements for prescription drugs
    - 63.11(a) – Definitions for:
        - 63.11(a)(1): "Covered pharmacy"
        - 63.11(a)(2): "Corporate entity"
        - 63.11(a)(3): "Limited English proficiency individual"
        - 63.11(a)(4): "Translation"
        - 63.11(a)(5): "Competent oral interpretation"
        - 63.11(a)(6): "Pharmacy primary languages"
        - 63.11(a)(7): "Mail order pharmacy"
    - 63.11(b) – How competent oral interpretations are provided
        - 63.11(b)(1) – Covered pharmacies must provide oral translation services for patient counseling for free on request
        - 63.11(b)(2) – Covered pharmacies must provide oral translation services of medication/warning labels or other written materials for free on patient request
        - 63.11(b)(3) – Translations must be provided on site unless list of languages exceed seven
        - 63.11(b)(4) – Staff or third-party contractors are allowed to provide translated information
    - 63.11(c) – Notification requirements
        - 63.11(c)(1) – Conspicuous signage for advertising translation services
        - 63.11(c)(2) – Font size and type, design element requirements
        - 63.11(c)(3) – Placement of signage
    - 63.11(d) – Waivers for translation services
        - 63.11(d)(1) – One application per pharmacy
        - 63.11(d)(2) – Waiver applications must describe financial/physical constraints and impact on other services
        - 63.11(d)(3) – Reasons to deny waiver application
        - 63.11(d)(4) – Applicants must identify nearby services that can provide translation services
        - 63.11(d)(5) – Post notice of alternative services if waiver granted
        - 63.11(d)(6) – Waiver duration and renewal conditions
    - 63.11(e) – This section preempts local laws/ordinances, though cities of 100,000 or more may impose stricter regulations

Nevada

- NV Law 639.28013 – Requirement to provide prescription info in English and certain other languages on request
    - All pharmacies must comply except institutional pharmacies
    - Signage required:
        - Notice of the rights of a patient to request information in another language

        - A list of languages available for translation
    - Board responsible for adopting regulations prescribing each language required
    - Pharmacy/employees not liable in any civil action for injury if the pharmacy uses a third-party vendor to provide translation services

Oregon

- OR Law 689.564 – Prescription drug labels
    - 689.564(1) – Board of pharmacy responsible for rules establishing pharmacy printing of prescription drug labels in English and language requested by LEP individual. Rules must also:
        - 689.564(1)(a) – Define "limited English proficiency"
        - 689.564(1)(b) – Determine which sections with which pharmacies must comply
        - 689.564(1)(c) – Determine list of drugs eligible for translation
        - 689.564(1)(d)(A) – Minimum list length of 14 languages other than English
        - 689.564(1)(d)(B) – Board must reassess/update list every 10 years
    - 689.564(2)(a) – Third-party contractors may be used
        - 689.564(2)(b) – Liability exemptions for injury resulting from errors in third-party translations
    - 689.564(3) – Not applicable to institutional drug outlets
    - 689.564(4) – Grants board of pharmacy rulemaking authority
    - 689.564(5) – Signage posting requirements

Texas

- TX Rule 291.3 – Required notifications
    - 291.3(h)(2)(B)(viii) – Pharmacies must provide in their profile the type of language translation services, including translating services for persons with impairment of hearing
        - No requirements for services themselves, but that they need to announce any services pharmacies choose to use

Visual/print Accessibility

Arkansas

- Arkansas Rule 054.00.75-6
    - November 1, 2019
    - Font size for data elements in prescription drug card: 8 points or greater (no font type listed in this section of rule)

California

- California Rule 1707.5 – Patient-centered labels for prescription drug containers
    - The following elements, clustered together, must comprise at least 50 percent of the label:
        - Name of patient
        - Name of drug/strength of drug
        - Directions for use
        - The condition/purpose for which the drug was prescribed
    - Font: At least 12-point font in sans serif typeface
    - Provides suggested phrasing to accommodate compliance

Massachusetts

- MA Law MGLA 94C-21
    - November 1, 2019
    - On request, prescription label must be printed in a size "allowing no more than ten characters per inch."

Nevada

- NV Law 639.28015 – Notice of prescription readers
    - Pharmacies must let patients know about availability of prescription readers and provide them on request
    - Definitions provided for "prescription reader" and what applies as a "retail community pharmacy"

New Jersey

- New Jersey Rule 13-39-7.12 – Labeling
    - March 30, 2022
    - Font size directions for warning label/sticker only
        - Must be at least 10-point font (not cursive) that is "clear and readable" per subsection (2)(iii)

New York

- New York Rule Section 63.12 – Standardized patient-centered data elements to be used on all drug labels
    - Levels of information importance
        - Critical: Patient name, directions of use, drug name/strength
        - Important: Name/address/phone of pharmacy, patient's address, name of prescriber, filling date, prescription/identifying number
    - Critical elements must be at least 12-point font, with highlighting/bolding used for emphasis
        - No highlighting/bolding of "Important" info

Oregon

- Oregon Revised Statute (ORS) 689.561
    - November 1, 2019
    - Definitions for “blind” and “prescription reader”
    - Notification of prescription readers to patients except for drugs dispensed by “an institutional drug outlet”
        - Readers must last duration of prescription and meet needs of identified impairment
    - Labels must be compatible with prescription readers
- OR Rule 855-041-1131 – Prescription reader accessibility
    - Pharmacies must notify each person receiving a prescription that a prescription reader is available, and provide that reader if requested

Texas

- Texas Rule 291.33 – Operational Standards
    - December 14, 2020
    - Subsection TAC 291.33(a)(7)(A) includes language for “easily readable font size,” though later subsections describe this as at least ten-point Times New Roman.
    - Subsections with font size references:
        - TAC 291.33(a)(7)(A) – Dispensing container label
            - **NOTE:** There is also language in TAC 562.006(f) for the board to adopt rules requiring dispensing container labels be printed in an “easily readable font size”
        - TAC 291.33(7)(A)(ii) – Prescription drug ID number
        - TAC 291.33(7)(A)(vii) – Name of patient (or animal name/species if prescribed for animal)
        - TAC 291.33(7)(A)(viii) – Instructions for use

PQAC Rules Tracker

Title	Status	Short Description	Most Recent WSR #
COVID - CII Prescribing (emergency)	Filed October 20	Emergency rules for prescribing Schedule II drugs during COVID-19 pandemic	WSR 22-22-006 (Filed October 20, 2022)
Medication assistance (emergency - filed jointly with DOH)	Under division review in RMS	Medication assistance emergency rules in accordance with chapter 69.41 RCW	WSR 22-15-049 (Filed July 15, 2022)
Retired pharmacist (emergency)	Needs refile approval	Emergency rules for retired active pharmacist license status	WSR 22-20-023 (Filed September 23, 2022)
Accessible labeling (visual/print access and translated labels)	Survey data collected for November 2022 business meeting	Standard/significant rules for setting/improving standards for prescription drug information access/comprehension	WSR 22-09-065 (Filed April 19, 2022)
Retired pharmacist (standard)	CR-102 filed; public hearing conducted at November 2022 business meeting	Permanent rules for retired active pharmacist license status	WSR 22-20-101 (Filed October 4, 2022)
Medication assistance (standard - will file jointly with DOH)	Rule language under review	Medication assistance rules in accordance with chapter 69.41 RCW	WSR 22-02-015 (Filed December 27, 2021)
Remote dispensing OUD medications - SSB 6086 (standard)	SBEIS in review	SSB 6086 - Implementing remote dispensing of OUD medications	WSR 20-17-123 (Filed August 18, 2020)
Donation of unexpired drugs - SSB 6526 (standard)	CR-102 filed; public hearing conducted at November 2022 business meeting	SSB 6526 - Implementing the donation and reuse of unexpired drugs	WSR 22-20-100 (Filed October 4, 2022)

PQAC Rules Tracker (cont.)

Title	Status	Short Description	Most Recent WSR #
Health Equity Training – ESSB 5229 (standard)	CR-101 submitted for review in RMS	Amend sections in Chapter 246-945 WAC pertaining to continuing education standards and establishing health equity CE requirements per ESSB 5229.	Not yet filed
Uniform Controlled Substances Act – Title 21 CFR (expedited)	CR-105 drafted; updated proposal before committee (11/17)	Amend language in WAC 246-945-040 to incorporate by reference any changes in Title 21 CFR made after the rule's effective date	Not yet filed
Dialysate and dialysis device manufacturer licensing	CR-101 draft pending	Determine sections in chapter 246-945 WAC (subsection -090 through -093 at least) to amend to comply with SSB 1675	Not yet filed
Access to drugs stored outside pharmacy (standard)	CR-101 submitted for division review in RMS	Allowing access to drugs stored outside the pharmacy by unlicensed employees of a health care facility	Not yet filed
Mobile OTP unit licensing	CR-101 draft pending	Amend WAC 246-945-060 to clarify licensing standards for mobile OTP units	Not yet filed
Zero Order Reports and Suspicious Orders (standard)	CR-101 draft pending; proposal before committee	Amending WAC 246-945-001 and WAC 246-945-585 to adjust suspicious order and zero reporting requirement	Not yet filed
Technical fixes to chapter 246-945 WAC (expedited)	On hold	Typos and small edits to multiple sections in chapter 246-945 WAC	Not yet filed
AIDS education repeal - ESHB 1551 (expedited)	CR-105 draft under division review	ESHB 1551 - Repealing AIDS education and training requirements	WSR 22-22-092 (Filed November 1, 2022)