March 2, 2023

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
January 12, 2023 - Minutes

Convene: Chair, Teri Ferreira called the meeting to order January 12, 2023, 9:05 AM.

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

Staff:
Marlee O'Neill, Executive Director
Lindsay Trant-Sinclair, Deputy Director
Sierra McWilliams, AAG
Christopher Gerard, AAG
Irina Tiginyanu, Pharmacy Technician Consultant
Hope Kilbourne, Policy Analyst
Joshua Munroe, Legislative and Rules Consultant
Taifa "Nomi" Peaks, Pharmacist Consultant
Haleigh Mauldin, Program Consultant
Amy L Robertson, Communications Coordinator and Program Support
Desiré Gudmundson, Administrative Assistant

Commission Members Absent:
Bonnie Bush, Public Member

1. Call to Order Terri Ferreira, Chair.

1.1 Meeting Agenda Approval – January 12, 2023.

MOTION: Craig Ritchie moved to approve the business meeting agenda for January 12, 2023. Jerrie Allard, second. Motion carries, 12:0.

1.2 Meeting Minutes Approval – November 17, 2022.

MOTION: Craig Ritchie moved to approve the meeting minutes for November 17, 2022. Jerrie Allard, second. Motion carries, 12:0.

2. Consent Agenda.

2.1 Ancillary Utilization Plans Approval.
- **2.1.1** Albertson's Central Fill
- **2.1.2** Biocompound LLC
- **2.1.3** Geneva Woods
- **2.1.4** Moses Lake Professional Pharmacy
- **2.1.5** Omnicare of Seattle

2.1.6 Peace Health Locations
2.1.7 UWMC NW OPMC

2.2 Pharmacy Technician Training Program Approval.

2.2.1 Arlington Pharmacy
2.2.2 Fred Meyer Pharmacy
2.2.3 Valley Pharmacy
2.2.4 West Pasco Pharmacy
2.2.5 Whidbey Health Medical Center
2.2.6 Yakima Valley Farmworker
2.2.7 Saars Pharmacy

MOTION: Hawkins DeFrance moved to approve 2.1 and 2.2 with the exception of 2.1.1, 2.1.3, 2.2.1, 2.2.4, 2.2.6. Craig Ritchie, second. Motion carries, 12:0.

2.3 Regular Agenda/Items Pulled from 2.1 and 2.2.

Items pulled:

- 2.1.1 Albertson's Central Fill
- 2.1.3 Geneva Woods
- 2.2.1 Arlington Pharmacy
- 2.2.4 West Pasco Pharmacy
- 2.2.6 Yakima Valley Farmworker

MOTION: William Hayes moved to approve AUP 2.1.1 Albertson's Central Fill contingent upon the cooperationg adding appendix A and updating licensing to every two years. Hawkins DeFrance, second. Motion carries, 12:0.

MOTION: Teri Ferreira moved to approve AUP 2.1.3 Geneva Woods contingent upon updating language on administrative technician not included in ratio. Hawkins DeFrance, second. Motion carries, 12:0.

MOTION: William Hayes moved to approve 2.2.1 Arlington Pharmacy Technician Training Program contingent upon the pharmacy providing the requested information regarding trainee accreditation, program length requirements, exam score requirements, notification of changes to the program, and student record retention as outlined in the staff recommendation.The pharmacy must also ensure thetechnician immunization language is consistent with the commission's guidance document on technicians administering vaccinations. Craig Ritchie, second. Motion carries, 12:0.

MOTION: Hawkins DeFrance moved to approve 2.2.4. Technician Training Program contingent upon the pharmacy providing the requested information regarding trainee accreditation, exam score requirements, notification of changes to the program and student record retention as outlined in the staff recommendation.. Craig Ritchie, second. Motion carries, 12:0.

MOTION: Hawkins DeFrance moved to approve 2.2.6 Yakima Valley Farmworker Technician Training Program contingent upon the pharmacy providing the requested information regarding

trainee accreditation, notification of changes to the program and student record retention as outlined in the staff recommendation.. Craig Ritchie, second. Motion carries, 12:0.

3. Old Business.

3.1 2023 Self-Inspection Worksheets Review.

3.1.1 Pharmacy Self-Inspection Worksheet.

MOTION: Craig Ritchie moved to approve changes to general pharmacy self-inspection worksheet . Hawkins DeFrance, second. Motion carries, 12:0.

3.1.2 Hospital Self-Inspection Worksheet.

MOTION: Hawkins DeFrance moved to approve changes to the hospital self-inspection worksheet. Craig Ritchie, second. Motion carries, 12:0.

3.1.3 Health Care Entity Self-Inspection Worksheet.

MOTION: Hawkins DeFrance moved to approve changes to health care entity self-inspection worksheet. Craig Ritchie, second. Motion carries, 12:0.

3.1.4 Manufacturer Self-Inspection Worksheet.

MOTION: Hawkins DeFrance moved to approve changes to manufacturer self-inspection worksheet. Craig Ritchie, second. Motion carries, 12:0.

3.1.5 Wholesaler Self-Inspection Worksheet.

MOTION: Hawkins DeFrance moved to approve changes to wholesaler self-inspection worksheet. Craig Ritchie, second. Motion carries, 12:0.

3.1.6 Long-Term Care Self-Inspection Worksheet.

MOTION: Hawkins DeFrance moved to approve changes to long-term care self-inspection worksheet. Craig Ritchie, second. Motion carries, 12:0.

3.1.7 USP 795 Nonsterile Compounding Addendum.

MOTION: Hawkins DeFrance moved to approve USP 795 nonsterile compounding addendum with changes and to bring the commission's guidance document #61 (United States Pharmacopeia General Chapter <795> - Nonsertile Compounding – Information) to a future meeting for possible recision. Craig Ritchie, second. Motion carries, 12:0.

3.1.8 USP 797 Sterile Compounding Addendum.

MOTION: Hawkins DeFrance moved to approve USP 797 sterile compounding addendum with the changes addressed and retaining the 800 early adopter language. Craig Ritchie, second. Motion carries 12:0.

3.1.9 USP 825 Radiopharmaceuticals Self-Inspection Worksheet.

MOTION: Hawkins DeFrance moved to approve changes to USP 825 radiopharmaceuticals self-inspection worksheet. Craig Ritchie, second. Motion carries, 12:0.

3.1.10 USP 800 Hazardous Drugs Self-Inspection Worksheet.

MOTION: Hawkins DeFrance moved to approve changes to USP 800 hazardous drugs self-inspection worksheet. Craig Ritchie, second. Motion carries, 12:0.

4. New Business.

4.1 Health Care Entity (HCE) FAQ.

Marlee O'Neill: With the commission's rules re-write, one organization occupying multiple suites in one facility is deemed to be occupying one location requiring only one Health Care Entity (HCE) license as opposed to a separate HCE license for each suite under the old rules. As a result, the commission has received an increase in inquiries related to HCEs that program staff are working to address in an FAQ.

5. Panel Review- Study Plan (Panel B)

MOTION: Jerrie Allard moved to delegate item 5.1 Study Plan to Panel B – Hawkins DeFrance, Craig Ritchie, Timothy Lynch and Matthew Ray. Judy Guenther, second. Motion carries, 12:0.

5.1 PHRM.PH.61181493

MOTION: Hawkins DeFrance moved to approve Study Plan. Timothy Lynch, second. Motion carries, 4:0.

6. Rules and Legislative Updates.

6.1 Authorize CR-103P for HIV/AIDS Education Requirement Repeal (ESHB 1551).

MOTION: Craig Ritchie moved to adopt the rule language and approve filing the CR-103P to repeal the AIDS education and training requirement removed under ESHB 1551. Jerrie Allard, second. Motion carries, 12:0.

6.2 Authorize CR-105 for Incorporation by References Updates.

WAC sections in need of an update:

- WAC 246-945-010

- WAC 246-945-013
- WAC 246-945-030
- WAC 246-945-075
- WAC 246-945-550
- WAC 246-945-565

MOTION: Craig Ritchie moved to authorize staff to file the CR-105 to update the identified incorporations by reference. Hawkins DeFrance, second. Motion carries, 12:0.

6.3 Reauthorize CR-105 for Technical Edits in Chapter 246-945 WAC.

MOTION: Craig Ritchie moved to approve additional technical edits to the previously authorized CR-105 package for chapter 246-945 WAC. Jerrie Allard, second. Motion carries, 12:0.

MOTION: Craig Ritchie moved to direct staff, with legal assistance, to evaluate possible rulemaking pathways to amend WAC 246-945-355, including whether to amend "and" in the last sentence to "or needed" drug therapies. Matthew Ray second. Motion carries, 12:0.

6.4 Refile Request: CR-130E for Prescribing CIIs During COVID.

MOTION: Craig Ritchie moved to authorize the re-filing of an emergency rule CR-103E on prescribing Schedule II (CII) medications during the COVID pandemic. Hawkins DeFrance, second. Motion carries, 12:0.

6.5 Refile Request: CR-103E for Medication Assistance.

MOTION: Craig Ritchie moved to authorize the re-filing of CR-103 E and define that an emergency exists for public health. Hawkins DeFrance, second. Motion carries, 12:0.

6.6 Uniform Facility Enforcement Framework (UFEF) Update.

Marlee O'Neill provided the commission with an update on the UFEF.

6.7 Guiding Questions for Health Equity Continuing Education Rulemaking (ESSB 5229).

Commission staff filed a CR-101 statement of inquiry for health equity continuing education requirements on December 19, 2022. Health equity CE requirements were established in statute by ESSB 5229 in 2021 and the Department filed model rules in late 2022.

MOTION: Timothy Lynch moved to include a minimum of one hour health equity continuing education (CE) in the current required 30 hours by pharmacists and 20 hours by technicians that is due every two years. The CE can be ACPE accredited or approved by the Department of Health. Craig Ritchie, second. Motion carries, 12:0.

7. Summary of Meeting Action Items.

- **2.** Consent Agenda – Follow up with approvals and get information needed for contingent approvals.
- **3.1** Post all self-inspection worksheets with the edits reviewed today in both Word and PDF form.
    - Bring back policy statement 61 on USP 795 in March.
    - Bring back statement on early adoption of USP 800 on USP 797 self-inspection worksheet in March.
    - Bring USP 800 self-inspection worksheet to Compounding Subcommittee who will review if and how the commission regulates the administration of hazardous drugs.
    - Bring back technician administration guidelines to future commission meeting.
    - Send out GovDelivery directing folks how to submit questions to staff for the HCE FAQs.
- **5.1** Notify credentialing of approved study plan.
- **6.1** File CR-103P to repeal AIDS training and education requirements following ESHB 1551.
- **6.2** Bring back amendments to rules identified today in need of an update to incorporations by reference to the commission at a future meeting before filing the CR-105.
- **6.3** Bring amendments to WACs identified today in need of a technical fix for the commission to review before filing the CR-105. Staff will also conduct a legal analysis to determine which rulemaking options are available to address the various suggested changes to WAC 246-945-355 discussed. This will include an analysis of emergency, expedited, and standard rulemaking potential pathways.
- **6.4** Re-file emergency rules on prescribing schedule II drugs during the COVID pandemic.
- **6.5** Re-file the emergency rules on medication assistance in in-home and community-based care setting.
- **6.7** Begin drafting rule language on health equity CE with guidance from commission today to prepare for future rules workshop.

Business Meeting Adjourned

Teri Ferreira, Chair, called the meeting adjourned at 2:23 PM.

STATE OF WASHINGTON
Pharmacy Quality Assurance Commission
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Pharmacy Quality Assurance Commission Meeting
January 13, 2023 - Minutes

Convene: Chair, Teri Ferreira called the meeting to order January 13, 2023, 9:06 AM.

Commission Members:
Teri Ferreira, RPh, Chair
Jerrie Allard, Public Member, Vice Chair
Uyen Thorstensen, CPhT
Hawkins DeFrance, Nuclear Pharmacist
Craig Ritchie, RPh, JD
Patrick Gallaher, BS, BPharm, MBA, MPH
Bonnie Bush, Public Member
Judy Guenther, Public Member
Timothy Lynch, PharmD, MS, FABC, FASHP (joined at 12:00 P.M.)
Matthew Ray, PharmD
Ken Kenyon, PharmD, BCPS
Ann Wolken, PharmD, RPh
William Hayes, PharmD CCHP

Staff:
Traci Orr, OHP Director
Marlee O'Neill, Executive Director
Lindsay Trant-Sinclair, Deputy Director
Christopher Gerard, AAG
Irina Tiginyanu, Pharmacy Technician Consultant
Hope Kilbourne, Policy Analyst
Joshua Munroe, Legislative and Rules Consultant
Taifa "Nomi" Peaks, Pharmacist Consultant
Haleigh Mauldin, Program Consultant
Amy L Robertson, Communications Coordinator and Program Support
Desiré Gudmundson, Administrative Assistant

1. Call to Order Terri Ferreira, Chair.

1.1 Meeting Agenda Approval – January 13, 2023.

MOTION: Craig Ritchie moved to approve the business meeting agenda with revisions for January 13, 2023. Bonnie Bush, second. Motion carries, 12:0.

2. New Business.

2.1 Gates Healthcare Associates.

Dan Parisi and Denise Frank of Gates Healthcare Associates presented their inspection program for nonresident pharmacies to the commission. Gates requested approval as defined in RCW 18.64.360(1)(b)(i).

MOTION: Hawkins DeFrance moved to approve Gates Healthcare Associates as an approved inspection program for nonresident pharmacies. Craig Ritchie, second. Motion carries, 12:0.

2.2 Panel Review- Study Plan (Panel A).

MOTION: Hawkins DeFrance moved to delegate item 4.1 Study Plan to Panel A – Teri Ferreira, Patrick Gallaher and Judy Guenther. Craig Ritchie, second. Motion carries, 12:0.

2.2.1 PHRM.PH.61313480

MOTION: Patrick Gallaher moved to approve study plan. Teri Ferreira, second. Motion carries, 3:0.

3. Rules and Legislative Updates.

3.1 2023 Legislative Session Bill Report.

The 2023 Legislative Session began on January 9 and commission staff are tracking numerous bills that merit the commission's attention. Joshua Munroe, Legislative and Rules Consultant, provided a report focusing on the bills most relevant to commission business. The following bills were discussed:

- HB 1041 – Prescriptive authority of Psychologists
- SB 5120 – 23-hour crisis receiving centers
- HB 1009 – Military spouse employment
- SB 5263 – Psilocybin services
- SB 5271 – Uniform Facilities Enforcement Framework

3.2 Outline Draft Review for Accessible Label Rulemaking.

Joshua Munroe presented a brief background of the current stage of the rulemaking and an overview of public comments received.

The commission reviewed the draft outline, section by section, taking feedback from commissioners and stakeholders that staff will use to inform the first draft of the rule. This draft will be presented and the March commission meeting.

Staff will draft rule language and hold a rules workshop at the March business meeting. Staff will also conduct an analysis of Title VI obligations and present at the March meeting.

4. Open Forum. No comments presented.

5. Commission Member Reports.

5.1 Compounding Subcommittee.

The compounding subcommittee has been engaged in stakeholdering regarding the directive, *Nonresident Pharmacy: Approved List of Recognized States*. It has sought to examine currently approved, recognized states (18 total) to determine if they have substantially equivalent compounding standards to those of Washington State and provide feedback to pharmacy commission staff. Ten of the states were discussed at the December 13 meeting, with the remaining eight to be discussed on February 23. A few states' standards warranted additional research and inquiry. PQAC program staff will research and bring back to the subcommittee for review in February.

5.2 Budget Subcommittee.

The budget subcommittee met on December 22. A drop in revenue is expected next year as there will be substantially less renewals for personnel due to the transition to the 2-year renewal cycle. Increased costs in AAG support and WRAPP are currently being reviewed by staff. The commission is also adding staff to both the program and inspection teams. The commission retains a reserve of 15% of annual expenditures (largely as an emergency fund). Most other programs calculate a 15% of biennial expenditures reserve. The department has asked that the commission consider using a reserve of 15% of biennial expenditures, which would increase the total reserve funds available.

MOTION: Craig Ritchie moves to increase reserve 15% of biennial expenditure. William Hayes, second. Motion carries, 13:0.

5.3 Stategic Planning Subcommittee.

A strategic planning session will be held at the commission's May business meeting. Staff will solicit feedback from commissioner's about what priorities should be included in the strategic plan. Stakeholder input will be requested at the May meeting as well.

5.4 Open Discussion Relevant to Commission Business/Pharmacy Practice.

Ann Wolken, commissioner, suggested sending out an FAQ about the update from SAMHSA on the removal of x-waiver to prescribe buprenorphine for the treatment of opioid use disorder (OUD). Staff agreed and will send out a GovDelivery regarding the update.

6. Staff Reports.

6.1 Executive Director – Marlee O'Neill.

At the November meeting, the commission asked staff to reach out to the Medical Commission and Nursing Commission regarding IV and Hydration therapy. Connections have been made with the medical and nursing commissions about this issue. The Unlicensed Practice Program has also been contacted.

6.2 Deputy Director – Lindsay Trant-Sinclair.

The pharmacist recruitment packet is still with the Govenor's office. The public member packet will be sent to the Govenor's office soon. The reappointment packet is nearly finalized for William Hayes, Bonnie Bush, and Craig Ritchie.

6.3 Pharmacist Consultant – Nomi Peaks.

Throughout the last year, Nomi Peaks has been involved with the Sexually Transmitted Infection (STI) and Hepatitis B (HBV) Legislative Advisory Group, and the Pandemic After Action Report (AAR) Task Force as a representatitive of the Pharmacy Commission program staff. The final meetings for the STI and HBV group was in November of 2022, and the final report is currently being reviewed by members of the State Legislature. The AAR will continue meeting throughout the Summer of 2023.

6.4. Assistant Attorney General – Christopher Gerard. Nothing to report.

7. Summary of Meeting Action Items.

- 2.1 – Add Gates Healthcare to the nonresident pharmacy directive as an approved inspection report for nonresident pharmacies.
- 2.2 – Communicate study plan approval to credentialing.
- 3.1 – Staff took several notes of concerns and feedback on the bills presented today and will provide that feedback to the relevant programs at the Department.
    - If needed: staff will communicate the need for an amendment to the Legend Drug Act for the prescribing psychologist bill to the psychology program.
    - Staff will also reach out to the Oregon BOP to see what their involvement has been with psilocybin becoming legal in Oregon.
    - Staff will provide feedback on the athletic trainer bill to the athletic training program at DOH.
- 3.2 – Draft rule language and hold rules workshop at March business meeting. Conduct analysis of Title VI obligations and present finding at March meeting.
- 5.2 – Staff report back to the budget team to change the reserve amount to 15% of biennial expenditures rather than annual expenditures.
- 5.4 – Send out GovDelivery on update from SAMHSA on the removal of x-waiver to prescribe buprenorphine for the treatment of opioid use disorder (OUD).
- 6.1 – Continue to send out GovDeliveries about the Rx Fraud Alert on the commission's website.

Business Meeting Adjourned

Teri Ferreira, Chair, adjourned at 2:25 PM.

Commission SBAR Communication

Agenda Item/Title: USP Compliance Expectations

Date SBAR Communication Prepared: 02/23/2023

Reviewer: T. Nomi Peaks

Link to Action Plan:

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

Situation:

The Pharmacy Commission (commission) has received a number of inquiries asking when licensees will be expected to comply with the revised USP General Chapters <795> and <797>.

Background:

As a reminder, 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."

The United States Pharmacopeia (USP) announced in November 2022 that it had published the final versions of General Chapters <795> and <797>. These are updated nonsterile and sterile compounding standards, which are frequently referred to as the "**revised <795> and <797>.**" These updated chapters are scheduled to become official on November 1, 2023.

The currently official versions of USP <795> and <797>, which were last revised in 2014 and 2008, respectively, are enforced by the commission per RCW 18.64.270 and WAC 246-945-100. The currently official versions of <795> and <797> do not reference USP General Chapter <800> Hazardous Drugs-Handling in Healthcare Settings.

The updated standards *do* directly reference USP <800>, and once they become official, USP <800> will become compendially applicable.

As a reminder, the Pharmacy Commission announced in September 2022 that its enforcement discretion related to USP <800>, due to its conflicts with the current USP <797>, will continue until it is officially withdrawn during an open public meeting.

The commission can consider the compliance expectations on the revised <795> and <797>.

Assessment/Consideration of Options:

The commission has several options to consider: early adoption (before 11/1/2023), enforcement on the effective date (11/1/2023), or delayed enforcement (after 11/1/2023). The commission did allow for early adoption of USP <800> due to the chapter's conflicts with the current USP <797>, which is described in the commission policy #60.1 on the *Regulation of the Handling of Hazardous Drugs.* However, early adoption of the revised <795> and <797> could be more challenging to implement, and the revised chapters are still subject to change by USP. To allow licensees sufficient time to come into compliance, staff recommend waiting to enforce the revised <795> and <797> until November 1, 2023, and extending enforcement discretion for a defined period of time following that date.

Recommendation:

1. Staff recommend that the commission consider enforcing the **revised** USP General Chapters <795> and <797> on the date they are expected to become official, which is November 1, 2023.
2. The commission can also consider extending enforcement discretion for a specified period of time following November 1, 2023 to allow licensees time to come into compliance with the new chapters.

Follow-up Action: The PQAC team will proceed as directed and communicate the commission's position on this matter via GovDelivery and the Pharmacy Commission's website.

Department of Health
Pharmacy Quality Assurance Commission

Policy Statement

Revised – 12/05/22

Title:	Enforcement of USP Chapters <800> and <825> *Number: 65.4*
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:	Marlee B. O'Neill, Executive Director
Phone:	(360) 236-4946
Email:	wspqac@doh.wa.gov
Effective Date:	October 1, 2022
Supersedes:	Policy 65.3 effective April 1, 2022
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).

During the March 24, 2022, business meeting, the commission voted to continue its position that it will not find deficiencies or take enforcement action against licensees for failure to comply with USP 800 through September 30, 2022. At the September 23, 2022, business meeting, the commission voted to extend its enforcement discretion of USP 800 until it is withdrawn by the commission at an open public meeting.

Compliance requirements for USP 825 began October 1, 2021, where applicable, per WAC 246-945-100 and RCW 18.64.270(2).

The revised USP chapters <795> (USP 795) and <797> (USP 797) will not be official until November 1, 2023. The commission will consider its use of enforcement discretion for USP 800 during this time. Any decision to modify the commission's use of enforcement discretion for USP 800 will be made during an open public meeting.

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 created some direct conflicts between the two chapters. 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' (L&I) 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 – TBA
USP 825	October 1, 2020 – September 30, 2021
Revised USP 795 and 797	Revised chapters were released on November 1, 2022 but are not official until November 1, 2023. Any decision(s) related to the revised chapters will be made at an open public meeting.
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 L&I'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. The commission also recognizes that the revised USP 795 and 797 are available, but not official until November 1, 2023. Any decisions related to the enforcement discretion of USP 800 will be made at an open public meeting.

Pharmacy Quality Assurance Commission
GUIDANCE DOCUMENT

Title:	United States Pharmacopeia General Chapter <795> - Nonsterile Compounding – Information	**Number:**	61
Reference:	RCW 18.64.270(2); USP Chapter <795>		
Contact:	Lauren Lyles-Stolz, PharmD., Executive Director		
Effective Date:	June 8, 2018 (reaffirm Aug 28, 2020)		
Supersedes:	N/A		
Approved:	Tim Lynch, PharmD, MS, FABC, FASHP Chair, Pharmacy Quality Assurance Commission		

According to the United States Pharmacopeia:

> USP General Chapter <795> provides standards for compounding quality nonsterile preparations. The chapter describes requirements for the compounding process, facilities, equipment, components, documentation, quality controls and training. General Chapter <795> also provides general guidelines for assigning beyond-use dates to nonsterile preparations.
>
> USP General Chapter <795> Pharmaceutical Compounding – Nonsterile Preparations

In 2013, United States Pharmacopeia General Chapter <795> (USP 795) was incorporated into Washington law (RCW 18.64.270(2)). This statutory provision requires full compliance with USP 795 when individuals and facilities licensed by the Pharmacy Quality Assurance Commission (Commission) are compounding nonsterile products, regardless of practice setting.

The exact requirements USP 795 places on licensees depends on the type of nonsterile compounding conducted at the facility. Relevant factors influencing USP requirements include, but are not limited to: (i) whether the facility compounds nonsterile products for animals, (ii) whether the facility compounds hazardous drugs, and (iii) whether the facility compounds nonsterile products according to a manufacturer's labeling instructions.

The following hypotheticals illustrate the impact of the factors listed above on applicable USP 795 requirements. Attached to this e-mail is the most recent copy of the USP self-inspection worksheet that has *not* been approved by the Commission. It currently contains sixty-three (63) questions.

Hypothetical#1: A pharmacy only compounds nonhazardous nonsterile products according to a manufacturer's labeling instructions for human patients (also does not compound sterile products). This pharmacy would be able to mark N/A to the following questions in the USP 795 self-inspection worksheet:

- Training and Training Procedures: 4
- Compounding Facilities: 20, 27, 28, 29
- Compounding Documentation: 56
- Compounding for Animal Patients: 59, 60, 61, 62, and 63.

Hypothetical#2: A pharmacy only compounds nonhazardous nonsterile products for human patients (also does not compound sterile products). This pharmacy would be able to mark N/A to the following questions in the self-inspection worksheet:

- Training and Training Procedures: 4
- Compounding Facilities: 20, 27, 28, 29
- Compounding for Animal Patients: 59, 60, 61, 62, and 63.

A determination as to the difficulty of compliance with USP 795 is a decision for each facility. While the above hypotheticals note some of the questions a facility may be able to mark "N/A", there may be others e.g. compounding equipment questions depending on the set up of each facility.

PLEASE NOTE: the USP 795 Self-Inspection Addendum has not been published yet. The Pharmacy Quality Assurance Commission Compounding Subcommittee will be meeting to discuss and make final recommendations on this worksheet for presentation at the July 2018 regularly schedule Commission business meeting.

Washington State Department of Health

Pharmacy Quality Assurance Commission

Guidance Document

Title:	Ancillary Utilization Plans and Pharmacy Technician Administration
Reference:	RCW 18.64A.010(6), RCW 18.64A.030, RCW 18.64A.060, RCW 18.64.011
Contact:	Lauren Lyles-Stolz, Executive Director, Pharmacy Quality Assurance Commission
Effective Date:	August 28, 2020 (reaffirmed)
Supersedes:	June 8, 2018 version

Approved: Chairperson, Pharmacy Quality Assurance Commission

Summary

Pharmacy technicians may provide administration of medications or devices under the immediate supervision of a pharmacist and if the Pharmacy Quality Assurance Commission (Commission) has authorized the pharmacy technician to administer medications or devices by approving an ancillary utilization plan (AUP).

Pharmacists wishing to use pharmacy technicians to administer medications or devices should submit an AUP that meets the standards identified in this guidance document. A failure to meet the standards identified in this guidance document may result in rejection or modification of the proposed AUP (*see* RCW 18.64A.060).

This guidance document does not allow a pharmacy technician to engage in an assessment or discussion of the clinical appropriateness of a drug or device for a patient prior to administration.

Background

In December 2019, the Commission examined whether current law allows a pharmacy technician to administer medications or devices under the immediate supervision of a pharmacist. Based on its examination, the Commission determined that pharmacy technicians may provide administration of medications or devices under the immediate supervision of a pharmacist and if the Commission has authorized the pharmacy technician to administer medications or devices by

approving an AUP.

Pharmacy technicians may perform nondiscretionary functions associated with the practice of pharmacy under the immediate supervision and control of a licensed pharmacist and subject to restrictions adopted in rule by the Commission (RCW 18.64A.010(6) and RCW 18.64A.030(1)). In addition, pharmacy technicians may only be utilized by pharmacists to the extent the pharmacist has an AUP approved by the Commission (RCW 18.64A.040).

Whether an act falls within the scope of practice of a pharmacy technician is dependent on two criteria: (i) the act is nondiscretionary, and (ii) the act is associated with the practice of pharmacy. The Commission determined that administration of medications or devices is a nondiscretionary function and is associated with the practice of pharmacy (*see* RCW 18.64.011(1), (10), and (28)).

A pharmacy technician must be under the immediate supervision and control of a pharmacist when performing a nondiscretionary function associated with the practice of pharmacy (RCW 18.64A.030(1)). A pharmacy technician may not be supervised by anyone other than a pharmacist licensed by the Commission (*see* RCW 18.64.010(3) and RCW 18.64A.030(1)). Consequently, a pharmacist must supervise a pharmacy technician when the pharmacy technician is administering medications or devices.

A pharmacy technician may not engage in any nondelegable task associated with the practice of pharmacy. The Commission has a number of tasks that a pharmacist shall not delegate to ancillary personnel, including pharmacy technicians (WAC 246-945-320). The administration of medications or devices is not included as a nondelegable task.

Pharmacists may only use pharmacy technicians in a manner that is consistent with an AUP approved by the Commission. The Commission may approve, reject, or modify a proposed AUP (RCW 18.64A.060). Further, if the Commission receives a complaint that pharmacy technicians are being used in a manner that is inconsistent with an approved AUP, the Commission may withdraw any proposed AUP (RCW 18.64A.060).

Guidance to Pharmacists Submitting AUPs to Allow Pharmacy Technicians to Administer Medications or Devices

Pharmacies who would like to use pharmacy technicians, for delegation by a pharmacist, to administer medications or devices must submit an AUP to the Commission for approval. The Commission will consider proposed AUPs for approval that meet the following criteria as it applies to pharmacy technicians who are administering medications:

1. The pharmacist or pharmacy intern must retain the discretionary function to determine the patient's needs and all clinical assessments, including patient counseling regarding potential risks and side effects. The pharmacy technician can assist in preparation and administration of the medication or device.

2. The pharmacy technician must have completed adequate and appropriate training on what medication and devices they may administer.

3. Training for pharmacy technicians who will administer drugs and devices must include or address the following:

    a. Describe proper technique when preparing and administering medications;
    b. Recognize commonly used medications and their corresponding routes of administration;
    c. Distinguish proper needle length selection based on medications and patient age and size;
    d. Identify proper documentation procedures;
    e. Recall medications storage requirements;
    f. Describe safety measures to avoid accidental needle stick injuries;
    g. Recognize appropriate actions to take in emergency situations;
    h. Demonstrate a successful technique when administering an intramuscular and subcutaneous injection;
    i. Demonstrate appropriate distraction techniques during medication administration;
    j. Demonstrate the use of universal precautions as they pertain to blood borne pathogens; and
    k. Explain the procedures for managing a medication reaction emergency.

Conclusion

Pharmacy technicians may provide administration of medications or devices under the immediate supervision of a pharmacist and if the Commission has authorized the pharmacy technician to administer medications or devices by approving an AUP. Pharmacists wishing to use pharmacy technicians to administer medications or devices should submit an AUP that meets the standards identified in this guidance document.

Originally presented to the Legislative Subcommittee on October 7, 2022

Preliminary Review of White Bagging Legislation

October 2022

49 State Regulatory Bodies (all states except WA)

States with legislation applicable to white bagging

26 State Regulatory Bodies

AK, AZ, CA, FL, GA, IL, IN, KY, LA, MD, MA, MN, MO, NE, NJ, NY, NC, ND, OH, OK, TN, TX, VT, VA, WV, WI

★ **Primarily insurance-related legislation**

Sample of states with legislation (applicable to white bagging) that falls under the purview of the boards of pharmacy

MASS. 247 CMR 9.01 (4)

OHIO OAC 4729:5-3-16

NEW JERSEY State Board of Pharmacy 13:39-3.10

VIRGINIA 18VAC110-20-275

See page 2 for additional information

Preliminary Review of White Bagging Legislation

October 2022

MASSACHUSETTS	**247 CMR 9.01(4).** Current as of April 1, 2022. "Unless otherwise permitted by law, a pharmacist shall not redispense any medication which has been previously dispensed. "
NEW JERSEY	**State Board of Pharmacy 13:39-3.10.** Last revised March 7, 2022. "It shall be unlawful for a pharmacist to enter into an arrangement with a health care practitioner who is licensed to issue prescriptions, or any institution, facility, or entity that provides health care services, for the purpose of directing or diverting patients to or from a specified pharmacy or restraining in any way a patient's freedom of choice to select a pharmacy."
OHIO	**OAC 4729:5-3-16.** Effective March 9, 2020. "No drug that has been dispensed pursuant to a prescription or personally furnished by a prescriber and has left the physical premises of the terminal distributor of dangerous drugs shall be returned to the terminal distributor or dispensed or personally furnished again, except as follows:...Drugs dispensed for patients, which have not been dispensed or personally furnished directly to the ultimate user, that require further manipulation prior to administration."
VIRGINIA	**18VAC110-20-275.** Effective September 16, 2021. "One pharmacy may fill prescriptions and deliver the prescriptions to a second pharmacy for patient pickup or direct delivery to the patient provided the two pharmacies have the same owner, or have a written contract or agreement specifying the services to be provided by each pharmacy, the responsibilities of each pharmacy, and the manner in which each pharmacy will comply with all applicable federal and state law."

Washington State
Pharmacy Quality Assurance Commission
Sample Ancillary Personnel Utilization Plan

Overview

What is an AUP?

An Ancillary Personnel Utilization Plan (AUP) is a document that pharmacies licensed by the Pharmacy Quality Assurance Commission (commission) must submit to the commission for approval, prior to the utilization of pharmacy assistants or pharmacy technicians (RCW 18.64A.040 and RCW 18.64A.060).

What is an AUP required to include?

An AUP must contain information regarding how pharmacy assistants or pharmacy technicians will be utilized and supervised while working in the pharmacy, including explanations of delegated tasks, and the conditions under which pharmacy assistants or pharmacy technicians are expected to perform their tasks (WAC 246-945-410). All functions shall be listed in the AUP application. Specialized functions are no longer required to be submitted separately.

Who signs the AUP?

While an AUP must be approved by the commission, the responsible pharmacy manager maintains discretion regarding its implementation. Therefore, the AUP must be reviewed and signed by the responsible pharmacy manager before it is submitted to the commission for review. It is also important to note that the duties and responsibilities of the ancillary personnel are subject to the discretion of the supervising pharmacist on duty (WAC 246-945-315).

Where should Pharmacy Ancillary Utilization Applications be submitted?

The Pharmacy Ancillary Utilization Application, along with a completed, signed, and dated ancillary personnel utilization plan, and check or money order made payable to **Department of Health**, should be mailed to:

Department of Health
P.O. Box 1099
Olympia, WA 98507-1099

Please send any other documents not sent with the initial application to:

Pharmacy Quality Assurance Commission Credentialing
P.O. Box 47877
Olympia, WA 98504-7877

Washington State
Pharmacy Quality Assurance Commission
Sample Ancillary Personnel Utilization Plan

Please retain a copy of your submitted AUP and Pharmacy Ancillary Utilization Application for your records.

When should an initial Pharmacy Ancillary Utilization Application and AUP be submitted?

Pharmacies that are applying for an initial license with an AUP and Pharmacy Ancillary Utilization Application, must submit them at least 60 days prior to a Pharmacy Commission business meeting.

Why has the commission issued a sample AUP? Is my pharmacy required to use the sample AUP?

The commission has provided this sample AUP as a tool to assist licensees in creating a plan for utilizing its pharmacy personnel. The use of the sample AUP is **not** required, however, pharmacies may choose to use it as a template and format it to meet their specific practice needs.

How do I use the sample AUP?

Your pharmacy may use the sample AUP to document the duties and responsibilities to be performed by ancillary personnel. Tables are provided for you to input the duties and responsibilities of both pharmacy technicians and pharmacy assistants. Appendix A contains additional tables should you require more space to complete your plan. Appendix B contains a supplemental list of potential duties and responsibilities that may be helpful to pharmacies as they prepare their AUPs. Note: Appendix B does not contain an exhaustive list. It is intended to function as a resource, but its use is not required.

Where can I find information regarding staffing and the supervision of pharmacy personnel?

The commission recognizes that many pharmacies face challenges related to adequate staffing. For reference, WAC 246-945-410 addresses sufficient staffing in the pharmacy. WAC 246-945-460 specifically addresses the staffing and supervision of pharmacy personnel, which the responsible pharmacy manager determines. Chapter 18.64A RCW addresses the duties of pharmacy technicians and assistants and limitations on practice. This is noted on the next page in **Definitions and Duties**.

Washington State
Pharmacy Quality Assurance Commission
Sample Ancillary Personnel Utilization Plan

Definitions and Duties

"Pharmacy ancillary personnel" means pharmacy technicians and pharmacy assistants (RCW 18.64A.010(5)).

"Pharmacy technician" means: (a) A person who is enrolled in, or who has satisfactorily completed, a commission-approved training program designed to prepare persons to perform nondiscretionary functions associated with the practice of pharmacy; or (b) A person who is a graduate with a degree in pharmacy or medicine of a foreign school, university, or college recognized by the commission (RCW 18.64A.010(6)).

"Pharmacy assistant" means a person registered by the commission to perform limited functions in the pharmacy (RCW 18.64A.010(7)).

Scope of Practice:

"Pharmacy technicians" may assist in performing, under the supervision and control of a licensed pharmacist, manipulative, nondiscretionary functions associated with the practice of pharmacy and other such duties and subject to such restrictions as the commission may by rule adopt (RCW 18.64A.030(1)). Pharmacy technicians may not perform tasks identified by the commission as nondelegable in WAC 246-945-320.

"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 (RCW 18.64A.030(2)). A pharmacy assistant may also prepackage and label drugs for subsequent use in prescription dispensing operations; and count, pour, and label for individual prescriptions (WAC 246-945-315(3)). Pharmacy assistants may not perform any other pharmacy task other than those provided above.

Please also see WAC 246-945-315 for the Commission's rules on supervising and delegating tasks to pharmacy ancillary personnel.

Washington State
Pharmacy Quality Assurance Commission
Sample Ancillary Personnel Utilization Plan

Duties and responsibilities to be performed under the supervision and control of a licensed pharmacist *To be completed by the applicant. Please fill in the duties and responsibilities of the **pharmacy technician(s)** in the fields below.*
T1.
T2.
T3.
T4.
T5.
T6.
T7.
T8.
T9.
T10.
T11.
T12.
T13.
T14.
T15.
T16.
T17.
T18.
T19.
T20.

Please see Appendix A if you need additional pages to complete the plan.

Pharmacy Name:
Responsible Pharmacy Manager Name:
Responsible Pharmacy Manager Signature: Date:

Washington State
Pharmacy Quality Assurance Commission
Sample Ancillary Personnel Utilization Plan

Duties and responsibilities to be performed under the supervision and control of a licensed pharmacist *To be completed by the applicant. Please fill in the duties and responsibilities of the **pharmacy assistant(s)** in the fields below.*
A1.
A2.
A3.
A4.
A5.
A6.
A7.
A8.
A9.
A10.
A11.
A12.
A13.
A14.
A15.
A16.
A17.
A18.
A19.
A20.

Please see Appendix A if you need additional pages to complete the plan.

Pharmacy Name:
Responsible Pharmacy Manager Name:
Responsible Pharmacy Manager Signature: Date:

Washington State
Pharmacy Quality Assurance Commission
Sample Ancillary Personnel Utilization Plan

Appendix A
Additional Duties and Responsibilities

Duties and responsibilities to be performed under the supervision and control of a licensed pharmacist *To be completed by the applicant. Please fill in the duties and responsibilities of the **pharmacy technician(s)** in the fields below.*
T21.
T22.
T23.
T24.
T25.
T26.
T27.
T28.
T29.
T30.
T31.
T32.
T33.
T34.
T35.
T36.
T37.
T38.
T39.
T40.

Appendix A
Additional Duties and Responsibilities

Washington State
Pharmacy Quality Assurance Commission
Sample Ancillary Personnel Utilization Plan

Duties and responsibilities to be performed under the supervision and control of a licensed pharmacist *To be completed by the applicant. Please fill in the duties and responsibilities of the **pharmacy assistant(s)** in the fields below.*
A21.
A22.
A23.
A24.
A25.
A26.
A27.
A28.
A29.
A30.
A31.
A32.
A33.
A34.
A35.
A36.
A37.
A38.
A39.
A40.

Washington State
Pharmacy Quality Assurance Commission
Sample Ancillary Personnel Utilization Plan

Appendix B

Supplemental List of Potential Duties and Responsibilities
(Note: This is not an exhaustive list)
A, T = Assistants and technicians may perform
T = Only technicians may perform

Related to Prescription Processing

- Greets customers/patients arriving at the pharmacy. (A, T)
- Greets customers/patients calling the pharmacy and answers inquiries regarding
  a) The price of a prescription that has been filled and is ready for pick-up. (A, T)
  b) The pharmacy's hours of operation. (A, T)
  c) The number of refills remaining on a prescription. (A, T)
  d) The request to refill a medication when provided the prescription number. (A, T)
  e) The date a prescription medication will be returned to stock. (A, T)
  f) The date and time of a customer's/patient's vaccination appointment. (A, T)
  g) The availability of goods and services (may require directing the phone call to a pharmacist). (A, T)
- Handles calls to and/or from a prescriber's office regarding a customer's/patient's profile information that does not require interpretation (e.g., medication quantity, date last filled, and price). (A, T)
- Utilizes the pharmacy software system to enter new and refill prescription data electronically (T). Utilizes the pharmacy software system to enter refill corresponding labels (A).
- May generate a label for a refill prescription only when there has been no change to the required elements of the prescription (WAC 246-945-010). (A, T)
- Provides vaccine screening forms for customers/patients to complete and for the pharmacist to review. (A, T)
- Receives and unpacks deliveries containing supplies and drugs and stocks to shelf. (A, T)Stock automated dispensing machines. (T)
- Reviews a customer's/patient's medication profile to retrieve specific information related to third-party billing, adjudication, medication refill frequency, and vaccination history. (T)
- Handles calls from a prescriber's office authorizing refills provided that no changes in the prescription are involved. (A,T)
- Contacts a wholesaler or distributor to place or verify the status of an order. (A,T)

Washington State
Pharmacy Quality Assurance Commission
Sample Ancillary Personnel Utilization Plan

Appendix B

Supplemental List of Potential Duties and Responsibilities
(Note: This is not an exhaustive list)
A, T = Assistants and technicians may perform
T = Only technicians may perform

Related to Prescription Processing

- Pours and counts out medication from a stock bottle pulled from the shelf by a pharmacist or technician and labels for individual prescription(s). (A, T)
- Maintains assigned work area and equipment in clean and orderly condition, including the pharmacy counters and shelves. (A, T)
- Protects secure patient information from plain view and disposal in common wastebaskets. (A, T)
- Medication reconstitution (i.e., restoration of the original form of medication previously altered for preservation and storage by addition of a specific quantity of distilled water or provided diluent requiring no calculation). (T)

Related to Prescription Finalization

- Assists customers/patients waiting to check out at the pharmacy. (A, T)
- Calls customers/patients to let them know their medications are ready for pick-up. (A, T)
- Operates cash register and/or digital signature pad used to document prescription pick-up. (A, T)
- Hands out refills when specifically requested to do so by a pharmacist and when a pharmacist has determined that counseling is not necessary. (A, T)
- Systematically files completed prescriptions that have been verified and prepared by the pharmacist for customer/patient pick-up. (A, T)

Other Pharmacy Functions*

- Fills unit dose cassettes. (T)*
- Administers immunizations, medications, and devices. (T)*
- Files and retrieves various pharmacy records as required by the pharmacist, including order invoices and receipts. (A, T)

*Pharmacies and pharmacists who wish to use pharmacy technicians to administer medications or devices should submit an AUP that meets the standards identified in the Pharmacy Commission's Guidance Document: Ancillary Utilization Plans and Pharmacy Technician Administration.

Commission SBAR Communication

Originally presented at the September 2022 business meeting

Agenda Item/Title: Monitoring of Drug Therapy: Pharmacists Conducting Health Screenings and Point-of-Care Testing

Date SBAR Communication Prepared: 9/7/2022

Reviewer: Commission Staff

Link to Action Plan:

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

Situation: (Brief Description)

Over the last two years, Pharmacy Quality Assurance Commission (commission) staff have received questions related to the ability of pharmacists to conduct point-of-care (POC) testing and perform health screenings. Specifically, whether it is within the scope of practice for a pharmacist to conduct POC testing and perform health screenings related to a condition the individual has not received a diagnosis for and has not been prescribed any medication to treat.

Background: (Briefly state the pertinent history):

Commission staff have heard that conducting POC testing and performing health screenings on individuals related to a condition the individual has not received a diagnosis for and has not been prescribed any medication to treat is within the scope of practice for a pharmacist because it amounts to the "monitoring of drug therapy."

The scope of practice of a pharmacist is delineated in statute. A pharmacist is permitted to engage in the "practice of pharmacy" (RCW 18.64.011(25)). The Legislature has defined the "practice of pharmacy" to include:

> the practice of and responsibility for: Interpreting prescription orders; the compounding, dispensing, labeling, administering, and distributing of drugs and devices; the monitoring of drug therapy and use; the initiating or modifying of drug therapy in accordance with written guidelines or protocols previously established and approved for his or her practice by a practitioner authorized to prescribe drugs; the participating in drug utilization reviews and drug product selection; the proper and safe storing and distributing of drugs and devices and maintenance of proper records thereof; the providing of information on legend drugs which may include, but is not limited to, the advising of therapeutic values, hazards, and the uses of drugs and devices.

RCW 18.64.011(28).

The Commission has further explained in rule that, in the absence of a collaborative drug therapy agreement (CDTA), "monitoring of drug therapy and use" shall mean:

a review of the drug therapy regimen of patients by a pharmacist for the purpose of evaluating or rendering advice to the prescribing practitioner or patient regarding the patients drug therapy. Monitoring of drug therapy includes, but is not limited to, the evaluation of the patient through history taking, physical examination, ordering, administering or reviewing laboratory tests, imaging, and social evaluation related to an existing diagnosis and drug therapies for optimization of drug therapy.

WAC 246-945-355.

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

Assessment: (Summarize the facts and give your best assessment. What is going on? Use your best judgment)

Commission staff have concluded that based on current law, pharmacists are authorized to engage in POC testing and health screenings as part of their scope without a CDTA or protocol; however, it must be related to an existing diagnosis and drug therapy as stated in WAC 246-945-355.

Recommendation: (What actions are you asking the commission to take? What do you want to happen next?)

The commission can reaffirm its rule (WAC 246-945-355) as being in line with the parameters placed in statute and provide licensees with the following clarification:

Pursuant to the terms of a collaborative drug therapy agreement (CDTA), or other standing order or protocol developed by an interdisciplinary team that includes a prescribing practitioner, a pharmacist can:

- Screen individuals for previously undiagnosed acute and chronic conditions and provide a report of the results to the individual;
- Monitor an individual's diagnosed condition, regardless of whether the individual takes medication to treat the diagnosed condition, and report the outcome of monitoring to the patient; and
- Perform CLIA-waived point-of-care testing, interpret the results of this testing, and make recommendations for care to the patient.

Commission SBAR Communication

In the absence of a CDTA, or other standing order or protocol, a pharmacist can:

- Monitor an individual's diagnosed condition and report the outcome of the monitoring to the individual or prescribing practitioner so long as the individual takes medication to treat their diagnosed condition; and
- Perform CLIA-waived point-of-care testing, interpret the results of this testing, and make recommendations for care to the patient or prescribing practitioner if the individual has received a diagnosis and been prescribed medication to treat the diagnosed condition and the pharmacist is monitoring the individual's drug therapy.

In the absence of a CDTA, or other standing order or protocol, a pharmacist cannot:

- Screen individuals for previously undiagnosed acute and chronic conditions and provide the individual with a report;
- Monitor an individual's diagnosed condition if they have not been prescribed medication to treat the diagnosed condition; and
- Perform CLIA-waived point-of-care testing, interpret the results of this testing, and make recommendations for care to the individual if they do not have a related diagnosis and prescribed medication.

Follow-up Action: (Next Steps After the meeting – Document the commission's decision and/or any additional steps or follow-up requested; such as, report back in 6- months, etc.)

- Staff will follow-up as determined by the commission.

WAC 246-945-040 Uniform Controlled Substance Act. (1) The commission adopts and incorporates Title 21 of the C.F.R. in effect as of November 17, 2022 by reference. The following sections of Title 21 C.F.R. do not apply: Sec. 6.1 – 6.5, Sec. 58.1 – .15, Sec. 83 - 98, Sec. 100 - 199, Sec. 225 - 226, Sec. 291, Sec. 370-499, Sec. 501.1 – 501.110, Sec. 502.5 – 502.19, Sec. 505, Sec. 507.1 – 507.215, Sec. 508, Sec. 509.3 – 509.30, Sec. 536, 539, 540, 544, 546, 548, 555 and 564, Sec. 556.1 – 556.770, Sec. 558.3 – 558.665, Sec. 570, 571, and 573, Sec. 579.12 – 579.40, Sec. 584, Sec. 589, Sec. 590 – 599, Sec. 601 - 607, Sec. 620, Sec. 630.1 – 630.40, Sec. 640.1 – 640.130, Sec. 650, Sec. 700 – 799, Sec. 804 – 805, Sec. 813, Sec. 897, Sec. 900, Sec. 1000-1050, Sec. 1100-1150, Sec. 1210.1 – 1210.31, Sec. 1220, Sec. 1240.3 – 1240.95, Sec. 1250.3 – 1250.96, Sec. 1251-1269, Sec. 1270.1 – 1270.43, Sec. 1271.1 – 1271.440, Sec. 1272-1299, Sec. 1301.13, Sec. 1301.28, Sec. 1301.33, Sec. 1301.35-.46, Sec. 1308.41-.45, Sec. 1316.31-.67, and Sec. 1400 through 1499. Any inconsistencies between the material incorporated by reference in this subsection and the remainder of this this chapter should be resolved in favor of this chapter. Nothing in

this chapter applies to the production, processing, distribution, or possession of marijuana as authorized and regulated by the Washington state liquor and cannabis board.

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

(3) Registration. A separate registration is required for each place of business, as defined in 21 C.F.R. Sec. 1301.12, where controlled substances are manufactured, distributed, or dispensed. Application for registration must be made on forms supplied by the commission, and all requested information must be supplied unless the information is not applicable, which must be indicated by the applicant. An applicant for registration must hold the appropriate license provided for in chapter 18.64 RCW.

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

receipt and distribution of controlled substances. Records shall include:

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

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

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

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

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

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

(7) A federal order form is required for each distribution of a Schedule I or II controlled substance. Credential holders and pharmaceutical firms must keep and make readily available these forms and other records to the commission or its designee. [Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-040, filed 6/1/20, effective 7/1/20.]

Pharmacy Quality Assurance Commission
2021-23 Budget & Fund Balance Overview
For the Period July 1, 2021 through January 31, 2023

Health Professions Account Beginning Fund Balance on July 1, 2021	2,493,136
Revenue To-Date	16,511,347
21-23 HELMS Assessment To-Date	785,167
Expenses To-Date	10,266,294
Health Professions Account Fund Balance as of January 31, 2023	7,953,021

REVENUE	ESTIMATED REVENUE	ACTUAL REVENUE	VARIANCE	% OF ESTIMATED
To-Date	15,014,691	16,511,347	1,496,656	110.0%
Biennium Total	19,608,317			84.21%

EXPENSES - Health Professions Account	TOTAL BIEN BUDGET	BUDGET TO-DATE	EXPENSES TO-DATE	VARIANCE TO-DATE	VARIANCE TO-DATE %
Staff Salaries and Benefits	5,420,468	4,180,383	4,005,780	174,603	4.2%
Commission Pay	92,815	62,640	47,255	15,385	24.6%
Professional Service Contracts	15,456	12,236	485	11,751	96.0%
Attorney General Support	218,621	216,227	344,985	(128,758)	-59.5%
Goods and Services	93,331	74,123	31,004	43,119	58.2%
Travel	99,469	70,284	53,277	17,007	24.2%
IT Equipment	28,656	22,686	16,652	6,034	26.6%
WA Recovery Assist. Prog. for Pharmacy (WRAPP)	134,952	106,837	125,899	(19,062)	-17.8%
Intra-Agency Charges - Discipline	1,663,756	1,296,338	934,801	361,537	27.9%
Intra-Agency Charges - Credentialing	3,226,935	2,539,160	2,142,112	397,048	15.6%
Intra-Agency Charges - Other	660,067	514,825	432,616	82,209	16.0%
Total Direct Costs	**11,654,526**	**9,095,739**	**8,134,866**	**960,873**	**10.6%**
Agency Indirect Costs	1,946,851	1,519,158	1,283,499	235,659	15.5%
Division Indirect Costs	1,300,332	1,014,654	847,844	166,810	16.4%
Total Indirect Costs	**3,247,183**	**2,533,812**	**2,131,343**	**402,469**	**15.9%**
Grand Total	**14,901,709**	**11,629,551**	**10,266,209**	**1,363,343**	**11.7%**