October 22, 2021

Pharmacy Quality Assurance Commission

Public Meeting Materials

As of October 18, 2021

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
September 2, 2021 - Minutes

Convene: Chair, Teri Ferreira called the meeting to order September 2, 2021, 9:00 a.m.

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

Commission Member Absent:
Tim Lynch, PharmD, MS, FABC, FASHP
Bonnie Bush, Public Member

Staff Members:
Trina Crawford, Interim Executive Director, Pharmacy Commission
Lindsay Trant, Interim Deputy Director, Pharmacy Commission
Christopher Gerard, AAG
Marlee O'Neill, Deputy Director, OILS
Hope Kilbourne, Policy Analyst
Blake Maresh, Deputy Director, Office of Health Professions
Joanne Miller, Program Manager, Pharmacy
Amy L Robertson, Administrative Assistant, Pharmacy

1. Call to Order

1.1 Meeting Agenda Approval – September 2, 2021

MOTION: Craig Ritchie moved to approve the amended agenda. Patrick Gallaher, second. Motion carries, 9:0

1.2 Meeting Minutes Approval – July 16, 2021

MOTION: Craig Ritchie moved to approve the meeting minutes for July 16, 2021. Patrick Gallaher, second. Motion carries, 9:0

2. Consent Agenda

2.1 National Precursor Log Exchange January
2.2 Pharmaceutical Firms Application Report Approval
- July 1, 2021 thru August 14, 2021 – new and closed firms

2.3 Ancillary Utilization Plans Approval

2.3.1 CHAS
2.3.3 Fred Meyer Pharmacy
2.3.5 Overlake Pharmacy
2.3.6 Peninsula Community Health Services (Multiple locations)
2.3.7 Pharmacy Plus
2.3.8 QFC Fred Meyer

2.4 Pharmacy Technician Training Program Approval
2.4.5 Brewster Multiple Locations
2.4.6 Charter College

MOTION: Craig Ritchie moved to approve the consent agenda except for items 2.3.2, 2.3.4, and 2.3.9. Jerrie Allard, second. Motion carries, 9:0

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

William Hayes requested the following be pulled for further discussion:

2.3.2 Doctors Telepharmacy

MOTION: Craig Ritchie moved to approve the AUP contingent on the pharmacy amending the AUP to reflect that the pharmacist is the person to offer counseling; William Hayes, second. Motion carries, 9:0.

2.3.4 Harbor Health Apothecary

MOTION: William Hayes moved to approve AUP while also informing the licensee that citation to WAC 246-901 should be removed as the rules chapter no longer exists; Craig Ritchie, second. Motion carries, 9:0.

Patrick Gallaher requested the following be pulled for further discussion:

2.3.9 Sea Mar Community Health

MOTION: Patrick Gallaher moved to approve AUP with #9 “Reconstitution under the pharmacy assistants” being stricken; Craig Ritchie, second. Motion carries, 9:0.

3. Old Business

3.1 2022 Business Meeting Dates

MOTION: Craig Ritchie moved to approve 2022 business meeting dates; Hawkins DeFrance, second. Motion carries, 9:0.

3.2 Review Policy Statement on Enforcement of USP 800 & 825

MOTION: Craig Ritchie moved to extend policy statement #65.1 on USP 800 through March 31, 2022; excluding USP 825 as it will be immediately enforced on October 1; Patrick Gallaher, second. Motion carries, 9:0. (Hawkins second?)

Stakeholder Jenny Arnold, WSPA, supports delay enforcement of USP 800, but requests PQAC educate the pharmacy community about the existence of L&I's hazardous drug rules in chapter 296-62 WAC.

Stakeholder Richard Molitor, expanded on Jenny Arnold's remarks that in addition to L&I the environmental protection agency is interested in "key drugs."

3.3 Out-of-State OTC-only Wholesaler

MOTION: Ken Kenyon moved we approve Option 1 as amended below; Jerrie Allard, second. Motion carries, 9:0.

Option 1: Resume the option of in-state OTC wholesaler inspections AND refer people to NCDQS for an out-of-state inspection—especially for those states that require licensure for OTC wholesalers. If a state does not require licensure then the commission may need to develop guidance and future rulemaking to address this gap. This guidance may provide out-of-state applicants with an option to submit a letter in lieu of the inspection report and proof of licensure from their regulatory authority stating that they are not required to be licensed in their resident state. Secondly, the commission authorized rulemaking to either remove or modify WAC requirements, WAC 246-945-246(3)(a) and (b), for out-of-state OTC-only wholesalers.

3.4 HCE Self-Inspection Worksheet Public Comment

MOTION: Ken Kenyon moved to approve the HCE self-inspection worksheet as amended during the meeting, direct staff to expeditiously post with revisions, and clarify that licensees must complete before March 2022. Hawkins DeFrance, seconds. Motion carries, 9:0.

- Page 8, Question 9: add clarifying statement regarding freezer temperature ranges - "or acceptable standard range" and correct grammar.
- Page 13, Question 31-33: switch 31 and 32

MOTION: Ken Kenyon moved initiate rule-making under the expedited process that is currently open for WAC 246-945-417 to correct subsection 7 as noted; Craig Ritchie, second. Motion carries, 9:0.

4. Rules and Legislative Session Updates - Information/Action.

4.1 Reauthorize emergency rules deleting Epidiolex from Schedule V.

MOTION: Craig Ritchie moved to reapprove the refiling of the emergency rule; Patrick Gallaher, second. Motion carries, 9:0.

4.2 Emergency rules for prescribing Schedule II drugs during COVID-19.

MOTION: Craig Ritchie moved to approve the refiling of the emergency rule for prescribing Schedule II drugs during COVID-19; Ken Kenyon, second. Motion carries, 9:0.

4.3 Reauthorize medication assistance emergency rules.

MOTION: Patrick Gallaher moved to approve jointly refiling medication assistance emergency rules with the Department of Health; Craig Ritchie, second. Motion carries, 9:0.

4.4 Rules prioritization and strategizing for interim.

MOTION: Jerrie Allard moved to approve the prioritizations of rules list as presented; Patrick Gallaher, second. Motion carries, 9:0.

4.5 2022 Legislative Proposal Update

Blake Maresh presented an overview of the Board/Commission (BCC) Expansion bill. Key points:

- Change some qualifications to be a member of a BCC – removes US citizenship as a prerequisite to serve on BCCs. However, must be Washington State resident for at least five years.
- Changed the definition of a quorum – "a majority of members appointed and serving."
- Harmonizes all BCC as Class 5 groups under Chapter 43.03 – proposed compensation increase from $50 day to $250/day for attendance at official meetings or performance of statutorily prescribed duties.
- Gives PQAC authority to delegate to panels of three, four, etc. for facilities work.
- Gives PQAC authority to delegate to a health law judge for facilities.
- Gives the ability to do a more national search for Executive Director position without immediately being licensed in Washington State. Not effective immediately for this current recruitment.
- Additional housekeeping with old language, etc.

4.6 Review Uniform Facilities Enforcement Framework Recommendations

MOTION: Hawkins DeFrance moved to adopt the proposed recommendations with the additional comments (below); Patrick Gallaher, second. Motion carries, 9:0.

- Fine Limits listed are only a high-level overview from other sources. Not specific at this time.
- Consider a provision for reimbursement for costs of investigation.
- Scope and Severity Matrix will be of help for future use.

5. Open Forum (10 minutes) – None.

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

6.1 Commissioner Reports

Teri Ferreira, Jerrie Allard, and Trina Crawford were unable to attend the NABP regional meeting due to travel restrictions.

Jerrie Allard recognized Martin Pittioni for all his support and help to the commission during all of the recent staff changes.

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

PQAC Commission vacancies

Hawkins DeFrance –the fifteen-member commission currently shows four vacancies and three expire in January. What is the plan for filling these positions?

Per Joanne Miller:
- 2021 recruitment (3 positions) is now at the Governor's office
- 2022 recruitment has just been announced.

Blake Maresh confirmed members can serve until there is a replacement appointment made.

Licensing

Ken Kenyon raised the concern regarding the significantly extended time stakeholders are seeing their licensing completed.

Blake Maresh acknowledges there is delay, but the office of customer service is taking many different approaches to expedite licensing. Through the federal recovery act, we are bringing on inspectors on a temporary basis. The credentialling unit is also bringing on

staff to help expedite. We are also looking into LiveScan for fingerprinting, but the challenge is other states having it available.

Thanks to Staff

Patrick Gallaher, thanks Lindsay, Trina, and Marlee taking on these critical roles and taking on the extra work. All the staff should be commended on how they have stepped up with all the changes.

7. Staff Reports *Information/Action.*

7.1 OHP Deputy Director – Blake Maresh

- Status of PQAC transition and recruitment

Executive Director Position – recruitment is underway for this position. Applications review will begin September 17. Review panel: Jerrie Allard, Teri Ferreira, William Hayes

Deputy Director Position – While Lindsay is interim deputy director, we are trying to back-fill the rules coordinator. Candidates are in place, but not confirmed at the moment.

Pharmacy Consultant Position – interviews set for tomorrow. Panelist of seven (3 commissioners, 3 OHP, 1 HR).

Supervising Pharmacist – recruitment for this position is on hold.

Pharmacy Inspectors – One-time funding has come through and allows us to secure three inspectors in a non-permanent basis. Recruitment to begin later.

7.2 OILS Deputy Director– Marlee O'Neill

- Return to Routine Inspections Update

Routine Inspections – Inspectors will resume routine inspections soon. We are coordinating with the Office of Health Systems Oversight to ensure practices/procedures are consistent. Stakeholders will be receiving new "six-month notice" letters.

CMT Materials – Kirby will begin using Box.com to distribute CMT materials to panels.

Ivermectin Information – Thanks to the investigators and inspectors for distributing the ivermectin information so quickly.

7.3 Interim Executive Director- Trina Crawford

- FDA MOU Update – the FDA has extended the deadline to sign the MOU to Oct 27, 2022. If rulemaking is started, it can be pulled at any time.

Chris Gerard reminded the commission the MOU is required to be developed between the FDA and NABP. In short, it addresses the interstate shipping of compounded human drug products. If states decide to enter this MOU, they are subject to the significant data reporting to the FDA. Alternative to not signing restricts the amount of compounded human drug products that can be shipped in state to 5%. The MOU will not be tailored to each state.

MOTION: Hawkins DeFrance motioned to move forward with rulemaking to adopt/sign the MOU; Ken Kenyon, second. Motion carries, 9:0.

7.4 Interim Deputy Director – Lindsay Trant

- Sample AUP – would like to schedule the pharmacy practice committee to start the revision work on the sample AUP.

7.5 Assistant Attorney General – Christopher Gerard – nothing to report.

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

- 2.3.2 – Consent agenda Doctor's Telepharmacy – approved with restrictions.
- 2.3.4 – Consent agenda approved but strike 246-901. Irina will follow-up
- 2.3.9 – Sea Mar – strike #9 reconstitution by pharmacy assistants. Irina will follow-up
- 3.2 – Policy Statement –
  - Update Policy Statement
  - Staff create and FAQ and send via newsletter
- 3.3 – Out of State Wholesalers
  - Staff develop guidance letter for out of state wholesalers for the states that do not conduct inspections.
  - File CR101 with authorization rule making for WAC 246-945-246 in consideration of requiring self-inspections.
- 3.4 – HCE self-inspection sheets
  - Post revisions to the worksheet
  - Clarify self-inspection worksheets due by March 2022.
  - File CR105 to correct the technical error in WAC 246-945-417
- Refile Emergency rules for 4.1, 4.2, 4.3
- 4.6 – Uniform Facilities Enforcements
  - Make edits made during the meeting
- 7.3 – MOU FDA – file the CR101
- 7.4 – Sample AUP – schedule meeting of the pharmacy practice committee for review.

Business Meeting Adjourned. 12:15 p.m.

Pharmacy Quality Assurance Commission

Mission Statement

The mission of the Pharmacy Quality Assurance Commission is to promote public health and safety by establishing the highest standards in the practice of pharmacy and to advocate for patient safety through effective communication with the public, profession, Department of Health, Governor, and the Legislature.

Vision Statement

The Washington State Pharmacy Quality Assurance Commission leads in creating a climate for the patient-focused practice of pharmacy as an integral part of an accessible, quality–based health care system.

- As a result, the citizens of Washington State:
- Are well informed about medications;
- Take responsibility for their health;
- Utilize pharmacists and other health care providers appropriately; and
- Experience the highest level of health and wellness.

Next scheduled business meeting: **October 22, 2021**
Business Meetings
9:00 a.m.
Virtual – by Webinar

Accessibility: This meeting is accessible to persons with disabilities. Special aids and services can be made available upon advance request. Requests must be made no later than ten (10) days prior to the meeting. If you would like general information about this meeting, please call (360) 236-4947. If you need assistance with special services, you may leave a message with that request at 1-800-525-0127 or if calling outside Washington State call (360) 236-4052. TDD may be accessed by calling the TDD relay service at 711. If you need assistance due to a speech disability, Speech-to-Speech provides human voices for people with difficulty being understood. The Washington State Speech to Speech toll free access number is 1-877-833-6341.

From: Appriss Health
To: Weimer, Jamie; DOH WSPQAC; Miller, Joanne (DOH)
Cc: ndelavega@appriss.com; kmccormick@appriss.com; Accountspecialist@appriss.com; tnadrich@apprisshealth.com
Subject: Washington NPLEx Dashboard Report - Sep 2021
Date: Friday, October 1, 2021 9:04:08 AM
Attachments: WA_PHARMACY_TRX_REPORT_09012021.csv

External Email

MONTHLY PROGRAM ADMINISTRATOR'S DASHBOARD

10 Logins - 4 Searches - 1 Report Queries - 30 Active Watches - 3 Active Watch Hits

NEW USERS THIS MONTH

New Users = 2

Total Accounts = 141

Active Users = 5

TOP USAGE AGENCIES

1. Auburn Police Department
2. ICE - King County

TOP USERS BY USAGE

1. Eric Mattson, Auburn Police Department
2. Wa Test, ICE - King County

TOP AGENCIES BY ACTIVE WATCHES

1. ICE - King County (15)

TRANSACTION SUMMARY STATISTICS (2021)

	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	TOTAL
PURCHASES	58,504	51,943	70,640	82,986	78,777	84,242	79,222	72,763	67,789	**646,866**
BLOCKS	2,433	2,301	2,931	3,933	3,515	3,763	3,233	2,899	2,952	**27,960**
GRAMS SOLD	130,934	117,632	165,200	197,654	185,979	198,842	181,384	164,623	151,156	**1,493,404**
BOXES SOLD	66,771	59,470	79,346	92,123	87,787	93,305	88,636	82,270	76,812	**726,520**
GRAMS BLOCKED	6,569	7,011	8,009	11,356	9,993	10,793	8,922	7,961	8,214	**78,828**
BOXES BLOCKED	2,700	2,897	3,183	4,360	3,929	4,110	3,617	3,324	3,487	**31,607**
AVG GRAMS PER BOX BLOCKED	2.43	2.42	2.52	2.60	2.54	2.63	2.47	2.40	2.36	**2.48**

PHARMACY PARTICIPATION STATISTICS (Sep 2021)

Enabled Pharmacies	997

Pharmacies Submitting a Transaction	937
Pharmacies Logging in Without a Transaction	0
Inactive Pharmacies	60
Pharmacy Participation for Sep	93.98%

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
DRSD.FX.61218762	ACTIVE	09/08/2021	09/08/2021	09/30/2022
DRSD.FX.61213215	ACTIVE	09/08/2021	09/08/2021	09/30/2022
DRSD.FX.61219970	ACTIVE	09/08/2021	09/08/2021	09/30/2022
PHHC.FX.61215157	ACTIVE	09/08/2021	09/08/2021	09/30/2022

Credential #	Status	First Issuance Date	Effective Date	Expiration Date
PHWH.FX.61092992	CLOSED	08/04/2020	10/01/2021	10/01/2021

USP 800 825 SELF-INSPECTION WORKSHEET PUBLIC COMMENTS

DATE RECEIVED	TITLE OF INSPECTION SHEET	SECTION OF INSPECTION SHEET	PAGE NUMBER	QUESTION NUMBER	ISSUE (wording, clarification, procedure, etc)	COMMENTS	PQAC TEAM COMMENTS	COMMISSION REVIEW COMMENTS/Approval
8/12/2021						Regarding the USP 800 Self-Inspection Worksheet. I'm emailing regarding the requirement as a whole. It's important to have safe handling protocols in place when handling bulk hazardous drug product in a hospital or compounding pharmacy setting. However, there is very little contact at all in a traditional retail pharmacy. Can there be an exception to the requirement for traditional retail pharmacies that don't do any tablet manipulation of hazardous drugs?	Commission discretion	
8/19/2021	USP 825	Introduction	2	5		The question should be corrected to read "Are vial ~~septums~~ septa wiped with sterile 70% isopropyl alcohol prior to initial needle punctures?" This language was purposely selected by the Expert Panel as evidenced by the language used later on "Wipe the septum with sterile 70% IPA frequently whenever multiple punctures are occurring (e.g., removing several individual doses from a multiple dose container)." There is not a required one-to-one correspondence between wiping the septa with a sterile 70% IPA swab and an aseptic insertion of a needle. The language should be corrected to reflect this distinction.	question comes from "Wipe the vial septum with sterile 70% isopropyl alcohol (IPA) prior to initial needle puncture." portion of citation; septa is the plueral of septum; agree that "initial" should be added	
8/19/2021	USP 825	Radiation Safety Considerations	3	6a		The question should be corrected to remove the typo; "Knowledge, training, experience, and professional judgment related to the type, abundance, and energy of ~~theradioactive~~ the radioactive emissions"	agree	
8/19/2021	USP 825	Radiation Safety Considerations	4	9		This question should be deleted, ~~"Do individuals wear body and, as required, extremity dosimeters for long-term monitoring of personnel radiation exposure?"~~ The issuance and wearing of dosimeters (whole body and rings) to record occupational radiation exposure of employees is regulated by the Radioactive Materials (RAM) License and has no place here. This language was included so BOP inspectors understand that nuclear pharmacists must wear body dosimeters and dosimeter rings (as required by their RAM license) under their gloves and to not consider them as they would consider regular jewelry rings.	citation is a continuation of 2.4, suggest adding the entire citation to to the self-inspection worksheet at the end of the current citation, portion in red refers to questions 9 & 10 "RADIATION DETECTORS AND MEASURING DEVICES Radiopharmaceuticals require measurement with a suitable radiation measuring device (e.g., dose calibrator). These and other necessary equipment, (e.g., monitors, bar code scanner, label printer) may be placed inside an ISO Class 5 PEC but should be placed in a manner that minimizes disruptions of airflow. As per RAM license requirements, individuals must wear body and, as required, extremity dosimeters (e.g., a ring worn on a finger) for long-term monitoring of personnel radiation exposure. The body dosimeter should be worn underneath the gown. Any extremity dosimeter must be worn underneath gloves and must not interfere with proper fit of gloves."	
8/19/2021	USP 825	Radiation Safety Considerations	4	9		This question should be deleted, ~~"Do individuals wear body and, as required, extremity dosimeters for long-term monitoring of personnel radiation exposure?"~~ The issuance and wearing of dosimeters (whole body and rings) to record occupational radiation exposure of employees is regulated by the Radioactive Materials (RAM) License and has no place here. This language was included so BOP inspectors understand that nuclear pharmacists must wear body dosimeters and dosimeter rings (as required by their RAM license) under their gloves and to not consider them as they would consider regular jewelry rings.	see above on line 6	
8/19/2021	USP 825	Immediate Use of Sterile Radiopharmaceuticals	4, 5, 6	Questions 11, 11a, 11b, 11c, 11d, 11f, 11g, 11h, 11i, 11j, 11k, 11l, 11m, 11m, 11n, 11o, 11p, 11q		This section on immediate use is not applicable to radiopharmacies because our RAM license prohibits us from injecting patients with radiopharmaceuticals. USP <825> states "This chapter applies to all practice settings where radiopharmaceuticals are prepared, compounded, dispensed, or repackaged. Practice settings consist of state-licensed nuclear pharmacies, federal nuclear pharmacy facilities, and other healthcare facilities, including, but not limited to: nuclear medicine departments in hospitals and clinics, nuclear cardiology clinics (fixed site or mobile), and other specialty clinics." As radiopharmacies operate ISO classified cleanroom suites, or at a minimum SRPAs, they will not be preparing any sterile radiopharmaceuticals in ambient air, for immediate use and injection into a patient. This entire section should be deleted as it is only applicable to hospital and clinic nuclear medicine departments, not pharmacies.	a facility can check N/A if appropriate to their setting	
8/19/2021	USP 825	Personnel Qualifications, Training, and Hygiene	12	45, 45a, 45b, 45c		As radiopharmacies operate ISO classified cleanroom suites, or at a minimum SRPAs, they will not be preparing any sterile radiopharmaceuticals in ambient air, for immediate use and injection into a patient. These questions should be deleted as they are only applicable to hospital and clinic nuclear medicine departments, not pharmacies.	a facility can check N/A if appropriate to their setting	
8/19/2021	USP 825	Facilities and Engineering Controls	19	82		This question is incorrect because of a misquote. It should read; "If used to compound sterile radiopharmaceuticals, are PECs located within an ISO Class 7 or better buffer area with an ISO Class 8 or better anteroom?" The direct quote from USP <825> is "If used only to prepare, prepare with minor deviations, dispense, or repackage sterile radiopharmaceuticals the ISO Class 5 PEC may be placed in an unclassified SRPA. If used to compound sterile radiopharmaceuticals, the PEC must be located within an ISO Class 7 or better buffer area with an ISO Class 8 or better anteroom." I refer you to Table 7. Preparation Conditions for Sterile Radiopharmaceuticals which allows an "ISO Class 8 or better buffer area with ISO Class 8 or better ante-room" to achieve a 24 hour BUD or an "ISO Class 7 or better buffer area with ISO Class 8 or better ante-room to achieve a 96 hour BUD". Of the 4 verbs in the title of USP <825>, preparation including preparation with minor deviations, dispensing, and repackaging sterile radiopharmaceuticals may occur in an ISO Class 8 buffer area with an ISO Class 8 or better ante-room. Compounding, must occur in an ISO Class 7 or better buffer area with an ISO Class 8 or better anteroom.	Commission discretion to add"If used to compound sterile radiopharmaceuticals" to the question to be more complete and reflect the citation	

8/19/2021	USP 825	Facilities and Engineering Controls	26	126		This question should be deleted, "~~Do all RAM users comply with the conditions specified in their approved RAM license application and regulations?~~" This paragraph explains that different facilities will have different RAM license requirements depending on the activities they perform, and radionuclides handled. Some facilities may require specific rooms and facilities to contain radioactive gasses and volatile compounds. An example is presented in the text.	question is pulled from the citation, the question does not differentiate the diffeences in facility type, only that the facility must comply with their approved RAM license applicaiton and regulations. citation as follows: "USP Chapter 825– 5.7 Environmental Controls All RAM users must comply with the conditions specified in their approved RAM license application and regulations, and RAM license conditions may supersede the following requirements for environmental controls described in this section."	
8/19/2021	USP 825	Assigning BUD	55, 56, 57	247, 247a, 247b, 247c, 247,d, 247e, 247f, 247g, 247h, 247i, 247j, 247k		Section 10.4 is a section that specifically deals with the radiolabeling of red blood cells that occurs in ambient air hence the title "10.4 Preparation of Radiolabeled Red Blood Cells for Immediate Use". As radiopharmacies operate under section 10.3 Preparation of Radiolabeled Blood Components with ISO Class 7 buffer rooms and ISO Class 8 ante rooms we will not be preparing any radiolabeled red blood cells in ambient air, for immediate use. This entire section should be deleted as it is only applicable to hospital and clinic nuclear medicine departments, not pharmacies.	a facility can check N/A if appropriate to their setting	
8/19/2021	USP 825	Dispensing	61	269c, 269d		Question 269c should be a header for 269d. The patient name / identifier is only required for therapeutic and blood products.	suggest combining 269c and 269d to read:"For all therapeutic and blood-products, the patient name/identifier" to match citation	
8/19/2021	USP 825	Dispensing	62, 63, 64	271, 272, 272a, 272b, 273, 273a, 273b, 273c, 273d, 273e, 273f, 273g		This section is limited to the sterility and aseptic technique for direct infusion systems that infuse radiopharmaceuticals directly into patients. This entire section should be deleted as it is only applicable to hospital and clinic nuclear medicine departments, not pharmacies.	a facility can check N/A if appropriate to their setting	
8/19/2021	USP 825					LETTER INTRO: The Nuclear & Precision Health Solutions (NPHS) Business of Cardinal Health is pleased to submit comments on the draft Washington Pharmacy Quality Assurance Commission Pharmacy Self-Inspection Worksheet for USP <825> Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging addendum. In the spirit of full disclosure, I personally served on the Expert Panel that wrote USP <825> Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging and am on the current USP Expert Panel on radiopharmaceuticals. I have the following comments. LETTER CONCLUSION: Cardinal Health can trace its lineage in the nuclear pharmacy industry back to the inception of centralized radiopharmacy practice in 1972. From that simple beginning, we have become one of the industry's leaders with 132 specialized radiopharmacies operating in 45 States, including radiopharmacies in Seattle and Spokane WA. Thank you again for allowing me to provide these comments on the proposed self-inspection form. If you would like to discuss any of the above comments, please feel free to contact me at 614-757-3174.	great comments, thank you for submitting them!	
8/23/2021	USP 800	List of Hazardous Drugs		Missing question based on requirements in the chapter	There is no question pertaining to the requirement of antineoplastic drugs and all HD API (table 1,2 or 3) requiring manipulation to follow all containment requirements within USP <800>.	I suggest an additional question to this section that asks " Do antineoplastic drugs requiring manipulation prior to administration and all HD API (NIOSH table 1, 2 and 3) follow all containment requirements defined in this chapter	no changes required; this is covered throughout the self-inspection document and USP 800	
8/23/2021	USP 800	List of Hazardous Drugs		4	This is incorrectly stated. NIOSH table 1 drugs (antineoplastics) requiring manipulation prior to administration and all HD API are not eligible for an assessment of risk for alternative containment strategies.	I suggest changing the questions to state " Is an assessment of risk performed on eligible hazardous drugs?" (NIOSH table 1 antineoplastics not requiring manipulation, table 2 and table3 hazardous drugs, not including any HD API)	no changes required; USP 800 box 1 outlines the requirments for hazardous drugs that can be determined from the assessment of risk for alternative containment strategies and work practices	
8/23/2021	USP 800	Facilities and Engineering Controls		20	Antineoplastic drugs in their final dosage forms can be stored with other non-HD inventory	I suggest changing this question to " Do you have all antineoplastic HDs requiring manipulation other than counting or repackaging and and all HD API stored separately from non-HDs?"	suggest rewording question to include qualifier from citation ("Antineoplastic HDs requiring manipulation other than counting or repackaging of final dosage forms and any HD API must be stored separately from non-HDs in a manner that prevents contamination and personnel exposure.") suggest reworded question be: " Are all antineoplatic HDs requiring manipulation, other than counting or repackaging of final dosage forms, and any API HDs stored separately from non-HDs?"	
8/23/2021	USP 800	Facilities and Engineering Controls		31	C-PEC is incorrect. This should be the C-SEC maintains ISO 7. Additionally, this requires the ISO 7 classification to be maintained throughout the nonsterile compounding process, not just in general.	I suggest changing this question to "If compounding nonsterile and sterile HDs in the same room, is the C-SEC able to maintain ISO 7 classification continuously throughout the non-sterile compounding activities?"	agree that rewording the question is a better reflection of citation; suggest: "If compounding nonsterile and sterile HDs in the same room, is the nonsterile C-PEC effective to allow the room to maintain ISO 7 classification throughout the nonsterile compounding activity?" citation is: "For entities that compound both nonsterile and sterile HDs, the respective C-PECs must be placed in separate rooms, unless those C-PECs used for nonsterile compounding are sufficiently effective that the room can continuously maintain ISO 7 classification throughout the nonsterile compounding activity.	

8/23/2021	USP 800	Facilities and Engineering Controls		Missing question based on requirements in the chapter	Under the section for 5.3.2 Sterile Compounding, there are no engineering requirements listed, except in the next section for C-SCAs. I suggest outlining the requirements for an HD Buffer room for sterile compounding, which does have additional requirements other than what have been listed in the above sections.	+ I suggest adding these two sections in this area: - "If the C-PEC is in an ISO 7 buffer room with an adjacent ISO 7 ante room, are the following requirements met?:" - The C-PEC is externally vented - The C-SEC is externally vented - The C-SEC has HEPA filtered air supply - The C-SEC has a minimum of 30 ACPH - The C-SEC maintains a negative pressure between 0.01 and 0.03 inches of water column - The C-SEC maintains an air quality of ISO Class 7 or better - A hand washing sink is located at in the ante room and is located at least 1 meter from the entrance into the HD buffer room - Both the anteroom and C-SEC have fixed walls + "If the C-PEC is located in an ISO 7 C-SEC with an ISO 7 ante room, does the room through which entry is made into the HD buffer room (e.g. ane room or non HD buffer room) meet the following requirements?": - Has a minimum of 30 ACPH of HEPA filtered supply air - Maintains a positive pressure of at least 0.02 inches of water column relative to all adjacent unclassified areas - Maintains an air quality of ISO Class 7 or better + I suggest editing #38, and combining #38 and #39, and adding an additional requirement regarding pass throughs. I recommend changing #38 to the following; - "If the negative pressure buffer room is entered through the positive pressure non-HD buffer room, are the following requirements met?" - A line of demarcation is defined in the negative pressure buffer room for donning and doffing PPE - A method to transport HDs, HD CSPs, and HD waste into and out of the negative pressure room is used that minimizes the spread of HD contamination - A refrigerator pass-through is not used to transport HDs, HD CSPs, and HD waste in and out of the negative pressure buffer room	agree that questions are missing based on USP 800 content, reference citation is also missing; suggest adding the following questions and citation found in additional questions tab (added as questions 38-48, incorporating old questions 38 and 39 renumbered):	
8/23/2021	USP 800	Facilities and Engineering Controls		41		+ Per current version of USP <800>, the terms category 1 and category 2 are not used + This should be changed to match the current language in USP <800> to, " Are only low and medium-risk HD CSPs prepared in the C-SCA?"	Commission discretion, please advise which language should be used. the terms category 1 and category 2 in the 2019 version of USP 800 match the proposed USP 797. The USP 800 offical version, effective May 2020, using the terms low- and medium-risk to match the current version of USP 797 current citation in USP 800 effective May 2020: "The C-PEC is placed in an unclassified C-SCA that has fixed walls, a negative pressure between 0.01 and 0.03 inches of water column relative to all adjacent areas, and a minimum of 12 ACPH. The C-SCA must be externally vented. A hand-washing sink must be placed at least 1 meter from C-PEC and may be either inside the C-SCA or directly outside the C-SCA. Only low- and medium-risk HD CSPs may be prepared in a C-SCA. HD CSPs prepared in the C-SCA must not exceed the BUDs described in <797> for CSPs prepared in a segregated compounding area."	
8/23/2021	USP 800	Personal Protective Equipment		53		+The way this question is worded makes it seem like you would exit the C-SEC without any shoe covers on. I recommend changing this question to the following; -Is a second pair of shoe covers donned prior to entering the C-SEC and doffed upon exiting C-SEC?"	Commission discrection	
8/23/2021	USP 800	Receiving		71 and 73		These questions appear to be duplicative. I recommend removing #73	agree, question 73 is the same as question 71, except question 71 uses the same language as the citation	
8/23/2021	USP 800	Dispensing Final Dosage Forms		91		- This question is misleading. Per USP <800>, this restriction only applies to antineoplastic HDs, not all HDs. I suggest changing this question to the following: + "Does the facility not place antineoplastic HDs in automated counting or packaging machines?"	Commission discretion	
8/23/2021	USP 800	Deactivating, Decontaminating, Cleaning and Disinfecting		117		As radiopharmacies operate ISO classified cleanroom suites, or at a minimum SRPAs, they will not be preparing any sterile radiopharmaceuticals in ambient air, for immediate use and injection into a patient. These questions should be deleted as they are on	a facility can check N/A if appropriate to their setting	
8/24/2021	USP 800	General Rule Reference				Is this worksheet's intent required for all pharmacies or just pharmacies that compound with hazardous products? In general, the form is very long and onerous for pharmacies that do not compound with hazardous products and would take away from patient care activities. If the intent is to address both compounding and traditional dispensing, I would suggest adding a question that asks if the pharmacy compounds and create a section for only the questions required for a pharmacy that does not compound.	Commission discretion	
8/24/2021	USP 800	List of Hazardous Drugs	2	4		The way the question is worded implies that all HDs need an assessment of risk. Propose to change the wording to “Did entity perform an assessment of risk?” and then use current question 5 (“If an assessment is not completed…”) as a subpart of question 4. Also propose to add back to the USP reference “For dosage forms of other HDs on the NIOSH list, the entity may preform an assessment of risk to determine alternate containment strategies and work practices.” to help clarify the question.	no changes required; USP 800 box 1 outlines the requirments for hazardous drugs that can be determined from the assessment of risk for alternative containment strategies and work practices	
8/24/2021	USP 800	Facilities and Engineering Controls	4	13		There is a typo in the question. Please correct “Do areas where HDs are handled have a hazard sign displayed before the entrance?”.	agree; correct typo to read "Do areas where HDs are handled have a hazard sign displayed before the entrance?"	
8/24/2021	USP 800	Facilities and Engineering Controls	5	23		Propose to add “Does sterile or non-sterile compounding of HDs occur in a C-PEC located in a C-SEC?” to further clarify.	Commission discretion	
8/24/2021	USP 800	Receiving	14	71 and 73		These questions are duplicative. Please remove one.	agree, question 73 is the same as question 71, except question 71 uses the same language as the citation	
8/24/2021	USP 800	Dispensing Final Dosage Forms	17	91		This question is missing clarifying verbiage that is in the USP reference. Propose to make the changes “Does the entity ~~facility~~ not place antineoplastic HDs in automated counting or packaging machines?”	"facility" is used to align with language in rules; Commission discretion on addition of antineoplastic	

8/25/2021	USP 800	List of Hazardous Drugs	2	1		USP Reference column must be updated with USP 800 revision statement on July 1st, 2020. It was published on USP 43-NF38. It states: “For the purposes of this chapter, the term antineoplastic only refers to antineoplastic drugs included in Table 1 of the most current NIOSH list.”	Commission discretion, please advise which language should be used. Language in the revised USP 800, that was changed in May 2020 and effective July 2020 reads: "The National Institute for Occupational Safety and Health (NIOSH) maintains a list of antineoplastic and other HDs used in healthcare. ▲For the purposes of this chapter, the term antineoplastic only refers to antineoplastic drugs included in Table 1 of the most current NIOSH List.▲ (RB 1-Jul-2020) An entity must maintain a list of HDs, which must include any items on the current NIOSH list that the entity handles. The entity’s list must be reviewed at least every 12 months. Whenever a new agent or dosage form is used, it should be reviewed against the entity’s list....."	
8/25/2021	USP 800	Responsibilities of Personnel Handling Hazardous Drugs	3	9		This question introduces a new term “entity HD program” which may confuse stakeholders since the terminology introduction from the L&I WAC. Would recommend revision to just ask if the entity has a qualified and trained person responsible for oversight of the entity’s hazardous drugs.	suggest changing entity to facility to align with Pharmacy rule language; the citation language indicates the designated individual is responsible for all aspects of the hazardous drug program (training, storage, environmental control, documentation) not just over the hazardous drugs, limiting the scope of the oversight in the question may not address the individual's full responsibility; citation: "Each entity must have a designated person who is qualified and trained to be responsible for developing and implementing appropriate procedures; overseeing entity compliance with this chapter and other applicable laws, regulations, and standards; ensuring competency of personnel; and ensuring environmental control of the storage and compounding areas."	
8/25/2021	USP 800	Responsibilities of Personnel Handling Hazardous Drugs	3	10		Consider removing this question. The responsible manager filling out the form may not be the designated person in USP 800, so the answer to this question would be very subjective. It would be the same as asking if all personnel who handle HDs understand the same principles.	Commission discretion	
8/25/2021	USP 800	Responsibilities of Personnel Handling Hazardous Drugs	3	11		Consider expanding the question to include all responsibilities mentioned in the chapter: Is the DP responsible for all of the following: • Developing and implementing appropriate procedures • Overseeing entity compliance with chapter USP 800 and other applicable laws, regulations and standards, • Ensure competency of personnel, • Ensure environmental control of storage and compounding areas • Overseeing facility monitoring and maintaining reports of testing/sampling performed and acting on the results.	question is derived from a portion of the entire citation, elements mentioned are included in question 9 under "HD program". the citation question 11 is derived from is: "The designated person must also be responsible for the oversight of monitoring the facility and maintaining reports of testing/sampling performed in facilities, and acting on the results."	
8/25/2021	USP 800	Facilities and Engineering Controls	5	20		Please specify that manipulation does not include counting and repackaging	please see line 18 above to address this comment	
8/25/2021	USP 800	Facilities and Engineering Controls	6	31		To add clarity that the ISO 7 classification is for the room (not the CPEC) please consider changing to say: If compounding sterile and non-sterile HDs in the same room, is the CPEC used for non-sterile compounding able to maintain ISO 7 classification of the room? In addition, please consider clarifying if sterile and non-sterile HD compounding can occur in the same Containment Segregated Compounded Area where the room does not have or need to maintain ISO7 classification.	please see line 19 above to address the first comment; Commission discretion on the second comment, question 31 is derived from the referenced citation, segregated compounding areas are discussed later in USP 800	
8/25/2021	USP 800	Facilities and Engineering Controls	6	34		To make it clear that manipulation does not include counting/repackaging please consider changing to say: Do C-PECs used for manipulation (not including counting/repackaging of tablets/capsules) of nonsterile HDs……..	Commission discretion; additional wording left out of the question to conserve space and the individual completeing the self-inspection has the citation next to the question to reference	
8/25/2021	USP 800	Facilities and Engineering Controls	8	38 and 39		Nothing wrong with these two questions however the section USP 800 5.3.2 Sterile Compounding has more information that should be provided thru more questions. i.e. There should be a question similar to question 33: “Does the facility follow USP <797> for sterile compounding? There should also be some questions about the Engineering Controls Configurations (ISO Class 7 buffer room with an ISO Class 7 ante-room or the Unclassified C-SCA) and types of BSC appropriate for HD sterile compounding. In addition a question about what to do when sterile compounding non-HDs in a BSC used for HD compounding is needed as this is a scenario that is likely to occur in pharmacies and there is guidance on what to do in section 5.3.2 Sterile Compounding of USP 800.	see line 20 above	
8/25/2021	USP 800	Facilities and Engineering Controls	8	40-42		USP Reference column is referencing a section of USP 800 that was revised in on the newest prints of USP 800. In previous version of USP 800 it used to state: “Only Category 1 HD CSPs….”The most current version (as of July 1st, 2020 published in USP 43-NF28) states: “Only low and medium-risk HD CSPs may be prepared in a C-SCA. HD CSPs prepared in the C-SCA must not exceed the BUDs described in <797> for CSPs prepared in segregated compounding area.”	see line above 21	
8/25/2021	USP 800	Facilities and Engineering Controls	8	41		See above comment. Consider changing the question to “Are only low and medium-risk HD CSPs prepared in the C-SCA?”	see line above 21	
8/25/2021	USP 800	Facilities and Engineering Controls	8	43		Consider removing this question. Administration of antineoplastics typically is not an activity performed by pharmacy personnel and as stated in the introduction of the worksheet, the self-inspection applies only to those activities performed by pharmacy personnel.	a facility can check N/A if appropriate to their setting	
8/25/2021	USP 800	Personal Protective Equipment	10	47e		Consider revision to “Outer gloves are changed every 30 minutes unless otherwise recommended…..” to add clarity to the process and the requirement from USP.	citation does not specifiy outer gloves only chemotherapy gloves, citation: "Chemotherapy gloves should be changed every 30 minutes unless otherwise recommended by the manufacturer’s documentation and must be changed when torn, punctured, or contaminated."	

8/25/2021	USP 800	Personal Protective Equipment	10	50		Consider adding clarity to this requirement as it may be taken out of context. “Clothing” means “Cloth laboratory coats, surgical scrubs, isolation gowns” as referenced in the previous paragraph of USP 800. If left as is it could also be interpreted as personal clothing which people may want to take home and properly wash if an accidental spill happened.	"clothing" is the language used in USP, an individual may reference the citation when completeing the self inspection, suggest updating citation to include entire citation (the portion in red was left out of the reference on the self-inspection): "When gowns are required, they must be disposable and shown to resist permeability by HDs. Gowns must be selected based on the HDs handled. Disposable gowns made of polyethylene-coated polypropylene or other laminate materials offer better protection than those made of uncoated materials. Gowns must close in the back (i.e., no open front), be long sleeved, and have closed cuffs that are elastic or knit. Gowns must not have seams or closures that could allow HDs to pass through. Cloth laboratory coats, surgical scrubs, isolation gowns, or other absorbent materials are not appropriate protective outerwear when handling HDs because they permit the permeation of HDs and can hold spilled drugs against the skin, thereby increasing exposure. Clothing may also retain HD residue from contact, and may transfer to other healthcare workers or various surfaces. Washing of non-disposable clothing contaminated with HD residue should only be done according to facility policy as drug residue may be transferred to other clothing. Potentially contaminated clothing must not be taken home under any circumstances. Gowns must be changed per the manufacturer’s information for permeation of the gown. If no permeation information is available for the gowns used, change them every 2–3 hours or immediately after a spill or splash. Gowns worn in HD handling areas must not be worn to other areas in order to avoid spreading HD contamination and exposing other healthcare workers.	
8/25/2021	USP 800	Personal Protective Equipment	12	57		Consider revision to : “Are outer chemotherapy gloves and sleeves covers carefully removed and discarded ….?” to add clarity to the USP 800 requirement. No ungloved hands should be inside a C-PEC so this requirement should only apply to the outer gloves. The inner gloves should be removed before leaving the C-SEC.	Commission discretion; language used in question is directly from USP 800	
8/25/2021	USP 800	Administering	17	97-103		Consider removing this section or asking more specifically; “Are HDs administered by pharmacy personnel in this facility? If yes continue to question 97. If no, skip to question 104. Administration is not activity usually performed by pharmacy personnel and not specifying whom the questions apply to would require the responsible manager to answer regarding other HCP activities (i.e. RNs).	Commission discretion; a facility can check N/A if appropriate to their setting	
8/25/2021	USP 800	Deactivating, Decontaminating, Cleaning and Disinfecting	20	115		Consider removing this question or revising to say: “If sodium hypochlorite is used as the deactivating agent, is there a neutralizing agent used afterwards to prevent corrosion?”. Again, not sure if this specific question is necessary since there are other EPA oxidizers with deactivation properties.	Commission discretion	

38. Does the facility follow <797> for sterile compounding?	In addition to this chapter, sterile compounding must follow standards in <797>. All C-PECs used for manipulation of sterile HDs must be externally vented. Sterile HD compounding must be performed in a C-PEC that provides an ISO Class 5 or better air quality, such as a Class II or III BSC or CACI. Class II BSC types A2, B1, or B2 are acceptable. For most known HDs, type A2 cabinets offer a simple and reliable integration with the ventilation and pressurization requirements of the C-SEC. Class II type B2 BSCs are typically reserved for use with volatile components. *Appendix 3* describes the different types of BSCs. A laminar airflow workbench (LAFW) or compounding aseptic isolator (CAI) must not be used for the compounding of an antineoplastic HD. A BSC or CACI used for the preparation of HDs must not be used for the preparation of a non-HD unless the non-HD preparation is placed into a protective outer wrapper during removal from the C-PEC and is labeled to require PPE handling precautions. The C-PEC must be located in a C-SEC, which may either be an ISO Class 7 buffer room with an ISO Class 7 ante-room (preferred) or an unclassified containment segregated compounding area (C-SCA). If the C-PEC is placed in a C-SCA, the beyond-use date (BUD) of all compounded sterile preparations (CSPs) prepared must be limited as described in <797> for CSPs prepared in a segregated compounding area. *Table 3* summarizes the engineering controls required for sterile HD compounding.
39. Are all C-PECs used for manipulation of sterile HDs externally vented?	
40. Do C-PECs maintain ISO class 5 or better air quality?	
41. Is an LAFW or CAI not used for compounding of an antineoplastic HD?	
42. Are non-HD preparations placed in a protective outer wrapper during removal from the C-PEC and labeled to require PPE handling precautions if prepared in a BSC or CACI?	
43. Is the C-PEC located in a C-SEC?	
44. Do BUDs of products compounded in a C-SCA follow <797>?	

45. If the facility has an ISO class 7 buffer room with an ISO class 7 ante-room:		ISO Class 7 buffer room with an ISO class 7 ante-room: The C-PEC is placed in an ISO Class 7 buffer room that has fixed walls, HEPA-filtered supply air, a negative pressure between 0.01 and 0.03 inches of water column relative to all adjacent areas and a minimum of 30 ACPH. The buffer room must be externally vented. Because the room through which entry into the HD buffer room (e.g., ante-room or non-HD buffer room) plays an important role in terms of total contamination control, the following is required: • Minimum of 30 ACPH of HEPA-filtered supply air • Maintain a positive pressure of at least 0.02 inches of water column relative to all adjacent unclassified areas • Maintain an air quality of ISO Class 7 or better An ISO Class 7 ante-room with fixed walls is necessary to provide inward air migration of equal cleanliness classified air into the negative pressure buffer room to contain any airborne HD. A hand-washing sink must be placed in the ante-room at least 1 meter from the entrance to the HD buffer room to avoid contamination migration into the negative pressure HD buffer room. Although not a recommended facility design, if the negative-pressure HD buffer room is entered though the positive-pressure non-HD buffer room, the following is also required: • A line of demarcation must be defined within the negative-pressure buffer room for donning and doffing PPE • A method to transport HDs, HD CSPs, and HD waste into and out of the negative pressure buffer room to minimize the spread of HD contamination. This may be accomplished by use of a pass-through chamber between the negative-pressure buffer area and adjacent space. The pass-through chamber must be included in the facility's certification to ensure that particles are not compromising the air quality of the negative-pressure buffer room. A refrigerator pass-through must
	a. does the buffer room have HEPA-filtered supply air?	
	b. is the C-SEC externally vented?	
	c. does the buffer room have 30 ACPH?	
	d. does the buffer room have negative pressure between 0.01 and 0.03 of water column relative to adjacent areas?	
	e. does the ante-room have a minimum of 30 ACPH of HEPA-filtered supply air	
	f. does the ante-room maintain a positive pressure of at least 0.02 inches of water column relative to all adjacent unclassified areas	
	g. does the ante-room maintain air quality of ISO Class 7 or better	
	h. does the ante-room have a hand-washing sink at least 1 meter from the entrance to the HD buffer room	

(old 38) 46. If using a negative-pressure HD buffer room, where the entrance is through the positive-pressure non-HD buffer room, does it have a line of demarcation?	not be used. Other methods of containment (such as sealed containers) may be used. HD CSPs prepared in an ISO Class 7 buffer room with an ISO Class 7 ante-room may use the BUDs described in <797>, based on the categories of CSP, sterility testing, and storage temperature.
(old 39) 47. If using a negative-pressure HD buffer room, where the entrance is through the positive-pressure non-HD buffer room, is there a method to transport HDs, HD CSPs, and HD waste into and out of the negative pressure buffer room that minimizes the spread of HD contamination?	
48. Does the facility not use a refrigerated pass-through?	

3.4

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

Department of Health
Pharmacy Quality Assurance Commission
Directive

Title:	Nonresident Pharmacy: Approved List of Recognized States
Reference:	House Bill 1412 RCW 18.64.360 (Effective July 28, 2019)
Contact:	Lauren Lyles-Stolz, PharmD., Executive Director
Effective Date:	July 28, 2019 (reaffirmed August 28, 2020)
Supersedes:	**N/A**
Approved:	Tim Lynch, PharmD, MS, FABC, FASHP, Pharmacy Quality Assurance Commission Chair

Background: In 2019 the Legislature passed HB 1412, this bill amends RCW 18.64.360 to state that upon initial licensure and at renewal a nonresident pharmacy must submit a copy of an inspection report that is conducted by a program with substantially equivalent standards to the commission and was issued within the last 2 years.

Determination of recognized states and third party inspection programs. Current RCW 18.64.270 requires that any medicinal products that are compounded shall at a minimum meet the standards of the official United States Pharmacopeia. Compliance with USP compounding standards was one of the primary focuses in determining the equivalency of states and recognized third party inspection programs. The Commission also used the National Association of Boards of Pharmacy (NABP) BluePrint Inspection criteria in making its determination.

- *List of Approved States* – these states inspect to substantially equivalent standards as Washington. This was determined by reviewing standards regarding compliance with USP, participating in NABP's BluePrint, or by using NABP Verified Pharmacy Program (VPP).

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

* Nonresident applicants and licensees may submit an inspection report from these states if the home state is not on the approved states list.

- *States that have substantially equivalent standards to Washington but do not meet Washington frequency standards* – these states hold pharmacies to substantially equivalent standards however they either do not perform inspections or inspections are not done within the 2 year requirement that is in law. Nonresident pharmacy applicants can work with their regulatory body to move up their inspection or use an approved third party inspection program to satisfy the requirements of RCW 18.64.360.

  - Delaware
  - Hawaii (no inspections)
  - Maine
  - Nebraska
  - New York

- *States that do not have substantially equivalent standards* – these states do not have substantially equivalent standards as Washington states, this includes not holding pharmacies to the minimum standard of USP. Pharmacies in these states would need to have an inspection done by an approved third party inspection program.

  - Alaska (inspections done on complaint)
  - Florida
  - Illinois (USP adopted in May 2019 but not 800)
  - Pennsylvania (inspected prior to USP adopted June 22, 2019)
  - South Carolina

- Wisconsin

- *Approved Third Party Inspection Program*
  - NABP VPP

The Commission will consider and reapprove the above list on an annual basis.

Need more information, see frequently asked questions.

Washington State Department of Health
Health Professions Quality Assurance

Application for Approval to Receive Lists

This is an application for approval to receive lists, not a request for lists. You may request lists after you are approved. Approval can take up to three months.

RCW 42.56.070(8) limits access to lists. Lists of credential holders may be released only to professional associations and educational organizations approved by the disciplining authority.

- A "professional association" is a group of individuals or entities organized to:
  - Represent the interests of a profession or professions;
  - Develop criteria or standards for competent practice; or
  - Advance causes seen as important to its members that will improve quality of care rendered to the public.
- An "educational organization" is an accredited or approved institution or entity which either
  - Prepares professionals for initial licensure in a health care field or
  - Provides continuing education for health care professionals.

☐ We are a "professional association" **X** We are an "educational organization."

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Street Address ⮥	City, State, Zip Code ⮥	

Survey of a sample of Washington State pharmacists

1. How will the lists be used? ⮥

Pharmacists

2. What profession(s) are you seeking approval for? ⮥

Please attach information that demonstrates that you are a "professional association" or an "educational organization" and a sample of your proposed mailing materials.
Attach completed application to your recent list request using the public portal:
https://www.doh.wa.gov/aboutus/publicrecords

Alternate options: Email to: PDRC@DOH.WA.Gov Mail to: PDRC - PO Box 47865 - Olympia WA 98504-7865

Signature ⮥ Date ⮥

If you have questions, please call (360) 236-4836.

For Official Use Only

Approved: _____ _____ (5-year / one-time)

Denied: _____

Authorizing Signature: _____

Printed Name: _____

Title: _____ Date: _____

Pharmacist experiences with Patient Mental Health

At work, how frequently have you encountered situations like these?	Never	Over a year ago	In the past year	In the past month
Person experienced a major life event (job loss, death of a loved one, end of relationship, loss of child custody)	☐	☐	☐	☐
Person appeared distressed (appeared depressed, tearful, anxious, overly tired)	☐	☐	☐	☐
Person was intoxicated	☐	☐	☐	☐
Person's dress/grooming showed a visible decline	☐	☐	☐	☐
Person's personality changed from friendly to withdrawn	☐	☐	☐	☐
Person mentioned their loneliness	☐	☐	☐	☐
Person mentioned their hopelessness	☐	☐	☐	☐

At work, how often have you encountered people in these situations?	Never	Over a year ago	In the past year	In the past month
Person made concerning statement suggesting suicide (E.g. world would be better off without them; wanted to go to sleep and not wake up)	☐	☐	☐	☐
Person told you they were planning to kill themselves	☐	☐	☐	☐
Person requested a lethal amount of medication	☐	☐	☐	☐
Person asked how much of a medication it would take to kill themselves	☐	☐	☐	☐
Person asked what would happen if they overdosed on a medication but didn't die	☐	☐	☐	☐

In the past year, how often have you done the following?	Never	1 time	2 or more times
Asked someone if they are considering suicide	☐	☐	☐
Referred someone to suicide crisis resources	☐	☐	☐
Counseled someone on locking up or restricting access to medications	☐	☐	☐
Counseled someone on disposing of medications	☐	☐	☐
Withheld/limited medication because you were concerned they may use it to harm themselves	☐	☐	☐

In what settings or contexts have you heard concerning statements about suicide? (select all that apply)

At work with patients	At work with co-workers	At work over the telephone	In my personal relationships
☐	☐	☐	☐

Please rate your level of agreement with the following statements	Strongly disagree	Disagree	Not sure	Agree	Strongly agree
Many suicides are preventable	☐	☐	☐	☐	☐
If a person wants to die by suicide, there is nothing I can do to stop them	☐	☐	☐	☐	☐
Asking directly about suicide will put the idea someone's head	☐	☐	☐	☐	☐
If I was concerned about someone, I would feel comfortable asking them if they were thinking about suicide	☐	☐	☐	☐	☐
There are adequate mental health resources in my community	☐	☐	☐	☐	☐
I have a good understanding of the mental health resources in my community	☐	☐	☐	☐	☐

Please rate your level of agreement with the following statements	Strongly disagree	Disagree	Not sure	Agree	Strongly agree	N/A
Locking and limiting access to medications can prevent suicides	☐	☐	☐	☐	☐	☐
I am comfortable talking to patients about who can access their medications	☐	☐	☐	☐	☐	☐
I am comfortable not dispensing medications to someone if i was concerned they may use them for suicide	☐	☐	☐	☐	☐	☐
I might offend my patients if i ask about their medication storage and disposal practices	☐	☐	☐	☐	☐	☐
My patients would not be interested in discussing medication storage and disposal	☐	☐	☐	☐	☐	☐

Please rate your level of confidence to do the following	Not confident	Not very confident	Neutral	Somewhat confident	Extremely confident
Identify suicide warning signs	☐	☐	☐	☐	☐
Listen non-judgmentally to someone in distress	☐	☐	☐	☐	☐
Ask a patient directly about suicide	☐	☐	☐	☐	☐
Ask a co-worker directly about suicide	☐	☐	☐	☐	☐
Ask a family member or friend directly about suicide	☐	☐	☐	☐	☐
Refer someone to suicide prevention resources	☐	☐	☐	☐	☐
Deliver simple messaging about locking and limiting access to medications	☐	☐	☐	☐	☐
The medications in my home are safe for preventing suicides	☐	☐	☐	☐	☐

Does your pharmacy or workplace have a policy about what to do if a patient or co-worker shares thoughts of suicide?

☐ Yes ☐ Not sure ☐ No

(Describe) _____

About you and your Workplace

What is your work setting? (Check all that apply)

- ☐ Independent Community
- ☐ Small Chain/Grocery
- ☐ Large Chain/Mass merchandiser
- ☐ Hospital Inpatient
- ☐ Clinic/Hospital Outpatient
- ☐ Other _____

What is your work role?

- ☐ Staff Pharmacist
- ☐ Clinical Pharmacist
- ☐ Manager/Owner
- ☐ Other _____

Do you consider your workplace to be in a small town / rural area? or a suburban / urban city?

- ☐ Rural/small town <50,000
- ☐ Suburban/urban city 50,000+

If you work with patients, which of the following services are offered at your site?

- ☐ Depression screening (PHQ-9, PHQ-2)
- ☐ Administer long-acting antipsychotic
- ☐ Dispense naloxone
- ☐ Drive thru pickup
- ☐ Comprehensive medication review
- ☐ Urgent care/minute clinic

Most of the time, how busy are you at work?

- ☐ I am often overwhelmed at work - always playing catch up
- ☐ Work steady, but manageable
- ☐ Work is usually slow and manageable

If you work in a pharmacy, for what fraction of your workday do you work as the only pharmacist?

- ☐ For 1/4 of my workday or less I work as the only pharmacist
- ☐ About half of my workday i work as the only pharmacist
- ☐ For most of my workday I work as the only pharmacist
- ☐ Not applicable to my role or workplace

What is your age group?

<30	30-39	40-49	50-59	60+
☐	☐	☐	☐	☐

For how many years have you been a pharmacist? _____

What is your gender? _____

What training in suicide prevention have you had? (Check all that apply)

☐ None

☐ Live **in person** program
(Mental health first aid, QPR, SAFER HOMES, etc)

☐ Online CE/Self study

☐ **Online virtual**, interactive training

Approximately how many hours of training related to suicide prevention have you had? _____

On a scale of 1-10, how useful was your training in suicide prevention to your professional and personal life?	**Not useful**									**Extremely useful**
Professional life	1	2	3	4	5	6	7	8	9	10
Personal life	1	2	3	4	5	6	7	8	9	10

In the past year, have you used your suicide prevention training with a patient? **Y**es / No

In the past year, have you used your suicide prevention training with a colleague? Yes / No

In the past year, have you used your suicide prevention training in your personal life? Yes / No

Is there an area at your workplace where you could have a private conversation with someone experiencing a mental health crisis? (E.g., counselling room, private office)

☐ Yes ☐ Yes, but not ideal ☐ No, not really

What other barriers do have to using your suicide prevention training in your professional life?

Thank you for completing this survey, your response along with responses from other pharmacists will help us better understand the experiences and needs of pharmacists who increasingly are working with patients with mental illness.

Please email **matthew-witry@uiowa.edu** with questions or concerns. If you would like to discuss these topics in more depth, please email matthew-witry@uiowa.edu to set up a time for an interview. We would like to hear your perspectives.

If you or someone you know is having thoughts of suicide, please call The National Suicide Lifeline at 800-273-8255

NATIONAL SUICIDE PREVENTION LIFELINE
1-800-273-8255

4.2

WAC 246-834-250 Legend drugs and devices. The midwife must have a procedure, policy or guideline for the use of each drug and device. A midwife may not administer a legend drug or use a legend device for which they are not qualified by education, training, and experience.

(1) Licensed midwives may purchase and use legend drugs and devices as follows:

(a) Dopplers, syringes, needles, phlebotomy equipment, sutures, urinary catheters, intravenous equipment, amnihooks, airway suction devices, electronic fetal monitors, tocodynamometer monitors, oxygen and associated equipment, glucose monitoring systems and testing strips, neonatal pulse oximetry equipment, hearing screening equipment, and centrifuges;

(b) Nitrous oxide as an analgesic, self-administered inhalant in a 50 percent blend with oxygen, and associated equipment, including a scavenging system;

(c) Limited, real time ultrasound of pregnant uterus for the confirmation of viability, first trimester dating, third

trimester presentation, placental location, and amniotic fluid assessment.

(d) Neonatal and adult resuscitation equipment and medication, including airway devices and epinephrine for neonates.

(2) Pharmacies may issue breast pumps, compression stockings and belts, maternity belts, diaphragms and cervical caps, glucometers and testing strips, iron supplements, prenatal vitamins, and recommended vaccines as specified in subsection (3)(e) through (j) of this section ordered by licensed midwives.

(3) In addition to prophylactic ophthalmic medication, postpartum oxytocic, vitamin K, Rho (D) immune globulin, and local anesthetic medications as listed in RCW 18.50.115, licensed midwives may obtain and administer the following medications:

(a) Intravenous fluids limited to Lactated Ringers, 5% Dextrose with Lactated Ringers, and 0.9% sodium chloride;

(b) Sterile water for intradermal injections for pain relief;

(c) Magnesium sulfate for prevention of maternal seizures pending transport;

(d) Epinephrine for use in maternal anaphylaxis and resuscitation and neonatal resuscitation, pending transport;

(e) Measles, Mumps, and Rubella (MMR) vaccine to nonimmune postpartum women;

(f) Tetanus, diphtheria, acellular pertussis (Tdap) vaccine for use in pregnancy;

(g) Hepatitis B (HBV) birth dose for any newborn administration;

(h) HBIG and HBV for any neonates born to hepatitis B+ mothers;

(i) Influenza vaccine for use in pregnancy;

(j) Any vaccines recommended by the CDC advisory committee on immunization practices for pregnant or postpartum people or infants in the first two weeks after birth, as it existed on the effective date of this section;

(k) Terbutaline to temporarily decrease contractions pending emergent intrapartal transport;

(l) Antibiotics for intrapartum prophylaxis of Group B beta hemolytic Streptococcus (GBS) per current CDC guidelines;

(m) Antihemorrhagic drugs to control postpartum hemorrhage including, but not limited to, oxytocin, misoprostol, methylergonovine maleate (oral or intramuscular), and prostaglandin F2 alpha: and

(n) Nasopharyngeal or nasal swabs for appropriate testing.

(4) The client's records must contain documentation of all medications administered.

[Statutory Authority: RCW 18.50.135 and 18.50.115. WSR 19-15-005, § 246-834-250, filed 7/5/19, effective 8/5/19. Statutory Authority: RCW 18.50.115. WSR 05-06-118, § 246-834-250, filed 3/2/05, effective 4/2/05. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-834-250, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 18.50.040(3) and 18.50.115. WSR 88-12-040 (Order PM 732), § 308-115-250, filed 5/27/88.]

Request for Consideration by the Pharmacy Quality Assurance Commission

N O T I C E

Documents submitted to the Pharmacy Quality Assurance Commission (Commission) are public records, subject to the Public Records Act, chapter 42.56 RCW, and presumptively open to public inspection and copying. The Commission will make meeting materials available for public inspection and copying on the Commission's website, including records submitted by you concerning your requests for review or approval to the Commission. If you believe any of these records may be exempt from disclosure under RCW 42.56.270(11) ("Proprietary data, trade secret, or other information that relates to (a) . . . unique methods of conducting business, (b) data unique to [your] product or services), then do not submit the records. Instead, you may seek a court order protecting those records as authorized in RCW 19.108.020(3), providing notice of the proceeding to the Commission. The materials may be submitted to the Commission in a manner consistent with an order of the court when the legal proceeding has concluded.*

Requester/Title/Credentials:	**Jennifer Santiago, Acting Midwifery Executive Director**
Contact Email/Phone #:	**360-236-4893**
Affiliation:	**Department of Health**

Complete the following fields if this request applies to an active or pending license (includes registration, or certification). If needed, include additional information on separate paper.

License Name:	**NA**
License/site Address:	
License Number:	

What is your preferred date to have your request considered by the Commission:	1st Date	October 21, 2021	2nd Date	
What is your expected outcome by the Commission?	☐ Action	☒ Information	☒ Follow-up	☐ Report only

Please attach any policies, procedures or other documentation deemed necessary to support his proposal. Visit the commission's webpage for approved guidelines, review forms or current laws and rules.

This completed form should be no longer than two pages, front to back.

Situation: (Briefly describe the current situation. Give a clear, succinct overview of relevant issues)

The midwifery program is in the process of updating the legend drugs and devices rule for licensed midwives in Washington. The midwifery statute, chapter 18.50 RCW, states "the secretary, after consultation with representatives of the midwife advisory committee, the pharmacy quality assurance commission, and the medical quality assurance commission, may adopt rules that authorize licensed midwives to purchase and use legend drugs and devices in addition to the drugs authorized in the chapter."

Request for Consideration by the Pharmacy Quality Assurance Commission

Background: (Briefly name any laws, rules, or guidelines relevant to the request):

The midwifery statute, RCW 18.50.115, states that midwives can obtain and administer certain legend drugs, and additionally purchase and use legend drugs and devices adopted in rule (WAC 246-834-250). This rule was last updated in 2017, after consultation with the Medical and Pharmacy Commissions.

The proposed language (attached) has been recommended by the Midwifery Advisory Committee (MAC).; a seven member Secretary-appointed committee with two physicians (one which must be an obstetrician), one certified nurse midwife, three licensed midwives, and one public member. The MAC discussed draft language during 2021open public meetings determining the appropriate language for the legend drugs and devices section.

The MAC is currently consulting with the Medical Quality Assurance Commission.

Assessment: (If approved, what would be the expected outcome for patient safety? What is the consequence if this request is not approved?)

In the spirit of public health, the midwifery legend drugs and devices section needs to be updated. Modernizing the rule section will continue to make out of hospital births a safe option.

Request: (What action(s) are you asking the commission to take? What do you want to happen next?

The statute requires that we consult with the pharmacy commission before adopting rule language. We would appreciate any feedback on the draft language.

Washington State Department of Health

4.3

Drug Other Controlled Substance Registration Application Packet

Contents:

In order to process your request:

Mail your application with initial documentation and your check or money order payable to:

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

Send other documents not sent with initial application to:

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

Contact us:

360-236-4700

(This page intentionally left blank.)

Washington State Department of Health

Drug Other Controlled Substance Registration Application Checklist and Instructions

☐ Indicate type of application—New, change of ownership, change of location, or name change.

- **New**—First time requesting a controlled substance registration.
- **Change of Ownership**—When name of legal owner/operator changes resulting from the sale of licensed agency.
- **Change of Location**— Change the location address. Be sure to include your current license number.
- **Name Change Only**— Changing the name of your organization. Be sure to list your current facility name.

☐ **Check One:**
Please check your legal owner/operator business structure type according to your Washington State Master Business License.

☐ **Application Fees:** Check one; with controlled substance or without controlled substance. Fees are non-refundable. You can check the online **fee page** for current fees.

☐ **1. Demographic Information:**

Uniform Business Identifier Number (UBI #): Enter your Washington State UBI #. All Washington State businesses must have UBI #'s. City, county, and state government departments also have UBI#'s.

Federal ID Number (FEIN #): Enter your Federal ID Number, if the business has been issued one.

Legal Owner/Operator Name: Enter the owner's name as it appears on the UBI/ Master Business License.

Mailing Address: Enter the owner's complete mailing address.

Phone and Fax Numbers: Enter the owner's phone and fax number.

Email and Web Address: Enter the owner's email and agency Web addresses, if they have them.

Facility/Agency Name: Enter the agency's name as advertised on signs, brochures or Web sites.

Physical Address: Enter the agency's physical street location including city, state, zip code, and county.

Phone and Fax Numbers: Enter the agency's phone and fax number.

Mailing Address: Enter the agency's mailing address, if different than physical address.

Email Address: Enter the agency's email address, if available.

☐ **2. Facility Specific Information:**
Check Facility Type:

- Analytical labs
- Methadone treatment facility
- School laboratories

Background Questions: Check yes or no and if you check yes, list and explain on a separate sheet of paper.

Drug Enforcement Administration (DEA) Number : Enter your DEA number

☐ **3. Key Individuals:**
Enter name, title, telephone number, and email address.

☐ **4. Primary Registrant Information:**
Enter name, telephone number, registration date, and date of appointment.

☐ **5. Additional Information:**
Corporation information: Enter date of incorporation, corporate number, and state of corporation.

Legal Owner: List the names, titles, addresses, and phone numbers of the corporate officers, partners, member, managers, etc. Attach additional sheet, if necessary.

Change of Ownership Information: If applicable, list the previous legal owner name, previous name of facility, previous license #, effective date of ownership change and physical address.

☐ **Signature:**

Signature of legal owner or authorized representative.

Date signed.

Print name of legal owner or authorized representative.

Print title of legal owner or authorized representative.

Washington State Department of Health

Date Stamp Here

Fees (check all that apply)
☐ Drug Other Controlled Registration
☐ Precursur Chemical
Check the **fee page** for current fees.
All application fees are nonrefundable

Revenue: 0262010000

Drug Other Controlled Substance Registration Application

This is for: ☐ New ☐ Change of Ownership

☐ Change of Location-Current License # _____

☐ **Name Change Only (Reissue Fee)**- Current Facility Name _____

Check One

☐ Association	☐ Limited Partnership	☐ Sole Proprietor
☐ Corporation	☐ Municipality (City)	☐ State Government Agency
☐ Federal Government Agency	☐ Municipality (County)	☐ Tribal Government Agency
☐ Limited Liability Company	☐ Non-Profit Corporation	☐ Trust
☐ Limited Liability Partnership	☐ Partnership	

1. Demographic Information

UBI #		Federal Tax ID (FEIN) #	
Legal Owner/Operator Name			
Mailing Address			
City	State	Zip Code	County
Phone (enter 10 digit #)		Fax (enter 10 digit #)	
Email Address		Web Address	
Facility/Agency Name (Business name as advertised on signs or Website)			
Physical Address			
City	State	Zip Code	County
Facility Phone (enter 10 digit #)		Fax (enter 10 digit #)	
Mailing Address (If different than physical address)			
City	State	Zip Code	County

2. Facility Specific Information

Check One:

☐ Analytical Labs ☐ Methadone Treatment Facility ☐ School Laboratories

Background Questions Yes No

1. Have any applicants, partners, or managers had a suspension, revocation, or restriction of a professional license? ..... ☐ ☐
   If yes, list and explain on a separate sheet of paper.
2. Have any applicants, partners, or managers been found guilty of a drug or controlled substance violation? ..... ☐ ☐
   If yes, list and explain on a separate sheet of paper.

Drug Enforcement Administration (DEA) Number

Enter Drug Enforcement Administration (DEA) #_____

3. Key Individuals

Contact Person Name _____ Title _____

Phone (enter 10 digit #) _____ Email Address _____

4. Primary Registration

Name _____ Phone (enter 10 digit #) _____

Registration Date _____ Date of Appointment _____

5. Additional Information

Date of Incorporation	Corporate Number	State of Corporation

Legal Owner Information–attach additional sheets as needed

List names, addresses, phone numbers, and titles of corporate officers, partners, members, managers, etc.

Name	Address	Phone number	Title

Change of Ownership Information

Previous Name of Legal Owner

Previous Name of Facility	Previous Pharmacy License #	Effective Date of Ownership Change

Physical Address

Signature

I certify I have received, read, understood, and agree to comply with state law and rule regulating this licensing category. I also certify the information herein submitted is true to the best of my knowledge and belief.

_____ _____

Signature of Owner/Authorized Representative of Pharmacy | Date

_____ _____

Print Name | Print Title

RCW/WAC and Online Website Links

RCW/WAC Links

Uniform Disciplinary Act, RCW 18.130

Administrative Procedure Act, RCW 34.05

Administrative Procedures and Requirements, WAC 246-12

Pharmacy Laws, RCW 18.64

Pharmacy Rules, WAC 246-879

On-Line

Pharmacy Quality Assurance Commission, Web Page

5.1

From: Trant, Lindsay A (DOH)
To: Miller, Joanne (DOH)
Subject: FW: URGENT REVIEW PLEASE: Request for ruling making for accessible medication labels
Date: Thursday, October 14, 2021 1:15:05 PM
Importance: High

Rules petition on accessible medication labels below.

From: Judiith Ingraham Brown <jeibrown726@gmail.com>
Sent: Wednesday, September 8, 2021 3:46 PM
To: DOH WSPQAC <WSPQAC@doh.wa.gov>
Cc: Dorene Cornwell <dorenefc@gmail.com>; Sheri Richardson <sherir938@gmail.com>
Subject: Request for ruling making for accessible medication labels

External Email

To Whom It May Concern,

The Washington Council of the Blind Advocacy and Governmental Affairs Committees are requesting that the Washington Pharmacy Compliance Board create rules to require pharmacies in Washington State to offer accessible labeling on medication bottles. The Food and Drug Administration Safety Innovation Act of 2012, section 904, tasked the US Access Board to develop Best Practices for Accessible Medication Labels. The National Council on Disability along with the American Council of the Blind put together an online information site (www.ncd.gov) and brochure highlighting best practices for pharmacies who serve low-vision and blind persons. However, these were only recommendations. Therefore, many pharmacies, including pharmacies based in Washington state either do not follow these recommendations or only offer large print but no other accessible labeling options.

Over 25 million Americans age 65 and older have low-vision or are blind. This makes reading labels impossible without accommodations. I am legally blind and cannot see or read medication labels. When I asked my local Costco pharmacy for large print labels, I was told they did not offer that service. I then asked how was I, as a legally blind person, supposed to read the small print on my medication bottle? I was told I needed to find someone to read the label to me. This is insulting. My privacy and independence are being taken away due to lack of understanding, professionalism and a failure to follow basic best practices guidelines for accessible medication labels. This is only one example of many such stories throughout Washington state involving other visually impaired persons. There is no consistency and therefore, patient safety is affected depending the pharmacy a person uses. In some areas of Washington, there

are very few pharmacy choices. So, if you have to use a pharmacy that does not offer accessible labeling you are at risk for an avoidable medication error.

With the advances that En-Vision has made with Script Talk labeling, accessible medication labels are now available to other patient populations. Those who are reading impaired (dyslexia, low reading comprehension, English as a second language and others) now have a way to have way to know what the label says in an easy to use manner. This means many more patients could be positively impacted with this technology. Patient/consumer safety will increase.

Patient caused medication errors is a major reason for emergency room visits and, at times, hospitalization. The CDC estimates that non-adherence to medication treatments cause 30 to 50% of the chronic disease treatment failures. Furthermore, medications are not taken as prescribed about 50% of the time. While non-adherence to medication regimens has several causes, one major cause is understanding or being able to properly read the label.

Patient caused medication errors are avoidable. Communication is a key component is stopping these errors. Offering accessible medication labels will go a long way in improving medication communication.

Thank you for considering this request. Please feel free to contact me with any questions.

Judy Brown, RN, BSN
Washington Council of the Blind
Co-Chair Advocacy Committee
Member Governmental Affairs Committee
Jeibrown726@gmail.com
207-944-1837
Shoreline, WA 98133

5.2

RULE-MAKING ORDER
EMERGENCY RULE ONLY

CR-103E (December 2017)
(Implements RCW 34.05.350 and 34.05.360)

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: September 30, 2021
TIME: 8:13 AM

WSR 21-20-076

Agency: Department of Health- Pharmacy Quality Assurance Commission

Effective date of rule:

Emergency Rules

☒ Immediately upon filing.
☐ Later (specify)

Any other findings required by other provisions of law as precondition to adoption or effectiveness of rule?

☐ Yes ☒ No If Yes, explain:

Purpose: WAC 246-945-171 Retired active pharmacist license status, establishing a new section of rule. This adopted emergency rule will extend WSR 21-12-096 filed on June 2, 2021 without change. On March 26, 2020, Governor Inslee signed proclamation 20-32 to help increase the number of healthcare workers available to meet the needs of patients during the coronavirus disease 2019 (COVID-19) pandemic. This proclamation included a provision that allows a pharmacist with a retired active pharmacist license status to practice pharmacy. Specifically, the proclamation amended WAC 246-863-080(2), which was effective at that time, to allow holders of a retired active pharmacist license status to practice pharmacy while the proclamation remains in effect.

The Pharmacy Quality Assurance Commission (commission) updated and consolidated all rules under its authority into one new chapter (chapter 246-945 WAC), effective July 1, 2020. In this rewrite process the requirements from WAC 246-863-080 and the retired active pharmacist license status were repealed. Beginning July 1, 2020 chapter 246-945 WAC took effect and the commission no longer enforces WAC 246-863-080. In order to meet the intent of the Governor's proclamation and allow retired pharmacists to assist with the COVID response with pharmacy services such as vaccine administration, there must be a retired active pharmacist license rule in place. The adopted rule will reinstate the retired active pharmacist credential and allow a pharmacist to apply for a retired active pharmacist license status. The holder of a retired active pharmacist license is allowed to practice during emergent or intermittent circumstances and assist with the COVID-19 response. This emergency rule also establishes the criteria for returning to active status.

Citation of rules affected by this order:

New: WAC 246-945-171
Repealed: N/A
Amended: N/A
Suspended: N/A

Statutory authority for adoption: RCW 18.64.005; RCW 18.64.205

Other authority:

EMERGENCY RULE

Under RCW 34.05.350 the agency for good cause finds:

☒ That immediate adoption, amendment, or repeal of a rule is necessary for the preservation of the public health, safety, or general welfare, and that observing the time requirements of notice and opportunity to comment upon adoption of a permanent rule would be contrary to the public interest.

☐ That state or federal law or federal rule or a federal deadline for state receipt of federal funds requires immediate adoption of a rule.

Reasons for this finding: The immediate adoption of WAC 246-945-171 is necessary for the preservation of public health, safety, and general welfare. This rule allows retired pharmacists to assist in the response during public health emergencies such as the COVID-19 pandemic and is in line with the intent of Governor Inslee's proclamation 20-32. This emergency rule allows retired pharmacists to help meet the needs of patients during the COVID-19 pandemic through performing pharmacy services such as vaccine administration. Observing the time requirements of notice and opportunity to comment upon adoption of a permanent rule would be contrary to the public interest and the Governor's orders.

The commission has also authorized permanent rules on this topic and is proceeding with standard rulemaking as the COVID-19 response allows. A CR 101 to begin the permanent rulemaking process was filed on April 19, 2021 (WSR 21-09-063), but will not be complete by the time the current emergency rules expire.

Note: If any category is left blank, it will be calculated as zero. No descriptive text.

Count by whole WAC sections only, from the WAC number through the history note. A section may be counted in more than one category.

The number of sections adopted in order to comply with:

Federal statute:	New	0	Amended	0	Repealed	0
Federal rules or standards:	New	0	Amended	0	Repealed	0
Recently enacted state statutes:	New	0	Amended	0	Repealed	0

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

	New	0	Amended	0	Repealed	0

The number of sections adopted on the agency's own initiative:

	New	1	Amended	0	Repealed	0

The number of sections adopted in order to clarify, streamline, or reform agency procedures:

	New	0	Amended	0	Repealed	0

The number of sections adopted using:

Negotiated rule making:	New	0	Amended	0	Repealed	0
Pilot rule making:	New	0	Amended	0	Repealed	0
Other alternative rule making:	New	1	Amended	0	Repealed	0

Date Adopted: July 16, 2021	**Signature:** 
Name: Teri Ferreira, RPh	
Title: Pharmacy Quality Assurance Commission Chair	

NEW SECTION

WAC 246-945-171 Retired active pharmacist license status. (1) A pharmacist may apply for a retired active pharmacist license status if they:

(a) Hold an active pharmacist license issued by the commission under chapter 18.64 RCW that is in good standing;

(b) Submit an application on a form provided by the commission; and

(c) Pay the retired credential application fee as specified in WAC 246-907-030.

(2) A pharmacist with a retired active pharmacist license status shall practice only in emergent or intermittent circumstances.

(a) "Emergent" includes, but is not limited to, earthquakes, floods, times of declared war or other states of emergency.

(b) "Intermittent" means no more than a total of ninety days each year in Washington state.

(3) A pharmacist with a retired active pharmacist license status must renew every year, comply with WAC 246-12-130 and pay the retired credential renewal fee in WAC 246-907-030.

(4) To return to active status, a retired active pharmacist must comply with WAC 246-12-140 and pay the pharmacist license renewal fee in WAC 246-907-030.