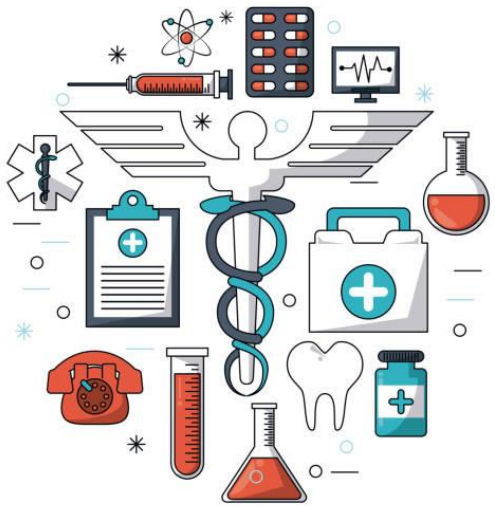
March 24, 2022

PQAC meeting packet



2.1

From: Appriss Health
To: Weimer, Jamie; DOH WSPQAC; Miller, Joanne (DOH)
Cc: [redacted]
Subject: Washington NPLEx Dashboard Report - Feb 2022
Date: Tuesday, March 1, 2022 3:43:05 AM
Attachments: [redacted]

External Email

MONTHLY PROGRAM ADMINISTRATOR'S DASHBOARD

3 Logins - 0 Searches - 0 Report Queries - 26 Active Watches - 0 Active Watch Hits

NEW USERS THIS MONTH	TOP USAGE AGENCIES	TOP AGENCIES BY ACTIVE WATCHES
New Users = 0	TOP USERS BY USAGE	1. ICE - King County (19)
Total Accounts = 141		
Active Users = 2		

TRANSACTION SUMMARY STATISTICS (2022)

	JAN	FEB	TOTAL
PURCHASES	75,034	57,367	**132,401**
BLOCKS	2,918	2,357	**5,275**
GRAMS SOLD	158,746	128,037	**286,783**
BOXES SOLD	84,585	63,935	**148,520**
GRAMS BLOCKED	7,592	6,488	**14,080**
BOXES BLOCKED	3,315	2,644	**5,959**
AVG GRAMS PER BOX BLOCKED	2.29	2.45	**2.37**

PHARMACY PARTICIPATION STATISTICS (Feb 2022)

Enabled Pharmacies	1003
Pharmacies Submitting a Transaction	933
Pharmacies Logging in Without a Transaction	0
Inactive Pharmacies	70
Pharmacy Participation for Feb	93.02%

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.

2.2 open and closed report

Credential #	Status	First Issuance Date	Effective Date	Expiration Date
PHNR.FO.61254339	ACTIVE	01/11/2022	01/11/2022	05/31/2022
PHNR.FO.61272130	ACTIVE	02/11/2022	02/11/2022	05/31/2022
PHNR.FO.61249943	ACTIVE	02/11/2022	02/11/2022	05/31/2022
PHWH.FX.61248068	ACTIVE	02/11/2022	02/11/2022	09/30/2022
PHAR.CF.61228965	ACTIVE	03/01/2022	03/01/2022	05/31/2023
PHNR.FO.61261235	ACTIVE	03/01/2022	03/01/2022	05/31/2023
PHWH.FX.61275448	ACTIVE	03/01/2022	03/01/2022	09/30/2022
PHAR.CF.61223512	ACTIVE	03/11/2022	03/11/2022	05/31/2023
PHNR.FO.61280716	ACTIVE	03/11/2022	03/11/2022	05/31/2023
PHWH.FX.61281521	ACTIVE	03/11/2022	03/11/2022	09/30/2022
PHWH.FX.61204612	ACTIVE	03/11/2022	03/11/2022	09/30/2022
PHWH.FX.61281621	ACTIVE	03/11/2022	03/11/2022	09/30/2022
PHWH.FX.61232174	ACTIVE	03/11/2022	03/11/2022	09/30/2022
PHWH.FX.61232048	ACTIVE	03/11/2022	03/11/2022	09/30/2022
PHWH.FX.61281631	ACTIVE	03/11/2022	03/11/2022	09/30/2022

NO firms closed during this time frame

Department of Health
Pharmacy Quality Assurance Commission

Policy Statement

Revised – 10/18/11

Title:	Enforcement of USP Chapters <800> and <825> *Number: 65.2*
References:	RCW 18.64.270(2); WAC 246-945-016, WAC 246-945-017, WAC 246-945-100, and WAC 246-945-490; United States Pharmacopeia Chapters <795>, <797>, <800>, and <825>; Commission Policy #60.1
Contact:	Lindsay Trant, Interim Deputy Director
Phone:	(360) 236-4946
Email:	wspqac@doh.wa.gov
Effective Date:	October 1, 2021
Supersedes:	Policy 65.1 effective April 1, 2020
Approved By:	Teri Ferreira, RPh, Pharmacy Quality Assurance Commission Chair

This policy clarifies the Pharmacy Quality Assurance Commission's (commission) approach to United States Pharmacopeia (USP) chapters <800> (USP 800) and <825> (USP 825) as it relates to WAC 246-945-100 and RCW 18.64.270(2).

At its September 2, 2021 business meeting, the commission voted to continue its position that it will not find deficiencies or take enforcement action against its licensees for failure to comply with USP 800 through March 31, 2022.

The commission expects compliance with USP 825 beginning October 1, 2021 where applicable, per WAC 246-945-100 and RCW 18.64.270(2).

When appropriate, the commission will revisit its use of enforcement discretion for USP 800. Any decision to modify the commission's use of enforcement discretion for USP 800 will be during an open public meeting before March 31, 2022.

The commission will consider extending its use of enforcement discretion for USP 800 if USP has not made the revised USP chapters <795> (USP 795) and <797> (USP 797) official. Additionally, if USP makes the revised USP 795 and USP 797 official prior to March 31, 2022, the commission will consider whether to extend its use of enforcement discretion for an additional period of time.

Standards for hazardous drug compounding were supposed to be eliminated in the initial proposed revision to USP 797 and only exist in USP 800. The delay in formal adoption or release of an updated revision draft for USP 797 has created some direct conflicts between the two chapters. The commission has considered and may revisit the delayed enforcement of USP 800 until the revised USP 795 and USP 797 are official to avoid licensees being subject to USP

standards that conflict with each other. For those licensees who choose to become early adopters of USP 800, the commission's approach to the discrepancies between USP 797 and USP 800 can be found in a separate policy statement (#60.1), "Regulation of the Handling of Hazardous Drugs" available on the commission's website. Policy Statement #60.1 also explains adherence to the Washington State Department of Labor and Industries' (LNI) General Occupational Health Standards rules on Hazardous Drugs (WAC 296-62-500 *et al).*

Table of PQAC's Enforcement Discretion Timeline	
USP Chapters	Enforcement Discretion
USP 800	October 1, 2020 – March 31, 2022
USP 825	October 1, 2020 – September 30, 2021
Revised USP 795 and 797	N/A; Revised Chapters have not been released
Current USP 795 and 797	These chapters will continue to be enforced.

Note: Please see Policy #60.1 regarding direct conflicts between USP 797 and USP 800.

In 2013, the Washington State Legislature adopted standards set by USP as the standards pharmacies must meet when sterile or non-sterile compounding. RCW 18.64.270(2) states, "Any medicinal products that are compounded for patient administration or distribution to a licensed practitioner for patient use or administration shall, at a minimum, meet the standards of the official United States pharmacopeia as it applies to nonsterile products and sterile administered products." As a result, the commission has enforced standards published by USP for sterile and non-sterile compounding since 2014.

The commission's new rule chapter (chapter 246-945 WAC) went into effect on July 1, 2020. This chapter rewrite took place over two and half years and included extensive collaboration with interested parties.

The new chapter includes enforcement of USP standards in accordance with RCW 18.64.270(2). Specifically, WAC 246-945-100 Compounding minimum standards requires that licensees comply with USP chapters 795, 797, 800, and 825. There are additional requirements for labeling compounded products in WAC 246-945-016 and WAC 246-945-017. WAC 246-945-490(3) and (4) also require nuclear pharmacies to prepare, compound, and dispense radiopharmaceuticals in accordance with the standards in USP 825.

The commission recognizes there are discrepancies between USP 797 and USP 800 in its current form; however, its approach to these discrepancies as well as adherence to LNI's rules on Hazardous Drugs (WAC 296-62-500 *et al)* is established in a separate policy statement (#60.1), "Regulation of the Handling of Hazardous Drugs" available on the commission's website.

If USP makes the revised USP 795 and USP 797 official prior to March 31, 2022, the commission will consider whether to extend its use for enforcement discretion on USP 800 for an additional period of time to allow licensees to comply with all applicable USP chapters at a future open public meeting.

3.3

STATE OF WASHINGTON

DEPARTMENT OF HEALTH

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NOTICE OF ADOPTION OF A POLICY STATEMENT

Title of Policy Statement: Enforcement of USP Chapters <800> and <825> | Policy Statement 65.2

Issuing Entity: Pharmacy Quality Assurance Commission

Subject Matter: This policy clarifies the Pharmacy Quality Assurance Commission's approach to United States Pharmacopeia (USP) chapters <800> and <825> as it relates to WAC 246-945-100 and RCW 18.64.270(2).

Effective Date: October 1, 2021

Contact Person: Lindsay Trant
Interim Deputy Director,
Pharmacy Quality Assurance Commission,
Washington State Department of Health
(360) 236-4946
wspqac@doh.wa.gov

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: September 28, 2021
TIME: 9:43 AM

WSR 21-20-046

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

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, 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.

The Board interprets “applicable USP standards” under Official Compilation of the Rules and Regulations of the State of Tennessee 1140-07-.02 to mean a pharmacy engaged in prescription drug compounding under either: (1) the active proposed / revised version of a USP chapter or (2) the currently official chapter and version of the USP compendium. The Board shall evaluate the compounding practices under the version of the USP chapter chosen by the pharmacy.

ADOPTED BY THE TENNESSEE BOARD OF PHARMACY ON January 12, 2022

Commission SBAR Communication

Agenda Item/Title: Clarifying Question on the Utilization of Pharmacy Assistants to Replenish Automated Drug Distribution Devices (ADDDs).

Date SBAR Communication Prepared: March 14, 2022

Reviewer: Taifa “Nomi” Peaks, Pharmacist Consultant

Link to Action Plan:

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

Situation:

Pharmacy Quality Assurance Commission (commission) Staff requests the commission's guidance on pharmacy assistants and the replenishment of automated drug distribution devices (ADDDs).

Under the commission's new rules, does the replenishment of an ADDD fall under a pharmacy assistant's scope of practice? Does the act of stocking include stocking an ADDD?

Background:

For reference, language specific to the replenishment of ADDDs in the since-repealed WAC 246-874-040(2)(a)(i) only allowed a pharmacist, a pharmacy intern, or a pharmacy technician (under the supervision of a pharmacist) to perform this task. In July 2020, the new rules codified in Chapter 246-945 WAC superseded Chapter 246-874 WAC. The new rules do not distinguish if a pharmacy assistant may or may not replenish an ADDD.

RCW 18.64A.030(2) states, "'*Pharmacy assistants'" may perform, under the supervision of a licensed pharmacist, duties including, but not limited to, typing of prescription labels, filing, refiling, bookkeeping, pricing, stocking, delivery, nonprofessional phone inquiries, and documentation of third-party reimbursements and other such duties and subject to such restrictions as the commission may by rule adopt.*" Historically, the word stocking has been interpreted to refer to the act of stocking pharmacy shelves.

WAC 246-945-315(3) states, "*A pharmacist may delegate to a pharmacy assistant those functions defined in 18.64A.030 and the following: (a) Prepackage and label drugs for subsequent use in prescription dispensing operations; and (b) Count, pour, and label for individual prescriptions*." Customarily, pharmacists or pharmacy technicians retrieve the drugs that pharmacy assistants are tasked with prepackaging, counting, pouring, and labeling.

Assessment:

The potential benefits of utilizing pharmacy assistants to replenish ADDDs include personnel support for those pharmacies burdened by staffing shortages, the opportunity for assistants to gain professional aptitude and confidence, and improved productivity for high-volume pharmacies. The potential challenges include establishing the appropriate ADDD training for assistants, estimating the impact on pharmacists' duties as they supervise the ADDD replenishment, and determining if that supervision may occur remotely.

Commission SBAR Communication

While the new rules delineate tasks that may be assigned to a pharmacy assistant per a supervising pharmacist's discretion, they do not specifically address if the act of stocking encompasses the replenishment of an ADDD.

Recommendations:

Option 1: Clarify that stocking includes stocking an ADDD. Direct staff to draft FAQ clarifying the commission's interpretation of the word stocking in RCW 18.64A.030(2). Function will need to be included in commission-approved AUP. The use of an electronic verification system equipped with barcode scanning to stock an ADDD may be noted as a best practice that is subject to the discretion of the responsible pharmacy manager.

Option 2: Clarify that stocking does **not** include stocking an ADDDs. Direct staff to draft FAQ or interpretive statement clarifying the commission's interpretation of the word stocking in RCW 18.64A.030(2).

Follow-up Action:

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