# December 17, 2021 Commission meeting materials

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 Meeting**
**October 22, 2021 - Minutes**

Convene: Chair, Teri Ferreira called the meeting to order October 22, 2021, 9:06 a.m.

***Commission Members***:
Teri Ferreira, RPh, Chair
Bonnie Bush, Public Member
Hawkins DeFrance, Nuclear Pharmacist
Patrick Gallaher, BS, BPharm, MBA, MPH
Judy Guenther, Public Member
William Hayes, PharmD, CCHP
Helen H. Jung, PharmD, MBA
Tim Lynch, PharmD, MS, FABC, FASHP
Craig Ritchie, RPh, JD
Ann Wolken, PharmD, RPh

***Commission Member Absent***:
Jerrie Allard, Public Member, Vice Chair
Ken Kenyon, PharmD, BCPS
Uyen Thorstensen, CPhT

***Staff Members***:
Trina Crawford, Interim Executive Director, Pharmacy Commission
Lindsay Trant, Interim Deputy Director, Pharmacy Commission
Christopher Gerard, AAG
Martin Pittioni, Director, OHP
Marlee O'Neill, Deputy Director, OILS
Blake Maresh, Deputy Director, Office of Health Professions
Joshua Munroe, Legislative and Rules Consultant
Taifa "Nomi" Peaks, Pharmacy Consultant
Joanne Miller, Program Manager, Pharmacy
Amy L Robertson, Administrative Assistant, Pharmacy

**1. Call to Order** Teri Ferreira, Chair ***Action***

**1.1** Meeting Agenda Approval – October 22, 2021

**MOTION:** Craig Ritchie moved to approve the meeting agenda for October 22, 2021. Bonnie Bush, second. Motion carries, 10:0.

**1.2** Meeting Minutes Approval – September 2, 2021

**MOTION:** Craig Ritchie moved to approve the minutes for September 2, 2021. Patrick Gallaher, second. Motion carries, 10:0.

**2. Consent Agenda**

**2.1** National Precursor Log Exchange January
**2.2** Pharmaceutical Firms Application Report Approval
- August 16, 2021 thru October 4, 2021 – new and closed firms

**2.3** Ancillary Utilization Plans Approval
**2.3.1** CityScript Pharmacy
**2.3.2** Geneva Woods Pharmacy

**2.3.3** Jim's Pharmacy and Home Health
**2.3.4** Mcleary Healthmart multiple locations
**2.3.5** Memorial Pharmacy at Cornerstone
**2.3.6** Seattle Cancer Care Alliance
**2.3.7** Willapa Harbor Hospital

**2.4** Pharmacy Technician Training Program Approval
**2.3.1** Credena Health

**MOTION:** Craig Ritchie moved to approve the consent agenda with the removal of item 2.3.2 Geneva Woods Pharmacy per Patrick Gallaher's request. William Hayes, second. Motion carries, 10:0.

**2.5** Regular Agenda/Items Pulled from 2.1-2.4. The commission will discuss items removed from the consent agenda and placed on the regular agenda for separate discussion.

2.3.2 – Geneva Woods Pharmacy

**MOTION:** William Hayes moved to return the AUP to the pharmacy for review, correction, and update the AUP. Patrick Gallaher, second. Motion carries, 10:0.

**3. Old Business –** The Commission will discuss, for clarification or decision, ongoing topics and issues from previous meetings. ***Information/Action.***

**3.1** USP 800 & 825 (self-inspection worksheets) ***Action***

Shelley Feldner-Schuerman is unable to present this today. This item will be discussed at the December meeting.

**3.2** Overview of case load and timeline ***information only***

Marlee O'Neill updated the commission that OILS is working to put a plan in place to more consistently meet case disposition timelines set out in chapter 246-14 WAC. Marlee will have more information at the December meeting about this plan. Due to staffing issues, pandemic, etc., it has been challenging for staff attorneys and commissioners to timely get their disciplinary work completed. For application cases, there are options for the commission in order to assist in moving these cases timelier. Options for the commission:

Distribute all materials for review to entire CMT panel via Box.com.
Assign a case to a specific commission member for presentation to the CMT panel.

Commissioners agree option two is the preferred action. In addition, if needed, allowing the presenter to have a written statement prepared for a staff member to read in the case the presenter cannot attend the CMT.

**3.3** FDA MOU Update- ***information only***

Christopher Gerard, AAG, provided commissioners with a summary of Wellness Pharmacy vs United States Health and Human Services (2021). A coalition of compounding pharmacies filed this action and challenged the FDA's Memorandum of Understanding Addressing Certain

Distributions of Compounded Human Drug Products (MOU). The Court remanded the MOU back to the FDA to either certify the MOU will not have a significant economic effect on small business or prepare a regulatory flexibility analysis. No action is required by PQAC at this time.

**3.4** Subcommittee Chair volunteers ***Action***

**MOTION:** Craig Ritchie moved to change membership and assign chairs as outlined during the meeting. Bonnie Bush, second. Motion carries, 10:0.

| Committee | Commission Members |
|---|---|
| **Leadership Committee:**<br>• Commission Recruitment<br>• Staffing/Training and SOP | **Chair**: Teri Ferreira<br>**Members**: Jerrie Allard, William Hayes |
| **Budget Committee:** HELMS | **Chair**: Patrick Gallaher<br>**Members**: Judy Guenther, William Hayes, Helen Jung, Ken Kenyon |
| **Compounding Committee:**<br>• FDA MOU<br>• Self-Inspection Worksheets<br>• Whitebagging | **Chair**: Hawkins DeFrance<br>**Members**: Tim Lynch, Ken Kenyon, Uyen Thorstensen |
| **Strategic Planning Committee** | **Chair**: Jerrie Allard (tentative)<br>**Members**: Bonnie Bush, Ann Wolken |
| **Pharmacy Practice Committee**<br>• Misfill and Pharmacy Work Condition Workgroup<br>• Sunrise Review<br>• CDTA WMC Committee (Tim/Teri)<br>• Sample AUP review | **Chair**: Craig Ritchie<br>**Members**: Hawkins DeFrance, Patrick Gallaher, Helen Jung, Ann Wolken |
| **Facility Committee**<br>• HPACs Committee<br>• Suspicious Orders<br>• Facility Enforcement Authority | **Chair**: Ken Kenyon (tentative)<br>**Members**: Teri Ferreira, William Hayes, Helen Jung, Tim Lynch |
| **Legislative Committee** | **Chair**: William Hayes<br>**Members**: Hawkins DeFrance, Tim Lynch, Craig Ritchie |
| | Updated 10/27/21 |

**3.5** Review Policy on Approved List of Recognized States for Nonresident Pharmacies ***Action***

**MOTION:** Craig Ritchie moved to include Illinois to the states that are substantially equivalent to Washington while PQAC's policy statement "Enforcement of USP Chapters <800> and <825>" is in effect, and for this directive to be reapproved at the December meeting. Bonnie Bush, second. Motion carries, 10:0.

**4. New Business**-- The commission will discuss, for clarification or decision, ongoing topics and issues from previous meetings. *Information/Action.*

**4.1** List and label request ***Action***

**MOTION:** Craig Ritchie moved to ask the requestor whether they still need the list and if yes, submit a declaration stating that the list will not be used for a commercial purpose. Judy Guenther, second. Motion carries, 10:0.

**4.2** Midwives legend drugs and devices consult ***Action?***

Kathy Weed presented proposed changes to administrative rules addressing legend drugs and devices that midwives can purchase and use (WAC 246-834-250). The secretary of health is required to consult with PQAC before adopting these rules pursuant to RCW 18.50.115.

**MOTION:** Tim Lynch moved to accept the changes as suggested. Patrick Gallaher, second. Motion carries, 10:0.

**4.3** Opioid Treatment Programs mobile unit credential ***information only***

Lindsay Trant updated the commission that the DEA has completed rules allowing OTPs to add a mobile component to their existing DEA registration. The department is pursuing licensing options for these mobile units. Currently, mobile components of OTPs will need to obtain separate "other controlled substance registrations" from PQAC. Staff will amend application to accommodate mobile licensing needs.

Michelle Weatherly and Julie Tomaro informed the PQAC that the Behavioral Health Agencies Program within the Department of Health are working on rules to regulate mobile components of OTPs. The timeline for those rules to be implemented is approximately July 2022.

Recommendations:

- License mobile OTPs as "other controlled substance" registrants
- Make the following changes to the application:
    - Add field for license plate number
    - Add field for VIN number
- Modifications to ILRS as needed to identify mobile units
- Applicant would need to apply for new credential for each OTP mobile unit

**MOTION:** Craig Ritchie moved approve the recommendations in the SBAR to move forward with the rule-making process. In the interim direct staff to investigate a legal analysis and present to the commission on a new rule that would exempt OTPs from a separate credential with the commission that mirrors the DEA OTP new regulation. Hawkins DeFrance, second. Motion carries, 10:0.

## 5. Rules and Legislative Session Updates - Information/Action.

**5.1** Rules Petition: Accessible Labeling ***Action***

**MOTION:** Craig Ritchie moved to approve the petition and begin the rulemaking process regarding accessible labeling. Hawkins DeFrance, second. Motion carries, 10:0.

**5.2** Reauthorize Retired Pharmacist Emergency Rules ***Action***

**MOTION:** Craig Ritchie moved to reauthorize the retired pharmacist emergency rules. Hawkins DeFrance, second. Motion carries, 10:0.

**6. Panel Review:**

**6.1** Study Plan review PHRM.PH.61170886

**MOTION:** Tim Lynch moved to accept the study plan and authorize applicant to retake the MPJE exam for a fourth time. Craig Ritchie, second. Motion carries, 10:0.

**7. Open Forum** (10 minutes)

**8. Commission Member Reports - *Information/Action*.**

**8.1** Commissioner Reports - No reports provided.

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

Patrick Gallaher will work with pharmacy staff to develop needle stick safety and prevention for the technician training program, FAQ, and guidance document.

**9. Staff Reports *Information/Action.***

**9.1** Interim Executive Director- Trina Crawford

- Trina Crawford shared the state auditor's office (SAO) has started an audit of the prescription monitoring program (PMP) system. This audit also includes prescribing boards and PQAC. Conference with SAO on October 11. Tim Lynch, Patrick Gallaher and some staff attended the conference. Overall to see if it could be better used to monitor opioid prescribing/dispensing patterns and help reduce opioid abuse/misuse. The recommendation will be completed by summer 2022. The recommendations are not legislatively mandated. They will be recommendations PQAC can consider if any changes are needed.

  Tim Lynch added that this was a good meeting and a great opportunity to educate our auditors on what the PQAC's role is in the PMP program and educate on pharmacy practice.

  Patrick agreed with Tim, and volunteered to act as a point of contact.

- Secondly, SSB 5092 passed and requires sexual transmitted infection workgroup to be formed by the DOH and within that workgroup, it specifically asks for a pharmacy staff member to participate. Nomi Peaks will be that member and reporting to PQAC.

**9.2** Interim Deputy Director – Lindsay Trant

**9.3** OILS Deputy Director– Marlee O'Neill

- Pharmacy Inspector Stephanie Martin has been activated to DOH's incident management team (IMT). Tentatively she will return as inspector in early 2022 after maternity leave.

- Currently interviewing for the project pharmacy inspector positions. These should be completed in the next few weeks.
- Thank you to inspectors for being kind and patient.

**9.4** Assistant Attorney General – Christopher Gerard

- A hearing on the John Worthington case will take place on November 19. PQAC will be provided an additional update at the December meeting.

**10. Summary of Meeting Action Items –** Commissioner and staff will revisit action items identified during today's business meeting.

- 2.5 – Geneva Woods Pharmacy – contact the pharmacy to update the AUP and application.
- 3.1 – moved to the December meeting
- 3.2 – option 2 on SBAR on 3.2
- 3.4 – Volunteers for subcommittees for the chair so staff will prepare and document update. Distribute to website and commissioners.
- 3.5 – policy on approved list of recognized states – staff will notify credentialling that we are accepting Illinois. Staff will bring the full list back to December meeting to be reviewed and/or approved
- 4.1 – List and Labels – staff contact the requestor to see if this documentation is still needed. If yes, please confirm and provide declaration this will not be used for commercial purposes.
- 4.3 – Opioid Treatment Program mobile unit credential – staff will approve the recommendation in the SBAR. Staff will look into options for exempting OTP mobile units from separate registration requirement.
- 5.1 – Rule Petition – staff will begin rule-making process
- 5.2 – reauthorizing the emergency rule
- 6.1 – Joanne will notify credentialling as well as NABP the panel's decision to approve the retake of the MPJE.
- Patrick to work with staff regarding current guidance document on technician immunization / needle safety.

**12:46 pm** (approximately)
**Business Meeting Adjourned.**

**From:** Appriss Health
**To:** Weimer, Jamie; DOH WSPQAC; Miller, Joanne (DOH)
**Cc:** ndelavega@appriss.com; kmccormick@appriss.com; Accountspecialist@appriss.com; tnadrich@appriss.com
**Subject:** Washington NPLEx Dashboard Report - Nov 2021
**Date:** Wednesday, December 1, 2021 3:28:09 AM
**Attachments:** WA_PHARMACY_TRX_REPORT_11012021.csv

External Email

MONTHLY PROGRAM ADMINISTRATOR'S DASHBOARD

**3 Logins - 0 Searches - 0 Report Queries - 29 Active Watches - 0 Active Watch Hits**

NEW USERS THIS MONTH

New Users = 0

Total Accounts = 141

Active Users = 2

TOP USAGE AGENCIES

TOP USERS BY USAGE

TOP AGENCIES BY ACTIVE WATCHES

1. ICE - King County (15)

**TRANSACTION SUMMARY STATISTICS (2021)**

| | JAN | FEB | MAR | APR | MAY | JUN | JUL | AUG | SEP | OCT | NOV | TOTAL |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| PURCHASES | 58,504 | 51,943 | 70,640 | 82,986 | 78,777 | 84,242 | 79,222 | 72,763 | 67,790 | 72,503 | 65,984 | **785,354** |
| BLOCKS | 2,433 | 2,301 | 2,931 | 3,933 | 3,515 | 3,763 | 3,233 | 2,899 | 2,952 | 2,947 | 2,491 | **33,398** |
| GRAMS SOLD | 130,934 | 117,632 | 165,200 | 197,654 | 185,979 | 198,842 | 181,384 | 164,623 | 151,157 | 158,114 | 142,713 | **1,794,232** |
| BOXES SOLD | 66,771 | 59,470 | 79,346 | 92,123 | 87,787 | 93,305 | 88,636 | 82,270 | 76,813 | 81,942 | 74,137 | **882,600** |
| GRAMS BLOCKED | 6,569 | 7,011 | 8,009 | 11,356 | 9,993 | 10,793 | 8,922 | 7,961 | 8,214 | 7,660 | 6,574 | **93,062** |
| BOXES BLOCKED | 2,700 | 2,897 | 3,183 | 4,360 | 3,929 | 4,110 | 3,617 | 3,324 | 3,487 | 3,288 | 2,872 | **37,767** |
| AVG GRAMS PER BOX BLOCKED | 2.43 | 2.42 | 2.52 | 2.60 | 2.54 | 2.63 | 2.47 | 2.40 | 2.36 | 2.33 | 2.29 | **2.45** |

**PHARMACY PARTICIPATION STATISTICS (Nov 2021)**

| | |
|---|---|
| Enabled Pharmacies | 998 |
| Pharmacies Submitting a Transaction | 936 |
| Pharmacies Logging in Without a Transaction | 0 |
| Inactive Pharmacies | 62 |
| Pharmacy Participation for Nov | 93.79% |

**DISCLAIMER:** This is an automated report meant to give you a quick snapshot of the NPLEx system in your state. The statistics listed in this report are only meant to be a general overview and not necessarily the exact final numbers. Prior to releasing any statistics mentioned in this report, we highly recommend that you verify the

numbers with your NPLEx customer relationship manager. For questions or issues, please contact kmccormick@appriss.com.

| Credential # | Status | | Facility Name |
|---|---|---|---|
| PHWH.FX.61231302 | ACTIVE | 10/27/2021 | Summit SD, LLC |
| PHWH.FX.61233167 | ACTIVE | 10/27/2021 | Validus Pharmaceuticals |
| PHWH.FX.61073573 | ACTIVE | 10/28/2020 | Reliance Inc. |
| DRSD.FX.61239585 | ACTIVE | 10/28/2021 | Allergan USA, Inc |
| PHHC.FX.61225886 | ACTIVE | 10/28/2021 | Multicare Silverdale Eye Physicians |
| PHHC.FX.61180730 | ACTIVE | 10/28/2021 | Seattle STEP Clinic at the Hepatitis Education Project |
| PHWH.FX.61239051 | ACTIVE | 10/28/2021 | Reliance Wholesale Inc |
| PHWH.FX.61184213 | ACTIVE | 10/28/2021 | Salaam Health |
| PHWH.FX.61215516 | ACTIVE | 11/01/2021 | Stratatech Corporation |
| PHHC.FX.61228928 | ACTIVE | 11/03/2021 | Multicare Indigo Urgent Care - Gig Harbor |
| PHNR.FO.61239609 | ACTIVE | 11/03/2021 | Albertson's Specialty Care Pharmacy |
| PHNR.FO.61238996 | ACTIVE | 11/03/2021 | giftHEALTH Pharmacy |
| PHNR.FO.61239112 | ACTIVE | 11/05/2021 | Innovation Compounding |
| PHWH.FX.61106559 | ACTIVE | 11/05/2021 | Albireo Pharma, Inc. |
| PHHC.FX.60944381 | ACTIVE | 11/10/2021 | American Behavioral Health Systems - Cozza |
| PHNR.FO.61243568 | ACTIVE | 11/12/2021 | Brooksville Pharmaceuticals, Inc |
| PHNR.FO.61244351 | ACTIVE | 11/12/2021 | Montecito Rx |
| PHWH.FX.61230110 | ACTIVE | 11/12/2021 | Paratek Pharmaceuticals, Inc. |
| DRDG.FX.61229868 | ACTIVE | 11/16/2021 | Swinomish Indian Tribal Community |
| PHHC.FX.61235498 | ACTIVE | 11/17/2021 | Swedish Neurology - Bellevue |
| PHNR.FO.61245770 | ACTIVE | 11/17/2021 | J's Pharmacy LLC |
| PHHC.FX.61202271 | ACTIVE | 11/18/2021 | Multicare Pacific Northwest PACE Partners and Adult Day Health |
| PHWH.FX.61186290 | ACTIVE | 11/18/2021 | Arcutis Biotherapeutics, Inc |
| PHWH.FX.61246781 | ACTIVE | 11/19/2021 | USAntibiotics, LLC |
| DRSD.FX.61189660 | ACTIVE | 11/23/2021 | BeiGene USA, Inc |
| PHHC.FX.61215450 | ACTIVE | 11/23/2021 | Cascade Eye and Skin Centers |
| PHWH.FX.61246422 | ACTIVE | 11/23/2021 | H2-Pharma, LLC |
| DRDG.FX.61207985 | ACTIVE | 11/24/2021 | DSHS/Special Commitment Center, McNeil Island |
| PHAR.CF.61234598 | ACTIVE | 11/24/2021 | Genoa Healthcare, LLC |
| PHAR.CF.61158928 | ACTIVE | 11/24/2021 | Ready Meds Pharmacy |
| PHNR.FO.61237270 | ACTIVE | 11/24/2021 | Pure Pharmacy |
| PHNR.FO.61248830 | ACTIVE | 11/24/2021 | Valley Veterinary Clinic, LLC |

| | | | |
|---|---|---|---|
| PHWH.FX.61202252 | ACTIVE | 11/24/2021 | Alembic Pharmaceuticals, Inc. |
| PHWH.FX.61247429 | ACTIVE | 11/24/2021 | MR Unlimited LLC |
| PHAR.CF.61220508 | ACTIVE | 11/29/2021 | Harborview LTC Pharmacy |
| PHNR.FO.61239034 | ACTIVE | 11/29/2021 | Pet Drug Store Inc. |
| PHNR.FO.61247950 | ACTIVE | 11/29/2021 | PRxP of California, LLC |
| PHWH.FX.61153791 | ACTIVE | 11/29/2021 | Kesin Pharma Corporation |
| PHWH.FX.61247894 | ACTIVE | 11/29/2021 | North American Rescue, LLC |
| PHWH.FX.61247912 | ACTIVE | 11/29/2021 | OurPharma |
| PHNR.FO.61249525 | ACTIVE | 11/30/2021 | LIFECARE SPECIALTY PHARMACY |

**Department of Health**
**Pharmacy Quality Assurance Commission**
**Directive**

| | |
|---|---|
| **Title:** | Nonresident Pharmacy: List of Approved Inspection Programs |
| **Reference:** | RCW 18.64.360 |
| **Contact:** | Lindsay Trant, MPP, Interim Deputy Director |
| **Effective Date:** | December 17, 2021 |
| **Supersedes:** | Nonresident Pharmacy: Approved List of Recognized States |
| **Approved:** | Teri Ferreira, RPh,<br>Pharmacy Quality Assurance Commission Chair |

RCW 18.64.360(1)(b) requires a nonresident pharmacy, upon initial licensure and at renewal, to submit a copy of an inspection report that is conducted by an inspection program approved by the Pharmacy Quality Assurance Commission (Commission) as having substantially equivalent standards to those of the Commission, and that was issued within the last two years. This directive identifies those inspection programs the Commission has approved as having substantially equivalent standards to those of the Commission.

The Commission considered multiple factors when choosing whether to approve an inspection program. This includes using the National Association of Boards of Pharmacy (NABP) Multistate Pharmacy Inspection Blueprint Program criteria. The Commission also considered whether the inspection program required nonresident pharmacies who engage in compounding to comply with the minimum standards of the official United States Pharmacopeia (USP).

**Approved Inspection Programs**

The Commission has approved the inspection programs of the following state boards of pharmacy (or equivalent state regulatory agency) and one third-party inspection program as having substantially equivalent standards to those of the Commission:

| | |
|---|---|
| Alabama | Montana |
| Arkansas | NABP's Verified Pharmacy Program |
| Arizona | Nevada |
| California | New Hampshire |
| Colorado | New Jersey |
| Connecticut | New Mexico |
| Georgia | North Carolina |
| Idaho | North Dakota |
| Illinois* | Ohio |
| Indiana | Oklahoma |
| Iowa | Oregon |
| Kansas | Pennsylvania (inspections conducted after June 22, 2019) |
| Kentucky | Rhode Island |
| Louisiana | South Dakota |
| Maryland | Tennessee |
| Massachusetts | Texas |
| Michigan | Utah |
| Minnesota | Vermont |
| Mississippi | West Virginia |
| Missouri | Wyoming |

*Approved while USP 800 is not enforced in Washington (*see* Policy #65.2).

## Approved Inspection Programs That Do Not Meet Commission Frequency Standards

The Commission has approved the inspection programs of the following state boards of pharmacy (or equivalent state regulatory agency) as having substantially equivalent standards to those of the Commission. The Commission also understands these inspection programs do not conduct inspections every two years. Nonresident pharmacies are reminded that inspection reports submitted as part of an application or as part of the renewal process must have occurred within the last two years. So while inspection reports conducted by the following state boards of pharmacy (or equivalent state regulatory agency) are acceptable, they must have occurred within the last two years or another inspection report from an approved inspection program will need to be submitted:

| | |
|---|---|
| Delaware | Nebraska |
| Maine | New York |

## Approved Inspection Programs for Nonresident Pharmacies Who Attest They Do Not Engage in Compounding

The Commission has approved the inspection programs of the following state boards of pharmacy (or equivalent state regulatory agency) as having substantially equivalent standards to those of the Commission ***but only for*** nonresident pharmacies who attest that they do not engage in compounding as defined in RCW 18.64.011(6). This is because the following inspection programs do not require nonresident pharmacies to comply with the minimum standards of USP when engaging in compounding.

| | |
|---|---|
| Florida | Pennsylvania |
| South Carolina | Wisconsin |

## Inspection Programs That Have Not Been Approved by the Commission

The Commission has determined that inspections from the following state board of pharmacy (or equivalent state regulatory agency) are not substantially equivalent to those of the Commission and will not be accepted:

| | |
|---|---|
| Alaska | |

The Commission is aware the Hawaii Board of Pharmacy does not conduct inspections. Nonresident pharmacies located in Hawaii are still required to comply with RCW 18.64.360(1)(b) and must provide an inspection report from an approved inspection program as outlined in this Directive.

The Commission will review this Directive on an annual basis.

*Need more information? See frequently asked questions.*

**DRAFT FAQ – Inventory Requirement for Other Controlled Substance Registrant**

**Q: How can the holder of a "Drug Other Controlled Substance Registration" comply with the requirement to perform an inventory every two years on the anniversary of the issuance of the registration, as required by WAC 246-945-060(4), if the holder is not aware of the anniversary date for their registration or is otherwise unable to complete the inventory on the anniversary date?**

**A:** The Pharmacy Quality Assurance Commission (Commission) will not find a holder of a "Drug Other Controlled Substance Registration" deficient or in violation of the requirement to perform an inventory on the anniversary of the issuance of their registration in WAC 246-945-060(4) so long as the registrant ensures that each inventory is taken within two years of the previous inventory. The registrant should also ensure that all other provisions of WAC 246-945-060(4) are complied with, such as maintaining the inventory list for two years.

For example, the holder of a "Drug Other Controlled Substance Registration" would not be found to be in violation of WAC 246-945-060(4) if they completed an inventory on 6/1/2018 and then completed a second inventory on 6/1/2020, even if the anniversary of the issuance of the registration was 1/1/2020. This is because the inventory on 6/1/2020 was taken within two years of the inventory on 6/1/2018.

This position is consistent with the inventory requirements of the United States Drug Enforcement Administration (DEA) for each location registered with the DEA (21 C.F.R. §§ 1304.04 and 1304.11). Additionally, the Commission believes this position protects the public health and will not undermine efforts to reduce diversion of controlled substances.

***Department of Health***
***Health Systems Quality Assurance***

# DRAFT Interpretive Statement

*Revised – 10/18/11*

| | | |
|---|---|---|
| *Title:* | Electronic Communication of Controlled Substance Prescriptions to Pharmacies Unable to Receive Electronic Prescriptions | *Number:* |
| *References:* | RCW 69.50.312 | |
| *Contact:* | | |
| *Phone:* | | |
| *Email:* | | |
| *Effective Date:* | | |
| *Supersedes:* | N/A | |
| *Approved By:* | ? | |

## Summary

The Department of Health (Department) does not interpret RCW 69.50.312(2) as providing an exemption from the requirement in RCW 69.50.312(1) to electronically communicate controlled substance prescriptions solely because a pharmacy is unable to receive prescriptions electronically. Nor does the Department interpret RCW 69.50.312(2)(k) and RCW 69.50.312(3) as allowing pharmacies to apply for a waiver from the requirement in RCW 69.50.312(1) because they are unable to receive controlled substance prescriptions electronically.

However, the Department does acknowledge specific situations may result in a practitioner issuing a non-electronic controlled prescription for dispensing and fulfillment at a pharmacy who cannot receive controlled substances electronically. These specific situations should fall within one of the exemptions in RCW 69.50.312(2).

To illustrate, one of the exemptions (RCW 69.50.312(2)(j)) permits practitioners to issue a valid non-electronic prescription when the "practitioner reasonably determines it is impractical for the patient to obtain the electronically communicated prescription in a timely manner, and such delay would adversely impact the patient's medical condition." The Department believes this exemption does apply when a practitioner, who is outside the Indian Health System, issues a controlled substance prescription for a patient who will be filling that prescription at a Tribal Pharmacy using the Indian Health Services' Resource and Patient Management System (RPMS).

## Definitions

"Controlled substance prescription" includes original prescription and refill authorization information for controlled substances included in Schedules II through V.

"Tribal Pharmacy" is a pharmacy owned or operated by a Tribe and located on Tribal land.

## Background

In 2019, the Legislature amended RCW 69.50.312 as part of Substitute Senate Bill 5380. The amendment requires ***electronic*** communication of ***all*** controlled substance prescriptions (RCW 69.50.312(1)), unless the controlled substance prescription is exempt. RCW 69.50.312(2) provides that a controlled substance prescription is exempt from the requirement in RCW 69.50.312(1) if one or more of the following situations applies:

- Prescriptions issued by veterinarians, as that practice is defined in RCW 18.92.010 (RCW 69.50.312(2)(a));
- Prescriptions issued for a patient of a long-term care facility as defined in RCW 18.64.011, or a hospice program as defined in RCW 18.64.011 (RCW 69.50.312(2)(b));
- When the electronic system used for the communication of prescription information is unavailable due to a temporary technological or electronic failure (RCW 69.50.312(2)(c));
- Prescriptions issued that are intended for prescription fulfillment and dispensing outside Washington state (RCW 69.50.312(2)(d));
- When the prescriber and pharmacist are employed by the same entity, or employed by entities under common ownership or control (RCW 69.50.312(2)(e));
- Prescriptions issued for a drug that the United States food and drug administration or the United States drug enforcement administration requires to contain certain elements that are not able to be accomplished electronically (RCW 69.50.312(2)(f));
- Any controlled substance prescription that requires compounding as defined in RCW 18.64.011 (RCW 69.50.312(2)(g));
- Prescriptions issued for the dispensing of a nonpatient specific prescription under a standing order, approved protocol for drug therapy, collaborative drug therapy agreement, in response to a public health emergency, or other circumstances allowed by statute or rule where a practitioner may issue a nonpatient specific prescription (RCW 69.50.312(2)(h));
- Prescriptions issued under a drug research protocol (RCW 69.50.312(2)(i));
- Prescriptions issued by a practitioner with the capability of electronic communication of prescription information under this section, when the practitioner reasonably determines it is impractical for the patient to obtain the electronically communicated prescription in a timely manner, and such delay would adversely impact the patient's medical condition (RCW 69.50.312(2)(j)); and
- Prescriptions issued by a prescriber who has received a waiver from the department (RCW 69.50.312(2)(k)).

## Situation and Response

The Department has become aware of Tribal Pharmacies that are unable to receive controlled substance prescriptions electronically because they utilize the RPMS for the management of clinical and administrative information. The RPMS cannot accept electronic prescriptions from providers outside of the Indian health system. This issue has resulted in questions to the Department asking whether controlled substance prescriptions sent to Tribal Pharmacies are exempt from the requirement in RCW 69.50.312(1).

The Department does not interpret RCW 69.50.312(2) as providing an exemption from the requirement in RCW 69.50.312(1) solely because a pharmacy is unable to receive controlled substance prescriptions electronically. Nor does the Department interpret RCW 69.50.312(2)(k) and RCW 69.50.312(3) as allowing pharmacies to apply for a waiver from the requirement in RCW 69.50.312(1) because they are unable to receive controlled substance prescriptions electronically.

However, the Department does acknowledge specific situations may result in a practitioner issuing a non-electronic controlled prescription for dispensing and fulfillment at a pharmacy who cannot receive controlled substances electronically. These specific situations should fall within one of the exemptions in RCW 69.50.312(2). Practitioners communicating controlled substance prescriptions should be familiar with these exemptions.

In particular, the Department would like to draw attention to the exemption in RCW 69.50.312(2)(j). This exemption permits practitioners to issue a valid non-electronic prescription when the "practitioner reasonably determines it is impractical for the patient to obtain the electronically communicated prescription in a timely manner, and such delay would adversely impact the patient's medical condition." The Department largely defers to the professional judgment of the individual practitioner as to whether any delay in accessing prescribed medication would adversely impact the patient's medical condition. However, the Department could envision a situation where a pharmacy's inability to receive electronic prescriptions impacts a practitioner's assessment whether the exemption in RCW 69.50.312(2)(j) applies. For example, the Department believes the impossibility of Tribal Pharmacies to receive electronic prescriptions from providers outside of the Indian health system if they utilize RPMS is one such situation that does justify the issuance of a non-electronic controlled substance prescription.

Finally, pharmacies are also reminded that RCW 69.50.312 does not require pharmacists to scrutinize whether an otherwise valid non-electronic controlled substance prescription qualifies for an exemption in RCW 69.50.312(2). RCW 69.50.312(4) is clear in its explanation that a pharmacist who "receives a written, oral, or faxed prescription is not required to verify that the prescription properly meets any exemptions under this section."

# 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: October 29, 2021
TIME: 8:20 AM

WSR 21-22-065

**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 246-945-056 Schedule V. The Pharmacy Quality Assurance Commission (commission) is adopting emergency rules to remove Epidiolex from the list of Schedule V controlled substances in Washington state. This adopted emergency rule will extend WSR 21-14-061 filed on July 2, 2021. The emergency which was originally filed on May 20, 2020 under WSR 20-11-078. Epidiolex is an FDA-approved cannabidiol with less than 0.3% tetrahydrocannabinal (THC). De-scheduling the drug from Schedule V will maintain the emergency rule. It also aligns Washington state rule with the federal decision to exclude all hemp products with less than 0.3% THC from the definition of marijuana and the United States drug enforcement agency's (DEA) rulemaking to remove Epidiolex from Schedule V, completed on August 21, 2020.

**Citation of rules affected by this order:**

New: None
Repealed: None
Amended: WAC 246-945-056
Suspended: None

**Statutory authority for adoption:** RCW 18.64.005; RCW 69.50.201

**Other authority:** 21 U.S.C. Ã‚Â§ 811

**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 amendment of this existing rule is necessary for the preservation of public health, safety, and general welfare. Epidiolex is an FDA-approved cannabidiol with less than 0.3% THC used to help treat some seizure disorders. The 2018 Agricultural Improvement Act amended the Controlled Substances Act and declassified hemp products with less than 0.3% THC from Schedule I; however, Epidiolex was placed on Schedule V until April 6, 2020 when the DEA announced that it would be de-scheduled as a federally controlled substance. The DEA finalized rulemaking to remove Epidiolex from Schedule V on August 21, 2020. This emergency rule will maintain the emergency rule already in effect and update Washington rule to align with the federal decision. Emergency rules are necessary to reduce burdens on practitioners prescribing Epidiolex and allow patients easier access to the care they need. This rule may also help reduce pressure on the health system during the ongoing COVID-19 pandemic. 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 has initiated permanent rulemaking. The CR-101 to permanently de-schedule Epidiolex (WSR 20-23-027) was filed on November 10, 2020.

**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 | 1 | 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:**

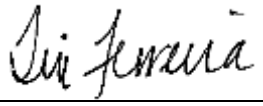
| | | | | | | |
|---|---|---|---|---|---|---|
| | New | 0 | Amended | 0 | Repealed | 0 |

**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 | 0 | Amended | 1 | Repealed | 0 |

| | |
|---|---|
| **Date Adopted: 9/2/2021** | **Signature:**  |
| **Name:** Teri Ferreira, RPh | |
| **Title:** Pharmacy Quality Assurance Commission Chair | |

AMENDATORY SECTION (Amending WSR 20-12-072, filed 6/1/20, effective 7/1/20)

**WAC 246-945-056 Schedule V.** The commission finds that the following substances have low potential for abuse relative to substances in Schedule IV under RCW 69.50.210 and WAC 246-945-055 and have currently accepted medical use in treatment in the United States and that the substances have limited physical dependence or psychological dependence liability relative to the substance in Schedule IV. In addition to the substances listed in RCW 69.50.212, the commission places each of the following drugs and substances by whatever official name, common or usual name, chemical name, or brand name in Schedule V.

Depressants. Unless specifically exempted or excluded or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts:

(1) Brivaracetam ((2S)-2-[(4R)-2-oxo-4-propylpyrrolidin-1-yl] butanamide); also referred to as BRV; UCB-34714; Briviact;

(2) Ezogabine [N-[2-amino-4-(4-fluorobenzylamino)-phenyl]-carbamic acid ethyl ester].

((~~(3) Approved cannabidiol drugs. A drug product in finished dosage formulation that has been approved by the U.S. Food and Drug Administration that contains cannabidiol (2-[1R-3-methyl-6R-(1-methylethenyl)-2-cyclohexen-1-yl]-5-pentyl-1,3-benzenediol) derived from cannabis and no more than 0.1 percent (w/w) residual tetrahydrocannabinols, also known as Epidiolex.~~))

# 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: October 25, 2021
TIME: 3:32 PM

WSR 21-22-029

**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 246-945-010 Prescription labeling, records, and advertising - Minimum requirements. The Pharmacy Quality Assurance Commission (commission) is adopting emergency rules to reduce burdens on practitioners prescribing Schedule II substances during the coronavirus disease (COVID-19) outbreak. This adopted emergency rule will extend WSR 21-14-059 filed on July 2, 2021.This emergency rule was originally filed on April 21, 2020 under WSR 20-09-133. It was re-filed on July 10, 2020 after the commission's new chapter went into effect under WSR 20-15-058. This emergency rule will continue the existing emergency rule amending WAC 246-945-010 to increase the duration of time a practitioner has to deliver a signed prescription of a Schedule II substance to the pharmacy from seven days to fifteen days when a prescription is dispensed in an emergency. It also defines what a "signed prescription" means and allows for a practitioner to accomplish this requirement through paper, electronic transmission, facsimile, photograph, or scanned copy. These alternative methodologies support patients, practitioners, and pharmacists' efforts to practice social distancing and to help mitigate communal spread.

**Citation of rules affected by this order:**

New: None
Repealed: None
Amended: WAC 246-945-010
Suspended: None

**Statutory authority for adoption:** RCW 18.64.005; chapter 69.50 RCW

**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 amendment of this existing rule is necessary for the preservation of public health, safety, and general welfare. Stakeholders and leaders from the pain community have highlighted this is an immediate need for Washingtonians. This emergency rule has been in effect since April 21, 2020. This emergency rule allows more time and more avenues for complying with the requirements during the ongoing COVID-19 pandemic, reducing burdens on practitioners and pharmacists, and sustaining patient access during this difficult time. The emergency rules follow guidance from the US drug enforcement agency and will help address this problem and reduce barriers for providers and patient populations in need of Schedule II prescriptions throughout this public health emergency. Observing the time requirements of notice and opportunity to comment upon adoption of a permanent rule would be contrary to public interest.

**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 | 0 | Amended | 1 | 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 | 0 | Amended | 1 | Repealed | 0 |

| | |
|---|---|
| **Date Adopted:** 09/02/2021 | **Signature:**  |
| **Name:** Teri Ferreira, RPh | |
| **Title:** Pharmacy Quality Assurance Commission Chair | |

AMENDATORY SECTION (Amending WSR 20-12-072, filed 6/1/20, effective 7/1/20)

**WAC 246-945-010 Prescription and chart order—Minimum requirements.** (1) For the purposes of this section, prescription does not include chart orders as defined in RCW 18.64.011(3).

(2) For the purposes of WAC 246-945-010 through 246-945-013, prescription includes written and electronic prescriptions.

(3) A prescription for a noncontrolled legend drug must include, but is not limited to, the following:

(a) Prescriber's name;

(b) Name of patient, authorized entity, or animal name and species;

(c) Date of issuance;

(d) Drug name, strength, and quantity;

(e) Directions for use;

(f) Number of refills (if any);

(g) Instruction on whether or not a therapeutically equivalent generic drug or interchangeable biological product may be substituted, unless substitution is permitted under a prior-consent authorization;

(h) Prescriber's manual or electronic signature, or prescriber's authorized agent signature if allowed by law; and

(i) If the prescription is written, it must be written on tamper-resistant prescription pad or paper approved by the commission pursuant to RCW 18.64.500;

(4) A prescription for a controlled substance must include all the information listed in subsection (1) of this section and the following:

(a) Patient's address;

(b) Dosage form;

(c) Prescriber's address;

(d) Prescriber's DEA registration number; and

(e) Any other requirements listed in 21 C.F.R., Chapter II.

(5) A chart order must meet the requirements of RCW 18.64.550 and any other applicable requirements listed in 21 C.F.R., Chapter II.

(6) A controlled substance listed in Schedule II can only be dispensed pursuant to a valid prescription in accordance with WAC 246-945-011 unless there is an "emergency."

(a) For the purposes of this subsection, an "emergency" exists when the immediate administration of the drug is necessary for proper treatment and no alternative treatment is available, and further, it is not possible for the practitioner to provide a written or electronic prescription for the drug at that time.

(b) If a Schedule II drug is dispensed in an emergency, the practitioner must deliver a signed prescription to the dispenser within ((~~seven~~)) fifteen days after authorizing an emergency oral prescription or if delivered by mail it must be postmarked within the ((~~seven~~)) fifteen day period, and further the pharmacist must note on the prescription that it was filled on an emergency basis.

(c) For the purposes of this subsection, a "signed prescription" shall be either:

(i) A paper prescription;

(ii) An electronic prescription;

(iii) A copy of the paper prescription sent via facsimile to the pharmacy; or

(iv) A photograph or scanned copy of the paper prescription sent to the pharmacy.

(7) A controlled substance listed in Schedule III, IV, or V, can only be dispensed pursuant to a valid prescription in accordance with WAC 246-945-011, or an oral prescription. An oral prescription for a controlled substance listed in Schedule III, IV, or V must be promptly reduced to a written or electronic prescription that complies with WAC 246-945-011.

(8) A noncontrolled legend drug can only be dispensed pursuant to a valid prescription in accordance with WAC 246-945-011, or an oral prescription. An oral prescription for a noncontrolled legend drug must be promptly reduced to a written or electronic prescription that complies with WAC 246-945-011.

***Department of Health***
***Pharmacy Quality Assurance Commission***

# Guidance Document

| | |
|---|---|
| *Title:* | Enforcement of Intern Registration Renewal Limit |
| *References:* | WAC 246-945-155(3), WAC 246-907-030, RCW 18.64.080 |
| *Contact:* | Dr. Lauren Lyles-Stolz, Executive Director, Pharmacy Quality Assurance Commission |
| *Phone:* | 360-236-4946 |
| *Email:* | WSPQAC@doh.wa.gov |
| *Effective Date:* | October 1, 2020 |
| *Supersedes:* | N/A |
| *Approved By:* | Tim Lynch, PharmD, MS, FABC, FASHP, Pharmacy Quality Assurance Commission Chair |

At its October 1, 2020 business meeting the Pharmacy Quality Assurance Commission (commission) determined that it will not enforce WAC 246-945-155(3), which states that an intern registration can only be renewed twice, until the 2-year license renewal cycle is implemented.

**Background:** The commission recently completed a 2.5-year process to consolidate thirty-three (33) chapters of WAC into one new chapter (chapter 246-945 WAC). Chapter 246-945 WAC went into effect on July 1, 2020. This effective date applied to all sections within the chapter, except the continuing education rules (clarified in another guidance document) and the fee rules (chapter 246-907 WAC). Rulemaking is currently in progress on the fee rules which, when complete, will implement a new fee schedule and the two-year license renewal cycle. Until this rules package is complete, the 1-year license renewal cycle remains in effect as determined by WAC 246-907-030(1).

RCW 18.64.080(3) states "Any person enrolled as a student of pharmacy in an accredited college may file with the department an application for registration as a pharmacy intern…" Further, "All certificates issued to pharmacy interns shall be valid for a period to be determined by the commission…" Under WAC 246-945-155(3), "A pharmacy intern registration can only be renewed twice." Any registration renewed prior to the completion of the fee rules is for a 1-year duration since WAC 246-907-030 remains in effect.

**Conclusion:** To ensure that pharmacy interns have adequate time to hold their registration, the commission will not enforce WAC 246-945-155(3) until the fee rules package is complete and the 2-year license renewal cycle is implemented.



DOH 590-337 December 2020

***Department of Health***
***Pharmacy Quality Assurance Commission***

# Policy Statement

*Revised – 10/18/11*

| | | |
|---|---|---|
| *Title:* New WAC Supersedes Old WAC: Clarification of Rules Enforcement After July 1, 2020 | | *Number:* P002 |
| *References:* | Chapter 246-945 WAC | |
| *Contact:* | Dr. Lauren Lyles-Stolz, Executive Director, Pharmacy Quality Assurance Commission | |
| *Phone:* | 360-236-4853 | |
| *Email:* | Lauren.Lyles@doh.wa.gov | |
| *Effective Date:* | July 1, 2020 | |
| *Supersedes:* | N/A | |
| *Approved By:* | Tim Lynch, PharmD, MS, FABC, FASHP, Pharmacy Quality Assurance Commission Chair | |

This policy statement clarifies that chapter 246-945 WAC ("new rules") became effective on July 1, 2020 and "old rules" no longer apply and are being repealed. The Pharmacy Quality Assurance Commission (commission) will not be requiring licensees to comply with its "old rules" while they are being repealed. The only exception to this policy statement relates to continuing education (CE) requirements, which the commission has addressed separately in resources available on the commission's website.

For the purposes of this policy statement:

"Old rules" refers to those rules contained within the following chapters of WAC *(This definition does not include CE chapter 246-861 WAC)*:

- 246-856 WAC
- 246-858 WAC
- 246-860 WAC
- 246-863 WAC
- 246-865 WAC
- 246-867 WAC
- 246-869 WAC
- 246-870 WAC
- 246-871 WAC
- 246-873 WAC
- 246-873A WAC
- 246-874 WAC
- 246-875 WAC
- 246-877 WAC
- 246-878 WAC
- 246-879 WAC
- 246-881 WAC
- 246-883 WAC
- 246-885 WAC
- 246-886 WAC
- 246-887 WAC
- 246-888 WAC
- 246-889 WAC
- 246-891 WAC
- 246-895 WAC
- 246-897 WAC
- 246-899 WAC
- 246-901 WAC[1]
- 246-903 WAC
- 246-904 WAC
- 246-905 WAC

[1] *This definition does not include those continuing education (CE) rules contained within WAC 246-901-061.*

"New rules" refers to those rules codified in chapter 246-945 WAC, except for CE rules contained within WAC 246-945-178 and WAC 246-945-220 which have a delayed effective date.

The commission recently completed a 2.5-year process to consolidate their 33 separate chapters of WAC into one new chapter, chapter 246-945 WAC. The new rules are effective, July 1, 2020, except for rules related to CE requirements. There are additional resources available on the commission's website that further clarify the effective dates for the CE requirements. The "new rules" supersede the "old rules" and therefore the commission will only enforce the "new rules." The commission has begun a separate rulemaking package to repeal the "old rules."

This statement is supplemented by the PQAC New Rules Live Implementation Plan, which includes efforts by the commission to provide education and technical assistance for licensees.

STATE OF WASHINGTON

DEPARTMENT OF HEALTH

Olympia, Washington 98504-7890

# NOTICE OF ADOPTION OF A POLICY STATEMENT

**Title of Policy Statement:** New WAC Supersedes Old WAC: Clarification of Rules Enforcement After July 1, 2020. Policy Number: P002

**Issuing Entity:** Pharmacy Quality Assurance Commission

**Subject Matter:** The Pharmacy Quality Assurance Commission (commission) will only enforce rules adopted under chapter 246-945 WAC, except for continuing education rules contained within WAC 246-945-178 and WAC 246-945-220, which have a delayed effective date. The commission has begun a separate rulemaking to repeal rules under Title 246 that have been replace with chapter 246-945 WAC.

**Effective Date:** July 1, 2020

**Contact Person**: Lauren Lyles-Stolz, Executive Director
lauren.lyles@doh.wa.gov
(360) 236-4853

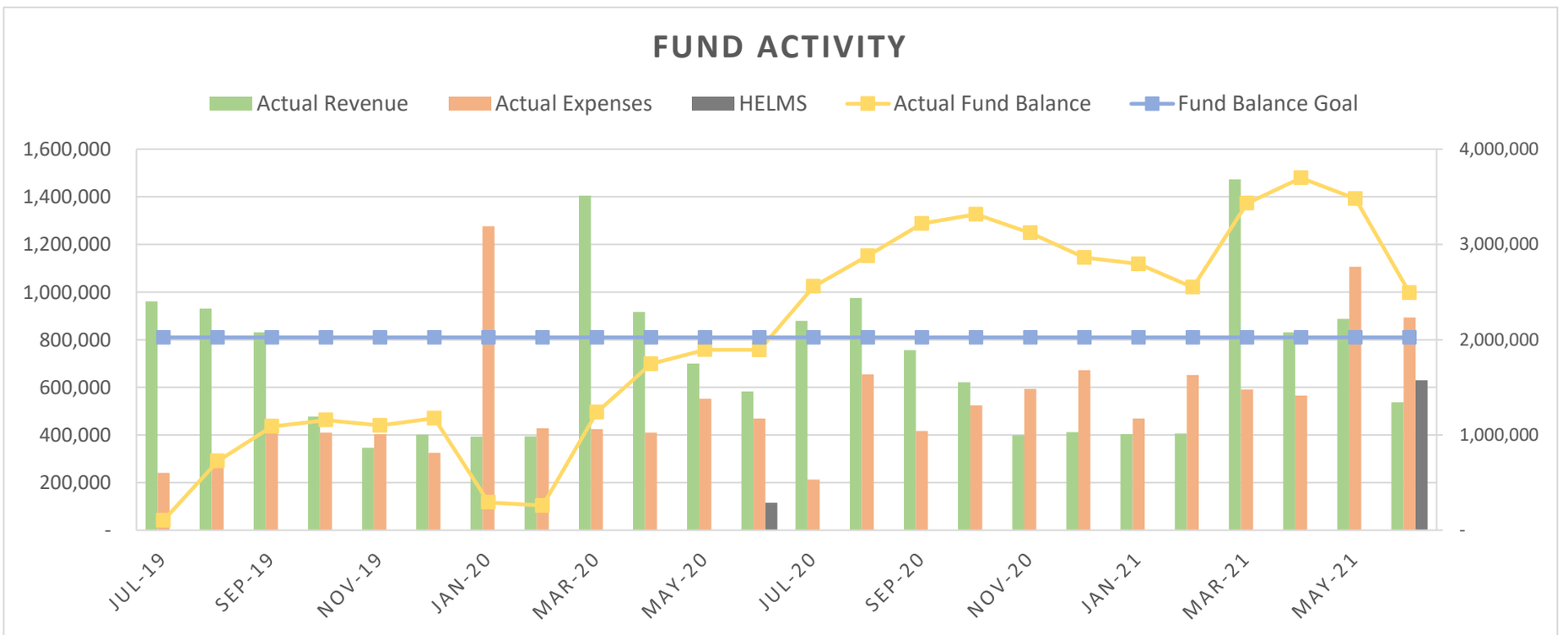
OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: August 06, 2020
TIME: 1:46 PM

WSR 20-17-017

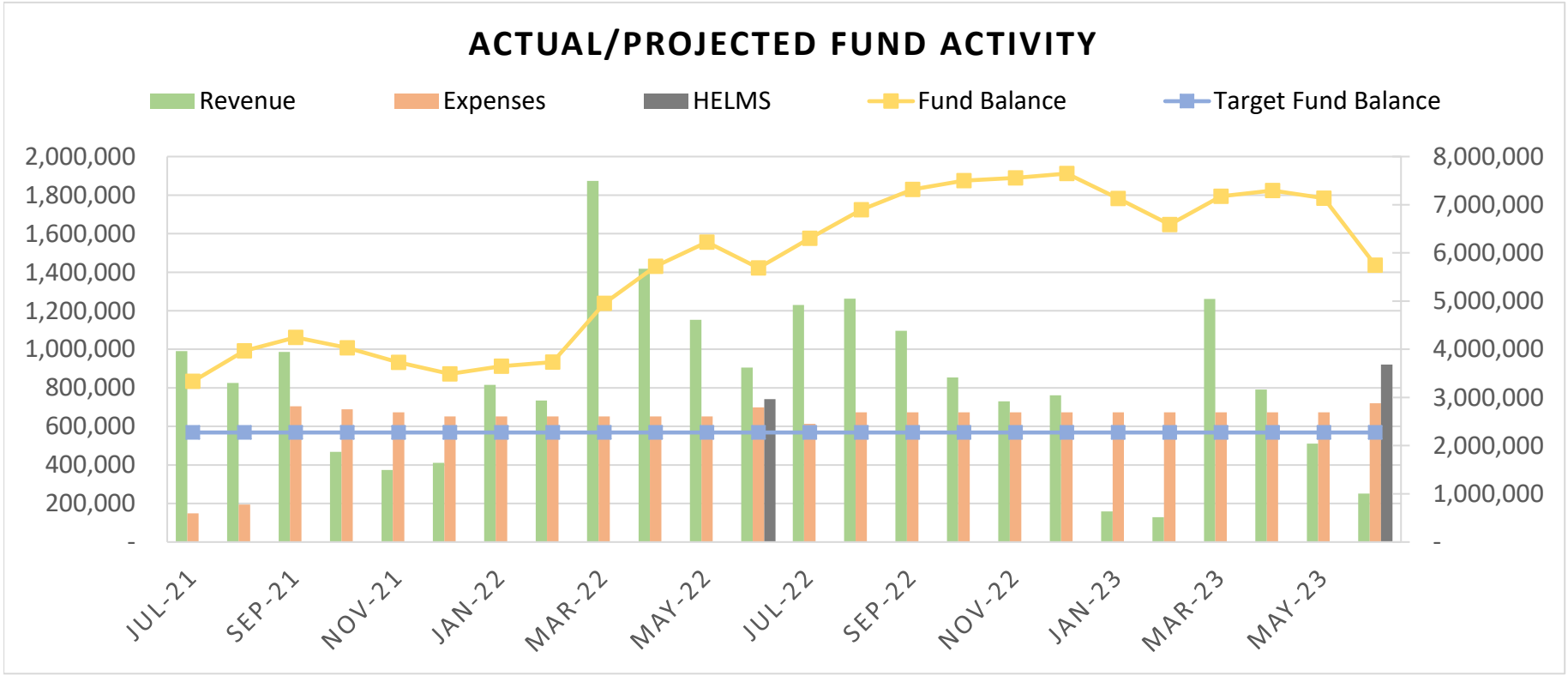
**Pharmacy Quality Assurance Commission**
**2019-21 Biennium Fund Balance Overview**
For the period of July 1, 2019 to June 30, 2021

| | |
|---|---|
| Health Professions Account Beginning Fund Balance on July 1, 2019 | (615,920) |
| Revenue | 16,920,870 |
| BIEN 19-21 HELMS Assessements | 745,441 |
| Expenses | 13,066,373 |
| Health Professions Account Ending Fund Balance on June 30, 2021 | 2,493,136 |



# Pharmacy Quality Assurance Commission
# 2021-23 Biennium Fund Balance Overview
For the Period of July 1, 2021 through October 31, 2021

| | |
|---|---|
| Health Professions Account Beginning Fund Balance on July 1, 2021 | 2,493,136 |
| Revenue To-Date | 3,272,005 |
| 21-23 HELMS Assessment To-Date | - |
| Expenses To-Date | 1,736,685 |
| Health Professions Account Fund Balance as of October 31, 2021 | 4,028,456 |



| Committee | Commission Members |
|---|---|
| **Leadership Committee:**<br>• Commission Recruitment<br>• Staffing/Training and SOP | **Chair**: Teri Ferreira<br>**Members**: Jerrie Allard, William Hayes |
| **Budget Committee:** HELMS | **Chair**: Patrick Gallaher<br>**Members**: Judy Guenther, William Hayes, Helen Jung, Ken Kenyon |
| **Compounding Committee:**<br>• FDA MOU<br>• Self-Inspection Worksheets<br>• Whitebagging | **Chair**: Hawkins DeFrance<br>**Members**: Tim Lynch, Ken Kenyon, Uyen Thorstensen |
| **Strategic Planning Committee** | **Chair**: Jerrie Allard (tentative)<br>**Members**: Bonnie Bush, Ann Wolken |
| **Pharmacy Practice Committee**<br>• Misfill and Pharmacy Work Condition Workgroup<br>• Sunrise Review<br>• CDTA WMC Committee (Tim/Teri)<br>• Sample AUP review | **Chair**: Craig Ritchie<br>**Members**: Hawkins DeFrance, Patrick Gallaher, Helen Jung, Ann Wolken |
| **Facility Committee**<br>• HPACs Committee<br>• Suspicious Orders<br>• Facility Enforcement Authority | **Chair**: Ken Kenyon (tentative)<br>**Members**: Teri Ferreira, William Hayes, Helen Jung, Tim Lynch |
| **Legislative Committee** | **Chair**: William Hayes<br>**Members**: Hawkins DeFrance, Tim Lynch, Craig Ritchie |

Updated 10/27/21