March 24, 2022 PQAC

meeting packet -

Updated 3/21/2022

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
January 28, 2022 - Minutes

Convene: Chair, Teri Ferreira called the meeting to order January 28, 2022, 9:20 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, Interim Executive Director, Pharmacy Commission
Lindsay Trant, Interim Deputy Director, Pharmacy Commission
Sasha De Leon, Acting Director, OHP
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, Administrative Assistant, Pharmacy

Commission Member Absent:
Ken Kenyon, PharmD, BCPS

Guest:
Ashley Bell, Behavioral Health Programs Coordinator, Office of the Assistant Secretary

1. Call to Order Teri Ferreira, Chair.

1.1 Meeting Agenda Approval – January 28, 2022

MOTION: Ken Kenyon moved to approve the meeting agenda for January 28, 2022. Jerrie Allard, second. Motion carries, 14:0.

1.2 Meeting Minutes Approval – December 17, 2021

MOTION: Craig Ritchie moved to approve the meeting agenda for December 17, 2021. Jerrie Allard, second. Motion carries, 14:0.

2. Consent Agenda

2.1 National Precursor Log Exchange Monthly Dashboard-November

2.2 Pharmaceutical Firms Application Report

- December 02, 2021 thru January 4, 2022 – new and closed firms (None to report)

2.3 Ancillary Utilization Plans Approval

2.3.1 Northwest Medication Management Services
2.3.2 Multicare Capital Medical Center
2.3.3 Olympic Pharmacy and Healthcare Services
2.3.4 Omak Pharmacy
2.3.5 Optum Infusion Services
2.3.6 Snoqualmie Valley Hospital

MOTION: Craig Ritchie moved to approve the consent agenda removing 2.3.2 and 2.3.5. Hawkins DeFrance, second. Motion carries, 14:0.

2.4 Pharmacy Technician Training Program Approval – None

2.5 Regular Agenda/Items Pulled from 2.3. The commission will discuss items removed from the consent agenda and placed on the regular agenda for separate discussion.

2.3.2 Multicare Capital Medical Center – Tim Lynch recused.

MOTION: Craig Ritchie moved to approve 2.3.2. Hawkins DeFrance, second. Motion carries, 13:0.

2.3.5 Optum Infusion Services - Ann Wolken recused.

MOTION: Craig Ritchie moved to approve 2.3.5. Hawkins DeFrance, second. Motion carries, 13:0.

3. Old Business – The commission will discuss, for clarification or decision, ongoing topics, and issues from previous meetings.

3.1 USP 800 & 825 self-inspection worksheets.

Shelley Feldner-Schuerman led the commission through the public comments.

MOTION: Craig Ritchie moved to approve the USP 800 and 825 self-inspection worksheets with the staff edits and the agreed changes made by the commission. Hawkins DeFrance, second. Motion carries, 14:0.

3.2 Research on White Bagging Regulations in Other States.

Nomi Peaks, PQAC Pharmacist Consultant, updated the commission how other states are addressing this issue from a legislative standpoint. The consensus is patient safety, quality assurance, and a focus to reduce the cost burden on patients. Recognition of the importance of medication pedigree, certification and adherence to the Drug Supply Chain Security Act which has updates that are set to become effective in 2023.

Massachusetts and New York have specifically expressed a requirement for medication pedigree to be certified so there is not a conflict when it comes down to being able to verify where the drug originated. In some cases of white bagging there is not always a second pharmacy involved.

Tim Lynch, commissioner, expressed concern that while these are important things to consider, this issue is outside the scope of this commission.

After significant discussion, the compounding committee has been assigned to review this issue and report to the commission to consider policy or rulemaking.

3.3 Suspicious Orders Requirement in WAC 246-945-585

MOTION: William Hayes motioned that 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. Craig Ritchie, second; Motion carries, 14:0.

3.4 ESSB 5229 Health Equity Continuing Education Implementation Update

Ashley Bell informed the commission of the importance of health equity, "when all people can reach their full health potential." ESSB 5229 establishes the requirement for health care professionals to take continuing education on health equity. This is a multi-phase project with a deadline of January 1, 2023 for the secretary of professions to develop these minimum standards continuing education. The deadline for boards and commissions is January 1, 2024.

To achieve these requirements prior to the rulemaking process, there will be multiple listening sessions with individuals who experience health inequity or racism. Once the listening sessions are complete, rulemaking workshops will commence where the comments gathered will be transformed into draft language for final the rulemaking process (CR-102, public comments, etc.)

4. New Business -- The Commission will review items of interest related to pharmacy practice for discussion, clarification, information or action by or on behalf of the commission. ***Information/Action***.

4.1 FAQ on Labeling Requirement for Pre-drawn Syringes of COVID-19 Vaccine

MOTION: Tim Lynch moved to approve only FAQ #1 as presented/written by Taifa "Nomi" Peaks below; Judy Guenther, second. Motion carries, 14:0.

Q: Should a label be affixed to a pre-drawn COVID-19 vaccine syringe? If so, what information should the label include?

A: It is important to appropriately label any pre-drawn syringe to minimize the risk of administration errors and vaccine mix-ups. This includes pre-drawn syringes of the COVID-19 vaccine. A label should be affixed to a syringe so that the markings on the barrel of the syringe are not obscured and pertinent label information is easily visible and legible. In keeping with WAC 246-945-018 and per guidance from the Centers for Disease Control and Prevention (CDC) and the United States Pharmacopeia (USP), best practices for pertinent label information include:

- *The vaccine name and amount*
- *The expiration date and exact beyond-use date and time*
- *Lot number*
- *Initials of preparer(s)*

At a minimum, the label should include the information specified in WAC 246-945-018. Other rules may be applicable under certain conditions.

While the CDC notes that the safest practice is to draw up a dose of COVID-19 vaccine immediately before administration, the WA Department of Health recognizes that there are circumstances in which the use of a pre-drawn syringe is necessary. Please consult the CDC website for current beyond-use dating for COVID-19 vaccines, and for further guidance related to storing and handling pre-drawn COVID-19 vaccine syringes.

4.2 List and label request

MOTION: Tim Lynch moved staff evaluate the commission's ability to approve this request. Patrick Gallaher, second. Motion carries, 14:0.

5. Rules and Legislative Updates

5.1 2022 Legislation Update – Bill Report

Joshua Munroe, Legislative and Rules coordinator, reported on the status of the 2022 legislative session regarding legislation under the commission's jurisdiction in Washington State.

- HB 1852 / SB 5840 – Language requirements for prescription drug labels. There is quite a bit of momentum on this bill. PQAC supports the goals of the bill but expresses concerns due to the aggressive start date of January 2023.

- SB 5507 / SHB 1675 – Dialysate and dialysis devices – amends a few RCWs to include additional entities related to dialysis programs and treatment. The substitute bill changed verbiage to grant the commission rulemaking authority, addressing an expressed concern that oversight authority might be removed in the original version of the bill manufacturers and wholesalers are still required to have manufacturer or wholesaler licenses.

- SSB 5546 – Insulin affordability. This amends RCW 70.14.160 reducing the 30-day insurance copay cap for insulin from $100 to $35. This has been moved on to Ways and Means.

- HB 1728 – Insulin affordability – Workgroup funding and report deadline. Focus on the workgroup and extend deadline to provide preliminary reports. Due to COVID the workgroup was unable to meet.

- SB 5547 / HB 1668 – Expanding regulatory authority over cannabinoids This bill adjusts the regulatory oversight on certain cannabinoid substances. The substitute bill adds distinctions on artificial and synthetic cannabinoids.

- SB 5767 – Regulating hemp-derived cannabinoids. No significant movement made on this bill as focus is more on SB 1668.

- SSB 5753 – Enhancing the capacity of health profession boards, commissions.

- SB 5660 – Establishment of psilocybin board for behavioral wellness.

- SB 5743 – Designating kratom as a controlled substance; not much momentum.

- SB 5941 – The Washington Kratom Consumer Protection Act – establishes a board similar to the psilocybin board to create a regulatory structure. There are a number of concerns regarding the stated effect of the bill.

- HB 1863 – Authorizing prescriptive authority of psychologist – no follow up discussion or hearings.

5.2 Medication Assistance Emergency rules reauthorize

MOTION: Craig Ritchie moved to reauthorize the medication assistance emergency rules. Tim Lynch, second. Motion carries, 14:0.

5.3 Rules Petition on Translated Directions of Rx Labels

WSPA petitioned PQAC to adopt a new rule to make translations of prescription medication directions on the label available to ambulatory or community-based patients. Also, "to reduce medication errors and increase adherence in patients with limited English proficiency in a safe and implementable way" WSPA requests to amend WAC 246-945-417 to include a new section stating, "pharmacy outpatient dispensing systems must have the ability to translate prescription medication directions by July 1, 2025." Response must be delivered no later than March 14, 2022.

Jenny Arnold, WSPA, addressed the commission: We felt this is probably where we need to go as a pharmacy profession to better serve patients. However, if the legislation is overly detailed, it is difficult to implement in a meaningful way in pharmacies. WSPA believes PQAC is integral in implementing this safely.

MOTION: Craig Ritchie moved to approve the WSPA petition filed on January 13, 2022 for rules related to translation prescription descriptions. William Hayes, second. Motion carries, 14:0.

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

Non-resident compounding pharmacies doing business in Washington State

Erika Anderson, Virginia Mason Franciscan Health, addressed the commission with a question regarding the directive for non-resident pharmacies and a list of inspection programs. In the latest revised directive under "approved inspection programs for non-resident pharmacies which do not engage in compounding" (four states), how do individuals verify if a pharmacy within one of these four states has either attested they do not compound or if they submitted an inspection report to the commission by an approved inspection program which would then allow them to send compounded products into our state? Is there an indicator on the non-resident pharmacy license that says "attested they do not engage compounding" or if they are one of these four states, they have submitted an inspection report from a commission approved inspection program? How do we find that out?

Commission response:

The commission/staff responded: There is no indicator on a non-resident pharmacy license to indicate if they are licensed to ship compounded drugs into Washington State. If an individual wanted to verify if a nonresident pharmacy could ship compounded drugs into Washington State they could make a public records request. If an individual believes a nonresident pharmacy is inappropriately shipping compounded drugs into Washington State then they could make a complaint.

The commission directed staff to investigate whether there is a way to operationalize (i.e., a list or website) or a way to make it easier for licensees to obtain the information and bring this back to the next meeting.

Routine Inspections / License/credentialling waiting period

Jenny Arnold, pharmacist, addressed the recent PQAC announcement / reminder about appropriate staffing. Pharmacies are in crisis right now, especially (but not only) community pharmacies. They are trying to staff but with COVID, it's tough to just keep medications flowing. In addition, our community pharmacies have given 42% of the COVID vaccinees in our state to date.

Due to the inundated pharmacies/pharmacists, she suggested pausing inspections again, because the pharmacies just do not have the time to go into an appropriate inspection or give the time for a good inspection at this point. No one wants to be judged by their worst day; and we are in some challenging days right now.

Secondly, she asked the commission to do something about the long turn-around time on licensing.

Lastly, she gave a heartfelt thank you to the pharmacy professionals out there every day serving patients.

Commission response:

The discussion regarding pausing inspections centered around finding a middle-ground, including whether the inspector could contact the pharmacy within a week (or so) to schedule the inspection. The pharmacy/pharmacist would then have time to adequately staff for the inspection. However, this issue would be better served at a special meeting or the next business meeting so PQAC inspectors/staff could gather information.

MOTION: Tim Lynch made a motion to 1) allow for scheduling routine inspections within a two-week time frame of first contact by the inspector and 2) the commission engage in further conversation about what we need to do long-term by the next meeting or special meeting and to consider precise steps needed related to routine inspections. Judy Guenther, second. Yay: 13; Nay, 1.

7. Commission Member Reports.

7.1 Commissioner Reports

7.1.1 Recognition of Service

The commission recognized the following for their service. Both will continue to serve until the positions can be filled, but their official term is completed.

- Tim Lynch – has served eight years on the commission as a member and chair. Also, Teri thanked Tim for being a mentor as former chair. Jerrie thanked Tim for staying on during this transition. Hawkins also thanked Tim for the newer commissioners, he has been a great source of information, setting a high bar for the rest of us. Marlee, thanked Tim for his support and guidance and taking all the phone calls. Helen Jung thanked Tim and mentioned she see the big part he played in this group of leaders. Tim is great role model and example for all of us.

  Tim replied: thank you all. I have learned so much being a part of the commission and working with amazing people It has been an honor and privilege.

- Bonnie Bush – has served three years. Teri stated she really appreciated Bonnie's patient advocacy approach and that you asked important questions.

  Bonnie stated it had been a pleasure and she had enjoyed working with the commission and phenomenal people. My only regret is not able to do it in person. Tim responded: I really appreciate Bonni the lens she brought to the work that we do.

7.2 Commissioners' open discussion related to items or issues relevant to commission business/pharmacy practice.

Tim Lynch recognized that we have the recent passing of Tim Fuller. Tim was a long-time supporter of the commission. On behalf of the commission, we are saddened by his loss. He was an incredible part of the commission and part of the pharmacy profession. Express the commission's thoughts and prayers for his family.

8. Staff Reports

8.1 Interim Executive Director – Marlee O'Neill

8.1.1 DOH Staff Farewell and Recognition

- Kirby Putscher, the commission's case manager, is celebrating 45 years of state service.
- Luke Park, staff attorney, will not be returning to the department after completing paternity leave.
- Project Pharmacy Inspector positions – on-going interviews.
- Pharmacy Inspector Supervisor position – interviews commencing soon.
- Pharmacy Inspector Stan Moore is retiring in February. Stan has served as both investigator and inspector with the department for ten years. His colleagues note his kindness, generosity, and great stories. He has unfailing dedication to pharmacy in the state of Washington.

8.2 Interim Deputy Director – Lindsay Trant

8.2.1 PREP Act Authorization for Oral Anti-virals

- Secretary Shah signed PREP Act Authorization on January 4, permitting hospitals to distribute the full course of antiviral drug authorized for the treatment of COVID-19.

8.2.2 Clarification on CE Rule

- The two-year renewal cycle went into effect with the new CE rules on December 1, 2021. Implementation is on-going. The commission voted to repeal the old CE rules. While we will need to repeal the old CE rules, the effective date will be December 1, 2022. Both sets of CE rules will need to be in place for a short time.

- The commission repealed guidance documents no longer needed at the December 17, 2021 meeting. DOH 690-346 states that CE credits will be applied for attending commission meetings. Licensees will no longer be able to earn CE for attending commission meetings.

8.3 Interim OHP Office Director – Sasha De Leon

Reported the search for PQAC's executive director and deputy director is on-going. This is a priority for OHP to fill these positions with quality candidates as soon as possible.

8.4 Assistant Attorney General – Chris Gerard

The lawsuit John Worthington filed against the commission, as well as Governor Jay Inslee and the Washington State Department of Health (Case No. 21-2-01099-34), was dismissed without prejudice in Thurston County Superior Court in November 2021.

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

- 1. Meeting Minutes Approval – December 17, 2021 post approved minutes to website (also we need to archive past meetings).
- 2.3 Ancillary Utilization Plans Approved all -staff will notify credentialing.
- 3.1 Finalize revision of the worksheets and post to website and send GovDelivery with guidance from the commission in accordance with policy statement #65.2.
- 3.2 Schedule meeting with compounding subcommittee to craft language to report back to the commission.
- 3.3 Suspicious order rule- Option one Schedule meeting with the Facilities Subcommittee to discuss potential solutions and bring options back to the full commission.
- 4.1 Staff will post FAQ #1 and distribute though GovDelivery without revisions and FAQ submitted to web team.
- 4.2 Staff will gather information on alternate options for list and label request.
- 5.2 Staff to refile emergency rules Medication Assistance.
- 5.3 Approve rules petition. The commission staff will work on draft of official response will provide by March 14, 2022 (or sooner).
- 6. Have staff look into ways to confirm that a non-resident pharmacy is permitted to compound medications. Report back on options.
- 6. Gather information from inspectors to bring back to next meeting regarding routine inspections.

Business Meeting Adjourned. 4:40 p.m.

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

PO Box 47890 • Olympia, Washington 98504-7890

Tel: (360) 236-4501 • FAX: (360) 586-7424 • TDD Relay Service: 1-800-833-6388

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

3.4 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

Commission SBAR Communication

Agenda Item/Title: Routine Inspections and Insufficient Staffing

Date SBAR Communication Prepared: March 17, 2022

Reviewer: Marlee O'Neill

Link to Action Plan:

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

Situation: As a result of the COVID-19 pandemic, many pharmacies in the state of Washington are navigating formidable workloads with limited staffing. During the January 2022 business meeting, the commission recognized that many Washington pharmacies are operating at crisis standards of care. To mitigate the impact of insufficient staffing on pharmacy personnel, the commission gave the option for pharmacy licensees to reschedule on-site routine inspections within a two-week timeframe in the event of a staffing shortage or workload challenges. The commission requested feedback from the pharmacist inspectors regarding this option's potential benefits, challenges, and feasibility.

Background: The pharmacy inspectors resumed on-site routine pharmacy inspections on approximately November 1, 2021. Historically, routine retail inspections have always been unannounced. There was a period of time where routine hospital inspections were announced, but this is no longer standard practice. Currently, the commission sends letters to pharmacies informing them that they are due for a routine inspection within six months. The pharmacies may provide blackout dates to the pharmacist inspectors within 10 days of receiving the six-month letter. The provision of blackout dates differs from the two-week rescheduling option discussed during the January 2022 Business Meeting. The two-week rescheduling option allows a pharmacy to inform a pharmacist inspector on the day of the routine inspection that it cannot proceed due to insufficient staffing. The pharmacy and inspector would then be responsible for rescheduling an inspection to take place within two weeks when the pharmacy anticipates adequate personnel will be present. The pharmacist inspector also has the option, without the pharmacy requesting it, to reschedule a routine inspection upon arrival at a pharmacy that is understaffed.

Commission SBAR Communication

Assessment:

Pros	Cons
• It may be highly beneficial for pharmacies that rely primarily on locums staffing to have an opportunity to schedule an inspection date that corresponds to a day when permanent staff members are available. • The opportunity for pharmacies to reschedule may be a tangible way to support pharmacists struggling with burnout and fatigue due to understaffing. • This option promotes a collaborative dialogue between pharmacies and pharmacist inspectors about insufficient staffing concerns.	• It creates a burden for inspectors who often travel considerable distances to various pharmacy locations. • The logistics of rescheduling could potentially become burdensome for both the inspectors and the pharmacies, leading to a decrease in productivity. Inspectors are balancing routine inspections with closure, new, remodel etc. inspections. • The delay in an inspection, even for two weeks, may mean a delay in identifying a critical issue that could jeopardize patient safety.

Recommendation:

Option 1 - Continue the 2-week re-scheduling window: During this time of unprecedented staffing shortages, the inspectors will continue to have an open dialogue with licensees. To help with this, if a pharmacy requests or an inspector feels it necessary, they can reschedule a routine inspection within two weeks due to staffing issues or other exceptional circumstances. The inspectors will also take into account their own workload and travel time. The pharmacy must make an effort to have adequate staffing on the reschedule date and communicate that desired date clearly with the pharmacist inspector. The commission will revisit this decision at its May 2022 meeting.

Option 2 - Return to standard practice: Inspectors have always had and utilized their discretion to reschedule routine inspections. Inspectors have rescheduled routine inspections due to staffing issues, pharmacy upgrading its software system, DEA inspectors being onsite, burst pipe, etc. The inspectors will continue to utilize their discretion and have an open dialogue with licensees when exceptional circumstances arise.

Follow-up Action:

PQAC inspectors and staff will proceed as directed by the commission.

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.