

September 22, 2022

**Washington State Pharmacy Quality
Assurance Commission**



**Commission Business
Meeting Materials**

SAFETY. QUALITY. INNOVATION.



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
July 14, 2022 - Minutes**

Convene: Chair, Teri Ferreira called the meeting to order July 14, 2022, 9:07 a.m.

Commission Members:

Teri Ferreira, RPh, Chair
Jerrie Allard, Public Member, Vice Chair
Bonnie Bush, Public Member
Uyen Thorstensen, CPhT
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
Matthew Ray, PharmD
Ann Wolken, PharmD, RPh

Staff:

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

Commission Member Absent:

Ken Kenyon, PharmD, BCPS

1. Call to Order Teri Ferreira, Chair.

1.1 Meeting Agenda Approval – July 14, 2022

MOTION: Craig Ritchie moved to approve the meeting agenda for July 14, 2022. Hawkins DeFrance, second. Motion carries, 13:0.

1.2 Meeting Minutes Approval – May 12-13, 2022

MOTION: Craig Ritchie moved to approve the meeting minutes for May 12-13, 2022. Hawkins DeFrance, second. Motion carries, 13:0.

2. Executive Session - CLOSED to the Public – The commission met in executive session to evaluate the qualifications of an applicant for public employment (the Executive Director) pursuant to RCW 42.30.110(1)(g).

3. New Business

MOTION: Tim Lynch moved to confirm Marlee O’Neill as permanent Executive Director and allow the Department of Health to make a formal offer. Craig Ritchie, second. Motion carries, 13:0.

4. Consent Agenda

4.1 National Precursor Log Exchange Monthly Dashboard-May-June 2022

4.2 Pharmaceutical Firms Application Report

May 2, 2022, thru June 28, 2022

4.3 Ancillary Utilization Plans Approval

4.3.1 Acts Pharmacy

4.3.2 Dayton General Hospital

4.3.3 Franciscan Multiple Locations

4.3.4 Key Compounding Pharmacy

4.3.5 Vashon Pharmacy

4.3.6 Pomeroy Pharmacy

4.3.7 Providence Centralia, Aberdeen, Lacey

4.3.8 Providence Inpatient Centralia, Lacey

4.4 Pharmacy Technician Training Program Approval

4.4.1 Costco Pharmacy

4.4.2 University of Providence Kadlec Regional

4.4.3 Puget Sound Drug Key Compounding

4.4.4 Lincoln Pharmacy LLC

4.4.5 Peace Health Island Medical

4.4.6 Providence Infusion and Pharmacy Services

4.4.7 Unity Care NW

4.4.8 Pharm-A-Save (Duvall Family Drugs)

4.4.9 MultiCare Health System

4.4.10 Albertsons Company

MOTION: Craig Ritchie moved to approve the consent except items 4.3.1, 4.3.2, 4.3.7, 4.3.8, 4.4.5, 4.4.6, 4.4.7, and 4.4.9 that were pulled for discussion in agenda item 4.5. Hawkins DeFrance, second. Motion carries, 13:0.

4.5 Regular Agenda/Items Pulled from 4.3 and 4.4

4.3.1 Acts Pharmacy

4.3.2 Dayton General Hospital

4.3.7 Providence Centralia, Aberdeen, Lacey

4.3.8 Providence Inpatient Centralia, Lacey

4.4.5 Peace Health Island Medical

4.4.6 Providence Infusion and Pharmacy Services

4.4.7 Unity Care NW

4.4.9 MultiCare Health System

MOTION: William Hayes moved to approve 4.3.1, 4.3.2, 4.3.7, 4.3.8, 4.4.5, 4.4.6, and 4.4.7 contingent on the ancillary utilization plans or pharmacy technician training program making the revisions– identified in the SBAR. Craig Ritchie, second. Motion carries, 13:0.

MOTION: William Hayes moved to approve 4.4.9 contingent on the pharmacy technician training program making the revisions identified in the SBAR. Craig Ritchie, second. Tim Lynch recused. Motion carries, 12:0.

MOTION: William Hayes moved to remove WAC 246-874 from items 4.3.7 and 4.3.8. Craig Ritchie, second. Motion carries, 13:0.

5. Old Business

5.1 Office of Customer Service Action Plan Action Plan Update – Josh Shipe, Deputy Director for the Office of Customer Service at DOH, provided an update on the Office of Customer Service Action Plan. Stakeholders may send applications in PDF form directly to hsqareview2@doh.wa.gov.

5.2 Presentation by the Washington Recovery and Assistance Program for Pharmacy – Will Rhodes was unable to join the meeting today. He will present at the next business meeting on September 22, 2022.

5.3 FAQ Compounding Animal Drugs from Bulk Drug Substances – Nomi Peaks

Members of the commission staff, following research of the FDA’s Guidance for Industry #256, as well as Washington State statutes and regulations. The commission determined that exceptions listed in RCW 18.64.011(21) would allow a pharmacy to compound animal drugs from bulk drug stock (BDS) for office-use in nonfood-producing animals so long as one of the exceptions in RCW 18.64.011(21) applied. The commission tasked staff with creating an FAQ on this topic that details these exceptions and clarifies that the definition of “drug” in RCW 18.64.011(14)(b) includes animals.

MOTION: Craig Ritchie moved to send the Q&A back to staff to add a reference to 18.64.011(14)(b). Once added, staff may publish the Q&A without further input from commission. Bonnie Bush, second. Motion carries, 13:0.

5.4 Discussion on Returning to In-Person Meetings

MOTION: For future regular and special meetings, the commission will follow or adhere to CDC and/or DOH guidelines for in-person meetings and use the more conservative of the two if there is a difference that exists. Bonnie Bush, second. Motion carries, 13:0.

MOTION: The August special meeting will be a hybrid meeting that may/can include in-person or remote attendance. Hawkins DeFrance, second. Motion carries, 13:0

5.5 Enforcement Discretion on Zero Order Reports

MOTION: Craig Ritchie moved to extend use of enforcement discretion on WAC 246-945-585(1)(b) for one year. Hawkins DeFrance, second. Motion carries, 13:0.

5.6 Sample Ancillary Utilization Plan (as reviewed by the Pharmacy Practice Subcommittee) – the commission recommended staff make edits as discussed and to bring the ancillary utilization plan back to the commission at a future meeting.

5.7 Mis-fill Guidelines (as reviewed by the Pharmacy Practice Subcommittee)

MOTION: Craig Ritchie moved to approve misfill guidelines as written. Patrick Gallaher, second. Motion carries, 13:0.

6. New Business

6.1 Prescription Drug Pick-up Lockers

MOTION: Tim Lynch moved to adopt permit pharmacies to use pharmacy-owned lockers to deliver filled prescriptions without the lockers being included as part of the pharmacy license (i.e., outside of the space licensed as a pharmacy) and requests staff to draft a guidance document for the commission to approve at a future meeting. William Hayes, second. Motion carries, 13:0.

6.2 Commission Delegation for 2022-2023

- **Determination of Maximum Daily Monetary Fine for Failing to Produce Documents Form 1-1-19E.**

MOTION: Craig Ritchie moved to keep the fine at \$100 per day for failing to produce documents under RCW 18.130.230 and approve the Determination of Maximum Daily Monetary Fine for Failing to Produce Documents Form 1-1-19E as presented. Bonnie Bush, second. Motion carries, 13:0.

- **BAP Proceedings**

MOTION: Craig Ritchie moved to approve Marc Defreyn as BAP officer. Hawkins DeFrance, second. Motion carries, 13:0.

- **Delegation of Signature Authority Form 1-1-19-A**

MOTION: Craig Ritchie moved to approve the Delegation of Signature Authority Form 1-1-19-A as presented. Hawkins DeFrance, second. Motion carries, 13:0.

- **Delegation of Decision Making Form 1-1-19C**

MOTION: Craig Ritchie moved to approve the Delegation of Decision Making Form 1-1-19C as presented, to delegate decision-making on cases involving pharmaceutical firms to a panel of at least three members, and to the adopt policy statement as presented. Hawkins DeFrance, second. Motion carries, 13:0.

6.3 2023 Commission Meeting Dates.

January 12-13
March 9-10
May 4-5
June 29-30
August 24-25
October 19-20
December 14-15

MOTION: Craig Ritchie moved to approve 2023 proposed commission meeting dates. Bonnie Bush, second. Motion carries, 13:0.

7. Summary of meeting action items

- 3.1 – The Department will move forward with the appointment of Marlee as the Executive Director of the commission.
- 4 – Follow-up with ancillary utilization plans and pharmacy technician training program applicants with contingent approvals as directed.
- 5.1 Send a GovDelivery on information for credentialing such as the relevant email addresses and encouraging online applications.
- 5.3 – Amend FAQ to include reference to RCW 18.64.011(14)(b) and publish on website.
- 5.4 – Plan for in-person meeting with remote option for August 5 Special meeting.
- 5.5 – Communicate extension of enforcement discretion on WAC 246-945-585(1)(b) for one more year.
- 5.6 – Revise sample ancillary utilization plan and bring back to pharmacy practice subcommittee.
- 5.7 – Post misfill guidelines on the commission’s website and begin using it.
- 6.1 – Draft guidance document on guidelines that licensees can consider when utilizing lockers.
- 6.2 – Implement and distribute updated delegation agreements. File policy statement on the commission’s delegation with the code reviser.
- 6.3 – File 2023 commission meeting dates with code reviser.

Business Meeting Adjourned. 4:04 p.m.



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
July 15, 2022 - Minutes**

Convene: Chair, Teri Ferreira called the meeting to order July 15, 2022, 9:01 a.m.

Commission Members:

Teri Ferreira, RPh, Chair
Bonnie Bush, Public Member
Uyen Thorstensen, CPhT
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
Matthew Ray, PharmD
Ann Wolken, PharmD, RPh
Ken Kenyon, PharmD, BCPS

Staff:

Marlee O’Neill, Executive Director
Lindsay Trant, Deputy Director
Christopher Gerard, AAG
Hope Kilbourne, Policy Analyst
Joshua Munroe, Legislative and Rules
Consultant
Taifa “Nomi” Peaks, Pharmacist Consultant
Joanne Miller, Program Manager, Pharmacy
Amy L Robertson, Communications
Coordinator and Program Support

Commission Member Absent:

Jerrie Allard, Public Member, Vice Chair

1. Call to Order Teri Ferreira, Chair.

1.1 Meeting Agenda Approval – July 15, 2022

MOTION: Craig Ritchie moved to approve the meeting agenda for July 15, 2022. Hawkins DeFrance, second. Motion carries, 13:0.

2. Rules and Legislative Updates – Joshua Munroe, Legislative and Rules Consultant briefed the commission on the following items:

2.1 Rulemaking on Accessible Labeling – Listening Session

Joshua Munroe informed the commission that staff are designing a survey for licensees to assess current capabilities surrounding both visual accessibility and the translation of prescription information.

Commissioners Tim Lynch, William Hayes, and Ann Wolken concur the commission needs to ensure access is not compromised for smaller, independent, or rural pharmacies that may not have the capability to fulfill this type of requirement to ensure patient safety, and that the rulemaking process should not be rushed.

Various stakeholders addressed the commission in support of this effort to have prescription labels accessible to all. All thanked the commission, relayed personal experiences as patients and/or pharmacists. Many reiterated Radio Frequency Identification (RFID) readers, large print, braille, and multiple language options are integral to patient safety and care.

- Jenny Arnold – Washington State Pharmacy Association
- Judy Brown – Washington Council of the Blind, co-chair Advocacy Committee, RN
- Zandra Brown – President, Capital City Council of the Blind (Olympia)
- Holly Chisa – Northwest Grocery Association
- Doreen Cornwell – Co-chair Washington Council of the Blind Advocacy Committee
- Hart Edmonson – medical student
- Jim Hedrick – Walgreens
- Matthew Hines – Vancouver, consumer
- Lis Houchen – retired, National Association of Chain Drug Stores
- Corey Grandstaff – President, National Federation of the Blind (Clark County chapter) and administrator Washington State School for the Blind.
- Domeg Moore – medical student, member of Health Equity Circle Language Access Team
- Luis Perez Velasquez – Senior Biologist, Spokane County medical interpreter
- Sheri Richardson – chair, Washington Council of the Blind Government Affairs Committee

2.2 FDA Proposed Rule: National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers

On February 4, 2022, the FDA released proposed regulation, *National Standards for the Licensure of Wholesale Drug Distributors and Third Party Logistics Providers*. The proposed regulation will entirely replace the current set of federal regulations applicable to wholesale distributors. The FDA is currently seeking public and stakeholder comment on the proposed regulation. The comment period was originally set to close on May 24, 2022, however, the FDA extended the comment period, which now closes on September 6, 2022.

The Commission was provided an overview of the proposed regulation. The Commission was also informed that if the FDA adopts this regulation it may require the Commission to engage in legislative and rulemaking work because of FDA's interpretation of the preemption provision in the DSCSA.

Commissioner DeFrance raised concerns about the scope of the proposed rulemaking and whether it would apply to 503B outsourcing facilities, or nuclear pharmacy.

MOTION: Hawkins DeFrance moved to task staff to send comments to the FDA for clarification about the FDA licensed facilities and for additional clarification regarding the draft rule related to inspections. Judy Guenther, second. Motion carries, 13:0.

2.3 Manufacturers and Wholesalers of Dialysate (SHB 1675) Policy Statement

Joshua Munroe briefed the commission that the purpose of this policy statement is to establish the commission's position on expected practices surrounding dialysate provided directly to home dialysis patients by wholesalers and manufacturers while standard rulemaking is ongoing. The statement sets an expectation that identified entities – wholesalers and manufacturers – must comply with WACs 246-945-090 through -093.

MOTION: Craig Ritchie moved to approve the proposed policy statement as written and for staff to distribute via GovDelivery and the commission website. Hawkins DeFrance, second. Motion carries, 13:0.

2.4 Rulemaking Authority Expansion on WAC 246-945-060 (Mobile OTP Units)

Joshua Munroe and Lindsay Trant briefed the commission on the history of this rulemaking project related to OTP mobile units. Inspections of OTP mobile units conducted jointly with the DEA revealed deficiencies that would apply to other licensed locations but are not covered in rule for mobile OTP units. WAC 246-945-060 would need to be amended to add additional requirements and adding a new WAC may also be needed.

Staff requests the commission consider expanding the scope of the previously authorized rulemaking project on WAC 246-945-060 and consider adding a new WAC to explore regulatory requirements for mobile OTP units.

MOTION: Craig Ritchie moved to expand scope of the previously authorized rulemaking project on WAC 246-945-060 and consider adding a new WAC to consider adding regulatory requirements for mobile OTP units. Hawkins DeFrance, second. Motion carries, 13:0.

2.5 Amended WAC Language for the AIDS Education Requirement Repeal (ESHB 1551)

Joshua Munroe presented on the history of this issue for newer commission members and an explanation of recent actions taken to advance the expedited rulemaking package. Staff requests the commission consider approving the amended language on WACs 246-945-162, -200, and -205. If approved, staff will proceed with filing the CR-105 for expedited rulemaking.

MOTION: Craig Ritchie moved to approve the amended language on WACs 246-945-162, -200, and -205 and authorize staff to proceed with filing the CR-105 for expedited rulemaking. William Hayes, second. Motion carries, 13:0.

2.6 Emergency Rule Refile Request: Retired Active Pharmacist License Status

Joshua Munroe provided an assessment of the emergency rule and a progress report on the same issue. The Proposal Phase rule packet (CR-102) is currently under division pre-review. In the meantime, emergency rules are still needed to allow pharmacists with retired active pharmacist licensure to practice during declared states of emergency. The current emergency rule is set to expire on September 24, 2022. Staff requests the commission approve the re-filing of the retired pharmacist emergency rule.

MOTION: Craig Ritchie moved to direct staff refile the emergency rule. Ken Kenyon, second. Motion carries, 13:0.

3. Panel Review Study Plan (Helen Jung, Patrick Gallaher, Judy Guenther)

MOTION: Craig Ritchie moved to delegate the authority to approve study plans in the cases listed in 3.1 and 3.2. to Commissioners Jung, Gallaher, and Guenther. Hawkins, second. Motion carries, 13:0.

3.1 PHRM.PH.60874656

MOTION: Patrick Gallaher moved to approve allowing candidate to take the exam a fourth time. Helen Jung, second. Motion carries, 3:0.

3.2 PHRM.PH.61230173

MOTION: Patrick Gallaher moved to approve allowing candidate to take the exam a fourth time. Judy Gallaher, second. Motion carries, 3:0.

4. Open Forum

5. Commission Member Reports

5.1 NABP Report – Teri Ferreira and Jerrie Allard attended the May NABP annual meeting.

Hearing our peers' issues and challenges was very informative. One of the biggest challenges is workforce. Other states have gone into rulemaking to address some of that. DSCSA was another popular topic. Discussion on what individual pharmacies' responsibilities will be and how to prepare.

5.2 Pharmacy Practice Subcommittee – Craig Ritchie – the subcommittee will be working on the AUP form to ensure it is easy to complete the form and have it approved.

5.3 Legislative Subcommittee – William Hayes – the subcommittee met in June where the Uniform Facilities Enforcement Framework was presented. We started opening up listening sessions to prepare for the 2024 legislative sessions. The meeting in August has been cancelled in lieu of the special meeting

5.4 Compounding Subcommittee – Hawkins DeFrance – the compounding subcommittee met Tuesday, July 12. Stakeholders contributed to a very robust conversation.

The practices known as white, brown, and clear bagging were discussed. Stakeholders were largely concerned with patient safety. The staff was asked to research the various forms and the extent to which they fit within the commission's regulatory framework.

The second topic was the non-resident pharmacy directive of approved inspection programs from other states. Nomi Peaks presented an analysis on NABP law assessments. Four states stood out as having non-equivalent requirements compared to Washington State. Stakeholder discussion centered on "what does sufficiently equivalent mean?" Consensus of stakeholders came down to, "it should not be harder to be a compounding pharmacy in Washington doing business than it is for an out-of-state pharmacy not held to the same standards." Suggestions were to look closer at USP requirements 795, 797, and 800.

Staff was asked to send out GovDelivery to solicit feedback from stakeholders that know more about laws in specific states related to compounding.. Staff will report to commission in the future.

5.5 Budget Subcommittee – Patrick Gallaher reviewed the 2021-23 Budget & Fund Balance Overview. The fund balance is strong. Recently paid for the HELMS project – a modernized electronic licensing system.

Marlee O’Neill informed the commission we received permission from the department to hire nine additional staff – four inspectors, pharmacist consultant, and a few program team staff. We will need to do a decision package for the 2024 legislative session so the allotment can be reallocated elsewhere. This allotment will not require a fee increase. Marlee O’Neill and Lindsay Trant also clarified the rubric used to determine how many staff and where they will be used.

Miceal Carnahan advised the commission that in general moving to the two-year renewal cycle for the profession side, there will be a net-neutral effect. Also, this spring, there will be facility-type renewals, and this will contribute to the spike in March 2023. Also, the revenue seen now is a combination of fee change as well as increases in licensure.

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

Craig Ritchie mentioned the prescription label translation issues. The commission should make sure we reach out to the communities that need translations to gain insight on the actual needs.

Hawkins DeFrance regarding unintentional gap in veterinary medicine for emergency prescriptions. What can PQAC do to help? Chris Gerard confirmed there would need to be legislative change. PQAC staff will reach out to the Veterinary Board of Governors.

Jenny Arnold, Washington State Pharmacy Association – welcomed Marlee O’Neill as Executive Director. Encouraged all to support Marlee in this time as she learns the pharmacy profession and rebuilds the staff in this new post-COVID landscape.

6. Staff Reports *Information/Action.*

6.1 Interim Executive Director – Marlee O’Neill

- Paxlovid EUA Update – pharmacists can now prescribe Paxlovid if they have a CDTA with a prescriber that authorizes the pharmacist to prescribe Paxlovid or following the 9th amendment to the declaration under the Public Readiness and Emergency Preparedness Act (PREP) for medical countermeasures against COVID-19. With this revision there are still challenges in the department; and the commission and association are in discussion about those challenges.

6.2 Deputy Director – Lindsay Trant – staffing updates:

- Sasha DeLeon – formerly acting office director for Office of Health Professions (OHP) is now the Assistant Secretary for the division.
- Shawna Fox – is now the new permanent director for OHP. Shawna has been invited to meet the commission at the September meeting.
- Haleigh Mauldin, Program Consultant (HSC4) – non-permanent, one-year position to assist with the backlog of work, including but not limited to: rules work, non-routine applications, preparing for all meetings, etc.
- Amy Robertson – is now our Communications Coordinator and Program Support. She will assist with “all things technology.” We will be posting the position of AA3 in the near future.

6.3 Assistant Attorney General – Christopher Gerard – will attend a webinar for attorneys in October via NABP for attorneys advising pharmacy boards/commissions.

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

- 2.1 – Survey on prescription label accessibility rulemaking to licensees
- 2.2 – Draft FDA comments to include asking for clarification on what is included as an FDA licensed facility; clarify inspection requirements for those seeking licensure for those seeking licensure from out of state.
- 2.3 – File policy on SHB 1675 with code revisor and distribute to licensees.
- 2.4 – Begin rulemaking to consider regulatory requirements for mobile OTP units and other controlled substance registrants.
- 2.5 – File CR-105 to continue expedited rulemaking on implementation of ESHB 1551 appealing aids education and training requirements.
- 2.6 – Refile emergency rules on the retired active pharmacists license status.
- 3.1 and 3.2 – Communicate with Office of Customer Service and the applicant(s) of a study plan as submitted
- 5 – Research ways to provide outreach and related materials on accessible label rulemaking in different languages.
- Correspond with veterinary board regarding emergency office use for short supplies for animals.

Business Meeting Adjourned. 4:04 p.m.

From: [Compliance](#)
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 - Aug 2022
Date: Thursday, September 1, 2022 5:43:38 AM
Attachments: [WA PHARMACY TRX REPORT 08012022.csv](#)

External Email

MONTHLY PROGRAM ADMINISTRATOR'S DASHBOARD

2 Logins - 0 Searches - 0 Report Queries - 23 Active Watches - 0 Active Watch Hits		
<p>NEW USERS THIS MONTH</p> <p>New Users = 0</p> <p>Total Accounts = 142</p> <p>Active Users = 2</p>	<p>TOP USAGE AGENCIES</p> <p>TOP USERS BY USAGE</p>	<p>TOP AGENCIES BY ACTIVE WATCHES</p> <p>1. ICE - King County (18)</p>

TRANSACTION SUMMARY STATISTICS (2022)									
	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	TOTAL
PURCHASES	75,034	57,362	79,004	89,983	91,435	94,303	80,068	64,849	632,038
BLOCKS	2,918	2,357	3,387	3,574	3,494	4,072	3,899	2,628	26,329
GRAMS SOLD	158,746	128,022	178,164	197,739	197,426	212,371	183,284	143,825	1,399,577
BOXES SOLD	84,585	63,930	88,582	100,384	101,052	103,419	89,179	73,713	704,844
GRAMS BLOCKED	7,592	6,488	9,141	9,857	9,505	11,496	11,390	7,998	73,467
BOXES BLOCKED	3,315	2,644	3,844	4,074	3,849	4,604	4,528	3,296	30,154
AVG GRAMS PER BOX BLOCKED	2.29	2.45	2.38	2.42	2.47	2.50	2.52	2.43	2.43

PHARMACY PARTICIPATION STATISTICS (Aug 2022)	
Enabled Pharmacies	1003
Pharmacies Submitting a Transaction	934
Pharmacies Logging in Without a Transaction	1
Inactive Pharmacies	68

Pharmacy Participation for Aug

93.22%

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.

From: [Appriss Health](#)
To: [Weimer, Jamie](#); [DOH WSPOAC](#); [Miller, Joanne \(DOH\)](#)
Cc: [ndelavega@appriss.com](#); [kmcormick@appriss.com](#); [Accountspecialist@appriss.com](#); [tnadrich@appriss.com](#)
Subject: Washington NPLEx Dashboard Report - Jul 2022
Date: Monday, August 1, 2022 5:30:38 AM
Attachments: [WA PHARMACY TRX REPORT 07012022.csv](#)

External Email

MONTHLY PROGRAM ADMINISTRATOR'S DASHBOARD

6 Logins - 0 Searches - 1 Report Queries - 23 Active Watches - 0 Active Watch Hits		
NEW USERS THIS MONTH New Users = 1 Total Accounts = 142 Active Users = 4	TOP USAGE AGENCIES 1. Seattle Police Dept TOP USERS BY USAGE 1. Kevin Dave, Seattle Police Dept	TOP AGENCIES BY ACTIVE WATCHES 1. ICE - King County (18)

TRANSACTION SUMMARY STATISTICS (2022)								
	JAN	FEB	MAR	APR	MAY	JUN	JUL	TOTAL
PURCHASES	75,034	57,362	79,004	89,983	91,435	94,303	80,068	567,189
BLOCKS	2,918	2,357	3,387	3,574	3,494	4,072	3,899	23,701
GRAMS SOLD	158,746	128,022	178,164	197,739	197,426	212,371	183,284	1,255,752
BOXES SOLD	84,585	63,930	88,582	100,384	101,052	103,419	89,179	631,131
GRAMS BLOCKED	7,592	6,488	9,141	9,857	9,505	11,496	11,390	65,469
BOXES BLOCKED	3,315	2,644	3,844	4,074	3,849	4,604	4,528	26,858
AVG GRAMS PER BOX BLOCKED	2.29	2.45	2.38	2.42	2.47	2.50	2.52	2.43

PHARMACY PARTICIPATION STATISTICS (Jul 2022)	
Enabled Pharmacies	1003
Pharmacies Submitting a Transaction	939
Pharmacies Logging in Without a Transaction	0
Inactive Pharmacies	64

Pharmacy Participation for Jul

93.62%

DISCLAIMER: This is an automated report meant to give you a quick snapshot of the NPLEEx 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 NPLEEx customer relationship manager. For questions or issues, please contact kmccormick@appriss.com.

2.1 Pharmaceutical Firms Application Report
 July 1, 2022 to September 12, 2022

PHAR.CF.61245559	ACTIVE	07/01/2022	07/01/2022	05/31/2023
PHNR.FO.61331781	ACTIVE	07/01/2022	07/01/2022	05/31/2023
PHNR.FO.61331796	ACTIVE	07/01/2022	07/01/2022	05/31/2023
PHNR.FO.61331836	ACTIVE	07/01/2022	07/01/2022	05/31/2023
PHNR.FO.61286959	ACTIVE	07/06/2022	07/06/2022	05/31/2023
PHNR.FO.61257326	ACTIVE	07/06/2022	07/06/2022	05/31/2023
PHAR.CF.61322075	ACTIVE	07/07/2022	07/07/2022	05/31/2023
PHNR.FO.61334432	ACTIVE	07/08/2022	07/08/2022	05/31/2023
PHAR.CF.61275618	ACTIVE	07/12/2022	07/12/2022	05/31/2023
PHNR.FO.61336459	ACTIVE	07/12/2022	07/12/2022	05/31/2023
PHMF.FX.61301668	ACTIVE	07/13/2022	07/13/2022	09/30/2023
PHNR.FO.61333771	ACTIVE	07/13/2022	07/13/2022	05/31/2023
PHNR.FO.61310389	ACTIVE	07/19/2022	07/19/2022	05/31/2023
PHNR.FO.61338766	ACTIVE	07/19/2022	07/19/2022	05/31/2023
PHNR.FO.61316944	ACTIVE	07/20/2022	07/20/2022	05/31/2023
PHNR.FO.61310112	ACTIVE	07/20/2022	07/20/2022	05/31/2023
PHNR.FO.61341425	ACTIVE	07/27/2022	07/27/2022	05/31/2023
PHNR.FO.61342003	ACTIVE	07/29/2022	07/29/2022	05/31/2023
PHAR.CF.61327145	ACTIVE	08/02/2022	08/02/2022	05/31/2023
PHAR.CF.61288719	ACTIVE	08/12/2022	08/12/2022	05/31/2023
PHNR.FO.61349232	ACTIVE	08/17/2022	08/17/2022	05/31/2023
PHAR.CF.61248895	ACTIVE	08/18/2022	08/18/2022	05/31/2023
PHNR.FO.61326097	ACTIVE	08/18/2022	08/18/2022	05/31/2023

PHNR.FO.61351206	ACTIVE	08/23/2022	08/23/2022	05/31/2023
PHAR.CF.61216909	ACTIVE	08/26/2022	08/26/2022	05/31/2023
PHAR.CF.61175241	ACTIVE	08/30/2022	08/30/2022	05/31/2023
PHNR.FO.61333831	ACTIVE	09/01/2022	09/01/2022	05/31/2023

Closed report

PHNR.FO.61342260	CLOSED	08/03/2022	08/03/2022	08/15/2022
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PQAC Rules Tracker

Title	Status	Short Description	Most Recent WSR #
COVID - CII Prescribing (emergency)	Needs Refile Approval	Emergency rules for prescribing Schedule II drugs during COVID-19 pandemic	WSR 22-13-180 (Filed June 22, 2022)
Medication assistance (emergency - filed jointly with DOH)	Needs Refile Approval	Medication assistance emergency rules in accordance with chapter 69.41 RCW	WSR 22-15-049 (Filed July 15, 2022)
Retired pharmacist (emergency)	Under division review; filing pending	Emergency rules for retired active pharmacist license status	WSR 22-12-066 (Filed May 27, 2022)
Accessible labeling (visual/print access and translated labels)	Survey link will be distributed by 9/22	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 under division review; possible delay due to departmental review system change	Permanent rules for retired active pharmacist license status	WSR 21-09-063 (Filed April 19, 2021)
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 under division review; possible delay due to departmental review system change	SSB 6526 - Implementing the donation and reuse of unexpired drugs	WSR 20-17-143 (Filed August 19, 2020)

PQAC Rules Tracker (cont.)

Title	Status	Short Description	Most Recent WSR #
Health Equity Training – ESSB 5229 (standard)	CR-101 draft pending; proposal before committee	Amend sections in Chapter 246-945 WAC pertaining to continuing education standards for the purpose of establishing health equity education requirements per ESSB 5229.	Not yet filed
Uniform Controlled Substances Act – Title 21 CFR (expedited)	CR-105 drafted; updated proposal before committee (9/22)	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 in draft stage	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	Not yet filed

CERTIFICATION OF ENROLLMENT
ENGROSSED SUBSTITUTE SENATE BILL 5229

67th Legislature
2021 Regular Session

Passed by the Senate April 15, 2021
Yeas 33 Nays 15

President of the Senate

Passed by the House March 24, 2021
Yeas 57 Nays 41

**Speaker of the House of
Representatives**

Approved

Governor of the State of Washington

CERTIFICATE

I, Brad Hendrickson, Secretary of the Senate of the State of Washington, do hereby certify that the attached is **ENGROSSED SUBSTITUTE SENATE BILL 5229** as passed by the Senate and the House of Representatives on the dates hereon set forth.

Secretary

FILED

**Secretary of State
State of Washington**

ENGROSSED SUBSTITUTE SENATE BILL 5229

AS AMENDED BY THE HOUSE

Passed Legislature - 2021 Regular Session

State of Washington 67th Legislature 2021 Regular Session

By Senate Health & Long Term Care (originally sponsored by Senators Randall, Das, Keiser, Lovelett, Nobles, Wilson, C., Dhingra, Hasegawa, Kuderer, Nguyen, and Stanford)

READ FIRST TIME 02/08/21.

1 AN ACT Relating to health equity continuing education for health
2 care professionals; amending RCW 43.70.615; adding a new section to
3 chapter 43.70 RCW; and creating a new section.

4 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

5 NEW SECTION. **Sec. 1.** The legislature finds that:

6 (1) Healthy Washingtonians contribute to the economic and social
7 welfare of their families and communities, and access to health
8 services and improved health outcomes allows all Washington families
9 to enjoy productive and satisfying lives;

10 (2) The COVID-19 pandemic has further exposed that health
11 outcomes are experienced differently by different people based on
12 discrimination and bias by the health care system. Research shows
13 that health care resources are distributed unevenly by intersectional
14 categories including, but not limited to, race, gender, ability
15 status, religion, sexual orientation, socioeconomic status, and
16 geography; and

17 (3) These inequities have permeated health care delivery,
18 deepening adverse outcomes for marginalized communities. This bill
19 aims to equip health care workers with the skills to recognize and
20 reduce these inequities in their daily work. In addition to their

1 individual impact, health care workers need the skills to address
2 systemic racism and bias.

3 NEW SECTION. **Sec. 2.** A new section is added to chapter 43.70
4 RCW to read as follows:

5 (1) By January 1, 2024, the rule-making authority for each health
6 profession licensed under Title 18 RCW subject to continuing
7 education requirements must adopt rules requiring a licensee to
8 complete health equity continuing education training at least once
9 every four years.

10 (2) Health equity continuing education courses may be taken in
11 addition to or, if a rule-making authority determines the course
12 fulfills existing continuing education requirements, in place of
13 other continuing education requirements imposed by the rule-making
14 authority.

15 (3)(a) The secretary and the rule-making authorities must work
16 collaboratively to provide information to licensees about available
17 courses. The secretary and rule-making authorities shall consult with
18 patients or communities with lived experiences of health inequities
19 or racism in the health care system and relevant professional
20 organizations when developing the information and must make this
21 information available by July 1, 2023. The information should include
22 a course option that is free of charge to licensees. It is not
23 required that courses be included in the information in order to
24 fulfill the health equity continuing education requirement.

25 (b) By January 1, 2023, the department, in consultation with the
26 boards and commissions, shall adopt model rules establishing the
27 minimum standards for continuing education programs meeting the
28 requirements of this section. The department shall consult with
29 patients or communities with lived experience of health inequities or
30 racism in the health care system, relevant professional
31 organizations, and the rule-making authorities in the development of
32 these rules.

33 (c) The minimum standards must include instruction on skills to
34 address the structural factors, such as bias, racism, and poverty,
35 that manifest as health inequities. These skills include individual-
36 level and system-level intervention, and self-reflection to assess
37 how the licensee's social position can influence their relationship
38 with patients and their communities. These skills enable a health
39 care professional to care effectively for patients from diverse

1 cultures, groups, and communities, varying in race, ethnicity, gender
2 identity, sexuality, religion, age, ability, socioeconomic status,
3 and other categories of identity. The courses must assess the
4 licensee's ability to apply health equity concepts into practice.
5 Course topics may include, but are not limited to:

6 (i) Strategies for recognizing patterns of health care
7 disparities on an individual, institutional, and structural level and
8 eliminating factors that influence them;

9 (ii) Intercultural communication skills training, including how
10 to work effectively with an interpreter and how communication styles
11 differ across cultures;

12 (iii) Implicit bias training to identify strategies to reduce
13 bias during assessment and diagnosis;

14 (iv) Methods for addressing the emotional well-being of children
15 and youth of diverse backgrounds;

16 (v) Ensuring equity and antiracism in care delivery pertaining to
17 medical developments and emerging therapies;

18 (vi) Structural competency training addressing five core
19 competencies:

20 (A) Recognizing the structures that shape clinical interactions;

21 (B) Developing an extraclinical language of structure;

22 (C) Rearticulating "cultural" formulations in structural terms;

23 (D) Observing and imagining structural interventions; and

24 (E) Developing structural humility; and

25 (vii) Cultural safety training.

26 (4) The rule-making authority may adopt rules to implement and
27 administer this section, including rules to establish a process to
28 determine if a continuing education course meets the health equity
29 continuing education requirement established in this section.

30 (5) For purposes of this section the following definitions apply:

31 (a) "Rule-making authority" means the regulatory entities
32 identified in RCW 18.130.040 and authorized to establish continuing
33 education requirements for the health care professions governed by
34 those regulatory entities.

35 (b) "Structural competency" means a shift in medical education
36 away from pedagogic approaches to stigma and inequalities that
37 emphasize cross-cultural understandings of individual patients,
38 toward attention to forces that influence health outcomes at levels
39 above individual interactions. Structural competency reviews existing
40 structural approaches to stigma and health inequities developed

1 outside of medicine and proposes changes to United States medical
2 education that will infuse clinical training with a structural focus.

3 (c) "Cultural safety" means an examination by health care
4 professionals of themselves and the potential impact of their own
5 culture on clinical interactions and health care service delivery.
6 This requires individual health care professionals and health care
7 organizations to acknowledge and address their own biases, attitudes,
8 assumptions, stereotypes, prejudices, structures, and characteristics
9 that may affect the quality of care provided. In doing so, cultural
10 safety encompasses a critical consciousness where health care
11 professionals and health care organizations engage in ongoing self-
12 reflection and self-awareness and hold themselves accountable for
13 providing culturally safe care, as defined by the patient and their
14 communities, and as measured through progress towards achieving
15 health equity. Cultural safety requires health care professionals and
16 their associated health care organizations to influence health care
17 to reduce bias and achieve equity within the workforce and working
18 environment.

19 **Sec. 3.** RCW 43.70.615 and 2006 c 237 s 2 are each amended to
20 read as follows:

21 (1) For the purposes of this section, "multicultural health"
22 means the provision of health care services with the knowledge and
23 awareness of the causes and effects of the determinants of health
24 that lead to disparities in health status between different genders
25 and racial and ethnic populations and the practice skills necessary
26 to respond appropriately.

27 (2) The department, in consultation with the disciplining
28 authorities as defined in RCW 18.130.040, shall establish, within
29 available department general funds, an ongoing multicultural health
30 awareness and education program as an integral part of its health
31 professions regulation. The purpose of the education program is to
32 raise awareness and educate health care professionals regarding the
33 knowledge, attitudes, and practice skills necessary to care for
34 diverse populations to achieve a greater understanding of the
35 relationship between culture and health. (~~The disciplining
36 authorities having the authority to offer continuing education may
37 provide training in the dynamics of providing culturally competent,
38 multicultural health care to diverse populations.~~) Any such
39 education shall be developed in collaboration with education programs

1 that train students in that health profession. (~~(A disciplining~~
2 ~~authority may require that instructors of continuing education or~~
3 ~~continuing competency programs integrate multicultural health into~~
4 ~~their curricula when it is appropriate to the subject matter of the~~
5 ~~instruction.)~~) No funds from the health professions account may be
6 utilized to fund activities under this section unless the
7 disciplining authority authorizes expenditures from its proportions
8 of the account. (~~(A disciplining authority may defray costs by~~
9 ~~authorizing a fee to be charged for participants or materials~~
10 ~~relating to any sponsored program.)~~)

11 (3) By July 1, 2008, each education program with a curriculum to
12 train health professionals for employment in a profession
13 credentialed by a disciplining authority under chapter 18.130 RCW
14 shall integrate into the curriculum instruction in multicultural
15 health as part of its basic education preparation curriculum. The
16 department may not deny the application of any applicant for a
17 credential to practice a health profession on the basis that the
18 education or training program that the applicant successfully
19 completed did not include integrated multicultural health curriculum
20 as part of its basic instruction.

--- END ---

PART 15
MINIMUM STANDARDS FOR HEALTH EQUITY CONTINUING EDUCATION TRAININGS FOR
HEALTH CARE PROFESSIONALS

NEW SECTION

WAC 246-12-800 Purpose. WAC 246-12-810 through 246-12-830 contain model rules establishing minimum standards for health equity continuing education trainings for health care professionals credentialed under RCW 18.130.040 with a continuing education requirement. The rule-making authority for each health profession credentialed under RCW 18.130.040 with a continuing education requirement may set standards that exceed the minimum standards in this chapter.

NEW SECTION

WAC 246-12-810 Definitions. The definitions in this section and RCW 43.70.613 apply throughout WAC 246-12-800 through 246-12-830 unless the context clearly requires otherwise.

(1) "Department" means the Washington state department of health.

(2) "Health care professional" means an individual credentialed or holding a retired active credential in one of the health professions listed in RCW 18.130.040 with a continuing education requirement.

(3) "Health equity" means all people have the same opportunities and equal access in order to attain their full health potential regardless of the color of their skin, ancestry, ethnicity, level of education, gender identity, sexual orientation, age, religion, socioeconomic status, the job they have, the neighborhood they live in, or their ability status.

NEW SECTION

WAC 246-12-820 Health equity continuing education training minimum hours. Health care professionals must complete a minimum of two hours in health equity continuing education training every four years, unless the relevant rule-making authority specifies a higher number of hours in rule.

NEW SECTION

WAC 246-12-830 Health equity continuing education training content. An education program providing health equity continuing education training must:

(1) Include implicit bias training to identify strategies to reduce bias during assessment and diagnosis and may include, but is not limited to, at least one of the topics included in RCW 43.70.613 (3)(c).

(2) Have trainers with demonstrated knowledge and experience related to health equity. Research referenced in the training must be based on current empirical research and known best practices.

(3) Have courses that assess the health care professional's ability to apply health equity concepts into practice in accordance with profession specific rules, which may include, but are not limited to:

(a) An assessment at the end of an in-person or virtual continuing education training to determine knowledge gained during that training; or

(b) A document provided at the end of an in-person or virtual continuing education training that attests attendance at the training.



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: June 22, 2022

TIME: 10:22 AM

WSR 22-13-180

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 22-06-017 filed on February 22, 2022. This emergency rule was originally filed on April 21, 2020 under WSR 20-09-133. It was refiled 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. Interested parties 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	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Federal rules or standards:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Recently enacted state statutes:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>

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

New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
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The number of sections adopted on the agency's own initiative:

New	<u>0</u>	Amended	<u>1</u>	Repealed	<u>0</u>
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The number of sections adopted in order to clarify, streamline, or reform agency procedures:

New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
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The number of sections adopted using:

Negotiated rule making:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Pilot rule making:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Other alternative rule making:	New	<u>0</u>	Amended	<u>1</u>	Repealed	<u>0</u>

Date Adopted: 06/22/2022

Name: Teri Ferreira, RPh

Title: Pharmacy Quality Assurance Chair

Signature:



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.



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: July 15, 2022

TIME: 10:11 AM

WSR 22-15-049

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: WACs 246-945-710, 246-945-712, 246-945-714, 246-945-716, 246-945-718, 246-945-720, 246-945-722, 246-945-724, 246-945-726, and 246-945-728 - Medication assistance. The Pharmacy Quality Assurance Commission (commission) and Department of Health (department) are filing jointly to reinstate medication assistance rules as permitted under chapter 69.41 RCW. This adopted emergency rule will extend WSR 22-07-063 filed on March 17, 2022. This rule establishes criteria for medication assistance in community-based and in-home care settings in accordance with chapter 69.41 RCW. The definition for medication assistance provided in RCW 69.41.010(15) states:

"Medication assistance" means assistance rendered by a nonpractitioner to an individual residing in a community-based care setting or in-home care setting to facilitate the individual's self-administration of a legend drug or controlled substance. It includes reminding or coaching the individual, handing the medication container to the individual, opening the individual's medication container, using an enabler, or placing the medication in the individual's hand, and such other means of medication assistance as defined by rule adopted by the department...

These emergency rules provide further definitions for terms used within this definition such as "enabler" and establish those "other means of medication assistance as defined by rule adopted by the department." These rules help impacted individuals retain their independence and live in the least restrictive setting, such as their own home, longer by providing means and guidance for medication assistance. Also, with the direction provided in RCW 69.41.010(15), the rules are being filed under the joint authority of the commission and the department.

Citation of rules affected by this order:

- New: WAC 246-945-710, 246-945-712, 246-945-714, 246-945-716, 246-945-718, 246-945-720, 246-945-722, 246-945-724, 246-945-726, 246-945-728
- Repealed: None
- Amended: None
- Suspended: None

Statutory authority for adoption: RCW 18.64.005; RCW 69.41.010(15); RCW 69.41.075

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 commission's new chapter, chapter 246-945 WAC, became effective in July 2020. The old rules, including the former rules on medication assistance (chapter 246-888 WAC), were repealed in March 2021. The commission's repeal of chapter 246-888 WAC has resulted in unintended disruptions for medication assistance in the community-based and in-home care settings permitted under chapter 69.41 RCW. Emergency rulemaking is necessary to immediately restore medication assistance regulations to preserve patient safety and welfare while the commission and the department work on permanent rulemaking. The CR101 was filed on December 27, 2021 under WSR 22-02-015. Permanent rulemaking progress has been authorized but delayed due to the ongoing coronavirus disease 2019 pandemic..

**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	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Federal rules or standards:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Recently enacted state statutes:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>

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

New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
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The number of sections adopted on the agency's own initiative:

New	<u>10</u>	Amended	<u>0</u>	Repealed	<u>0</u>
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The number of sections adopted in order to clarify, streamline, or reform agency procedures:

New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
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The number of sections adopted using:

Negotiated rule making:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Pilot rule making:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Other alternative rule making:	New	<u>10</u>	Amended	<u>0</u>	Repealed	<u>0</u>

Date Adopted: 07/14/2022

Name: Teri Ferreira, RPh and Kristin Peterson, JD

Title: Pharmacy Quality Assurance Chair and Deputy Secretary, Policy and Planning

Signature:



PART 5 - MEDICATION ASSISTANCE

NEW SECTION

WAC 246-945-710 Scope and applicability. (1) This section through WAC 246-945-728 only apply to medication assistance provided in community-based care settings and in-home care settings.

(2) The following definitions apply to this section through WAC 246-945-728 unless the context requires otherwise:

- (a) "Medication" means legend drugs and controlled substances; and
- (b) "Practitioner" has the same meaning as in RCW 69.41.010(17).

NEW SECTION

WAC 246-945-712 Self-administration with assistance, independent self-administration, and medication administration. (1) Self-administration with assistance means assistance with legend drugs and controlled substances rendered by a nonpractitioner to an individual residing in a community-based care setting or an in-home care setting. It includes reminding or coaching the individual to take their medication, handing the medication container to the individual, opening the medication container, using an enabler, or placing the medication in the hand of the individual/resident. The individual/resident must be able to put the medication into their mouth or apply or instill the medication. The individual/resident does not necessarily need to state the name of the medication, intended effects, side effects, or other details, but must be aware that they are receiving medication. Assistance may be provided by a nonpractitioner with prefilled insulin syringes. Assistance is limited to handing the prefilled insulin syringe to an individual/resident. Assistance with the administration of any other intravenous or injectable medication is specifically excluded. The individual/resident retains the right to refuse medication. Self-administration with assistance shall occur immediately prior to the ingestion or application of a medication.

(2) Independent self-administration occurs when an individual/resident is independently able to directly apply a legend drug or controlled substance by ingestion, inhalation, injection or other means. In licensed assisted living facilities, self-administration may include situations in which an individual cannot physically self-administer medications but can accurately direct others. These regulations do not limit the rights of people with functional disabilities to self-direct care according to chapter 74.39 RCW.

(3) If an individual/resident is not able to physically ingest or apply a medication independently or with assistance, then the medication must be administered to the individual/resident by a person legally authorized to do so (e.g., physician, nurse, pharmacist). All

laws and regulations applicable to medication administration apply. If an individual/resident cannot safely self-administer medication or self-administer with assistance or cannot indicate an awareness that they are taking a medication, then the medication must be administered to the individual/resident by a person legally authorized to do so.

NEW SECTION

WAC 246-945-714 Self-administration with assistance in a community-based care setting or an in-home setting. (1) An individual/resident, or their representative, in a community-based care setting or an in-home setting may request self-administration with assistance.

(2) No additional separate assessment or documentation of the needs of the individual/resident are required in order to initiate self-administration with assistance. It is recommended that providers document their decision-making process in the health record of the individual or resident health record.

(3) A nonpractitioner may help in the preparation of legend drugs and controlled substances for self-administration where a practitioner has determined and communicated orally or by written direction that such medication preparation assistance is necessary and appropriate.

NEW SECTION

WAC 246-945-716 Enabler. (1) Enablers are physical devices used to facilitate an individual's/resident's self-administration of a medication. Physical devices include, but are not limited to, a medicine cup, glass, cup, spoon, bowl, prefilled syringes, syringes used to measure liquids, specially adapted table surface, straw, piece of cloth, or fabric.

(2) An individual's hand may also be an enabler. The practice of "hand-over-hand" administration is not allowed. Medication administration with assistance includes steadying or guiding an individual's hand while he or she applies or instills medications such as ointments, eye, ear, and nasal preparations.

NEW SECTION

WAC 246-945-718 Alteration of medication for self-administration with assistance. Alteration of a medication for self-administration with assistance includes, but is not limited to, crushing tablets, cutting tablets in half, opening capsules, mixing powdered medications with foods or liquids, or mixing tablets or capsules with foods or liquids. Individuals/residents must be aware that the medication is being altered or added to their food.

NEW SECTION

WAC 246-945-720 Medication alteration. A practitioner practicing within their scope of practice must determine that it is safe to alter a legend drug or controlled substance. If the medication is altered, and a practitioner has determined that such medication alteration is necessary and appropriate, the determination shall be communicated orally or by written direction. Documentation of the appropriateness of the alteration must be on the prescription container, or in the individual's/resident's record.

NEW SECTION

WAC 246-945-722 Types of assistance provided by nonpractitioner. A nonpractitioner can transfer a medication from one container to another for the purpose of an individual dose. Examples include: Pouring a liquid medication from the medication container to a calibrated spoon or medication cup.

NEW SECTION

WAC 246-945-724 Oxygen order/prescription requirements. Under state law, oxygen is not a medication and is not covered under this rule. While oxygen is not considered a medication under state law, oxygen does require an order/prescription from a practitioner.

NEW SECTION

WAC 246-945-726 Self-administration with assistance of medication through a gastrostomy or "g-tube." If a prescription is written as an oral medication via "g-tube," and if a practitioner has determined that the medication can be altered, if necessary, for use via "g-tube," the rules as outlined for self-administration with assistance would also apply.

NEW SECTION

WAC 246-945-728 Other medication assistance requirements. A practitioner, nonpractitioner, and an individual/resident or their representative should be familiar with the rules specifically regulating the residential setting. The department of social and health services has adopted rules relating to medication services in assisted living facilities and adult family homes.

Commission SBAR Communication

Agenda Item/Title: Suspicious Order Requirements in [WAC 246-945-585](#)

Date SBAR Communication Prepared: January 20, 2022 (NOTE: previously presented to the commission at the January 28th business meeting)

Reviewer: Marlee O'Neill

Link to Action Plan:

Action **Information** **Follow-up** **Report only**

Situation:

In its new rules, effective July 1, 2020, the commission adopted [WAC 246-945-585](#) which, among other things, requires wholesalers to submit suspicious order reports. The commission exercised its enforcement discretion and did not find licensees deficient or take enforcement action against licensees for failure to comply with WAC 246-945-585(1)(a) through May 31, 2021.

Starting June 1, 2021, the commission began routinely receiving suspicious order reports. Since that time, commissioners and staff have realized there are challenges to implementing this rule. Wholesalers submit suspicious order reports in different formats (e.g., Excel spreadsheets, PDFs, etc) making it difficult for staff and commissioners to review, assess, and input the information. The number of suspicious orders reported by a wholesaler can be up to several hundred at a time. Wholesalers are reporting suspicious orders for drugs that are not controlled substances and not a drug of concern per commission rules such as Gabapentin. Wholesalers are not always reporting all the required information and, in one instance, cannot provide at one least piece of required data.

Background:

As part of the Commission's recent rules re-write, it adopted [WAC 246-945-585](#) which was taken directly from NABP's Model Pharmacy Act/Rules. This rule does several things.

- (1) requires wholesalers to design and operate a system that identifies and reports suspicious orders of controlled substances or drugs of concern and potential diversion to the Commission;
- (2) sets requirements for what must be included in suspicious order or potential diversion reports;
- (3) requires a wholesaler to submit a zero report if it identified no suspicious orders in a month;
- (4) requires wholesalers to exercise due diligence in identifying suspicious orders and sets out what due diligence looks like;
- (5) establishes when a wholesaler can sell controlled substances or drugs of concern to new customers; and
- (6) establishes when a wholesaler can provide a suspicious order to existing customers.

The Commission adopted this rule recognizing that it would have to implement and carry out this rule with its existing resources. In addition, as with many new things, the Commission was aware that it may have to adjust over time as it gained experience with this rule.

At the June 3, 2021 business meeting, the commission voted to authorize rulemaking to amend WAC 246-945-585(1)(b) in order to modify the zero report submission requirement. The scope of this rulemaking did not include revisiting the suspicious order reporting requirement.

Commission SBAR Communication

Assessment:

This rule was a new but important addition to the commission's new rules chapter. However, given the ongoing challenges experienced during implementation, commission staff suggest further examination of the rule is warranted.

Recommendation:

OPTION 1 (preferred): Commission staff recommends the commission task the facility subcommittee (Commissioners Kenyon, Ferreira, Hayes, Jung, and Lynch) with reviewing this rule and its implementation and preparing options and recommendations for the best way to proceed and presenting this at a future commission meeting.

OPTION 2: Instead of referring this work to the Facilities Subcommittee, the commission can consider action today. Available options include, but are not limited to, amending the scope of the previously authorized rulemaking on WAC 246-945-585 or directing staff to draft a guidance document or policy statement.

Follow-up Action:

Staff will proceed with steps as necessary to implement the commission's decision.