Washington State Department of HEALTH
Pharmacy Quality Assurance Commission
PO Box 47852 Olympia, WA 98504
www.doh.wa.gov · TDD Relay: 711

February 1, 2024
Business Meeting Agenda

Time:	9:00 AM (Open Session)
Location:	**Zoom:** https://us02web.zoom.us/j/87143495001 One tap mobile: US: +12532050468,,88256001236# or +12532158782,,88256001236# Or Telephone: (for higher quality, dial based on your location): US: +1 253 205 0468 or +1 253 215 8782 or +1 346 248 7799 **In Person:** Labor & Industries, Room S117 7273 Linderson Way SW, Tumwater, WA 98501
Contact:	Julia Katz, Program Consultant, 360-791-1167 and julia.katz@doh.wa.gov or
Commission Office:	wspqac@doh.wa.gov

No registration needed. **All attendees will join the call with their audio connection muted.**

The times on the agenda for this meeting are approximate and subject to change. The commission may need to adjust times or order of agenda items. The commission may take final action on any matter listed on the agenda, and/or on any matter added to the agenda in a regular meeting. The commission may meet in an executive session closed to the public for any reason listed in RCW 42.30.110 and may take final action in the public portion of the meeting following an executive session. The reason for the executive session and duration will be announced prior to the start of the executive session. The commission may meet in a closed session during this meeting for any reason listed in RCW 42.30.140, including but not limited to deliberations on enforcement (quasi-judicial) matters.

This meeting is being recorded for the Department of Health, Pharmacy Quality Assurance Commission's Official Rulemaking file and for future reference.

9:00 am

1. Call to Order *Action*

- **1.1.** Meeting Agenda Approval – February 1, 2024
- **1.2.** Meeting Minutes Approval – December 14, 2023
- **1.3.** Meeting Minutes Approval – December 15, 2023

9:10 am

2. Consent Agenda Items listed under the consent agenda are considered routine and necessary commission matters and will be approved by a single motion of the commission without separate discussion. If separate discussion is desired, that item will be removed from the consent agenda and placed on the regular business agenda. *Information/Action*

- **2.1.** Correspondence
  - **2.1.1.** National Precursor Log Exchange Monthly Dashboard – December

2.1.2. Pharmaceutical Firms Application Report

2.2. Ancillary Utilization Plans Approval

2.2.1. Accredo Health Group
2.2.2. Animal Health International Inc.
2.2.3. Multicare Infusion Pharmacies
2.2.4. Prescription Pharmacy
2.2.5. Rx Mart Pharmacy
2.2.6. SNP Rx Northwest
2.2.7. Tick Klock Drug
2.2.8. Valley View Health Care Pharmacy
2.2.9. Colton Pharmacy
2.2.10. One Point Patient Care OP Pharmacy LLC
2.2.11. Pharmacy4Humanity
2.2.12. Prime Pharmacy

2.3. Pharmacy Technician Training Program Approval

2.3.1. Seattle Indian Health Board
2.3.2. Prescription Pharmacy

2.4. Regular Agenda Items Pulled from 2.1, 2.2, or 2.3. The commission will discuss items removed from the consent agenda and placed on the regular agenda for separate discussion.

9:40 am

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

3.1. Presentation from Project Pathway

10:10 am

4. **Commission Member Reports**

4.1. Budget Report

10:30 am

5. **Old Business**

5.1. Presentation on Healthcare Enforcement and Licensing Management System (HELMS)
5.2. 2024 Self-Inspection Worksheets

11:20 am

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

6.1. 2024 PQAC Master Calendar Approval
6.2. Voting Delegates for 2024 NABP Annual Meeting

11:30 pm

7. **Rules Project Updates** *Information/Action*

7.1. Rules Workshop: Prescription Transfer Requirement
7.2. Emergency Rule Refile Request: Over-the-Counter Naloxone Incorporation by Reference
7.3. CR-103P Authorization: USP Incorporation by Reference

7.4. CR-103P Authorization: Technical Edits in Chapter 246-945 WAC
7.5. Policy Statement: Extension Process for Pharmacy Intern Renewal Limitation
7.6. Policy Statement: Temporary Practice Permits for Military Spouse Pharmacy Interns

12:30 pm
8. **Legislative Session Bill Report** *Information/Action*

1:00 pm
9. **Open Forum** (10 minutes). *Information Only.* The purpose of open forum is to provide the public an opportunity to address the commission on issues of significance to or affecting the practice of pharmacy. Discussion items may not relate to topics for which a hearing has or will be scheduled, or which are under investigation.

1:10 pm
10. **Commission Member Reports** Information
10.1. Open Discussion Related to Items or Issues Relevant to Commission Business/Pharmacy Practice

1:20 pm
11. **Staff Reports** *Information*
11.1. Executive Director – Marlee O'Neill
11.2. Pharmacy Inspector Supervisor – Si Bui
11.3. Assistant Attorney General – Christopher Gerard

1:30 pm
12. **Summary of Meeting Action Items** Commissioners and staff will revisit action items identified during today's business meeting.

1:35 pm (approximately)
Business Meeting Adjourned

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: **March 7, 2024**
9:00 a.m.
Labor and Industries and
Zoom ID# 871 4349 5001

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.

Commission Meeting Schedule

Agendas for the meetings listed below are made available in advance via e-mail list and the DOH website. Every attempt is made to ensure that the agenda is up-to-date. However, the commission reserves the right to change or amend agendas at the meeting. Meetings listed below are regular business meetings unless otherwise specified.

(Meeting times/locations subject to change – No registration required.)

Meeting	Date/Time	Location
Weekly Legislative Calls	**January 5 – March 15, 2024** 12 pm – 1 pm	Zoom # 871 4349 5001 Location: TBD
Business Meeting	**March 7-8, 2024** 9 am – 3 pm	Zoom # 871 4349 5001 and L&I, 7273 Linderson Way S.W.
Business Meeting	**May 2-3, 2024** 9 am – 3 pm	Zoom # 871 4349 5001 and ESD113, 6005 Tyee Dr., S.W.
Business Meeting	**June 27-28, 2024** 9 am – 3 pm	Zoom # 871 4349 5001 and ESD113, 6005 Tyee Dr., S.W.
Business Meeting	**August 22-23, 2024** 9 am – 3 pm	Zoom # 871 4349 5001 and L&I, 7273 Linderson Way S.W.
Business Meeting	**October 10-11, 2024** 9 am – 3 pm	Zoom # 871 4349 5001 and L&I, 7273 Linderson Way S.W.
Business Meeting	**December 12-13, 2024** 9 am – 3 pm	Zoom # 871 4349 5001 and L&I, 7273 Linderson Way S.W.

2.1.1. National Precursor Log Exchange Monthly Dashboard – December

MONTHLY PROGRAM ADMINISTRATOR'S DASHBOARD

0 Logins - 0 Searches - 0 Report Queries - 21 Active Watches - 0 Active Watch Hits

NEW USERS THIS MONTH	TOP USAGE AGENCIES	TOP AGENCIES BY ACTIVE WATCHES
New Users = 0	TOP USERS BY USAGE	1. ICE - King County (32)
Total Accounts = 144		
Active Users = 0		

TRANSACTION SUMMARY STATISTICS (2023)

	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC	TOTAL
PURCHASES	71,650	69,842	81,463	75,970	78,412	79,249	64,423	60,350	71,428	70,893	70,043	79,650	**873,373**
BLOCKS	3,237	3,382	3,985	3,657	4,049	4,169	3,161	2,720	3,003	3,960	3,090	3,278	**41,691**
GRAMS SOLD	149,571	145,519	177,064	166,664	180,078	181,015	147,213	134,301	150,884	147,981	145,274	162,032	**1,887,596**
BOXES SOLD	81,434	79,115	91,959	86,273	88,279	89,812	73,523	68,692	79,937	79,777	77,725	88,010	**984,536**
GRAMS BLOCKED	8,604	8,664	10,706	9,791	11,005	11,827	8,815	7,283	7,872	10,941	8,163	8,820	**112,491**
BOXES BLOCKED	3,774	3,863	4,516	4,164	4,507	4,775	3,744	3,122	3,557	4,420	3,446	3,877	**47,765**
AVG GRAMS PER BOX BLOCKED	2.28	2.24	2.37	2.35	2.44	2.48	2.35	2.33	2.21	2.48	2.37	2.27	**2.35**

PHARMACY PARTICIPATION STATISTICS (Dec 2023)

Enabled Pharmacies	966
Pharmacies Submitting a Transaction	888
Pharmacies Logging in Without a Transaction	0
Inactive Pharmacies	78
Pharmacy Participation for Dec	91.93%

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 krista.mccormick@equifax.com.

2.1.2. Pharmaceutical Firms Application Report

Credential #	Status	First Issuance Date
DRSD.FX.61483700	ACTIVE	12/04/2023
DRSD.FX.61510617	ACTIVE	12/04/2023
PHNR.FO.61503483	ACTIVE	12/04/2023
PHNR.FO.61503514	ACTIVE	12/04/2023
PHNR.FO.61511292	ACTIVE	12/04/2023
PHNR.FO.61508199	ACTIVE	12/04/2023
PHNR.FO.61502663	ACTIVE	12/04/2023
PHNR.FO.61502649	ACTIVE	12/06/2023
PHNR.FO.61487308	ACTIVE	12/06/2023
PHWH.FX.61510291	ACTIVE	12/06/2023
DRCS.FX.61496320	ACTIVE	12/07/2023
DRSD.FX.61512569	ACTIVE	12/07/2023
DRSD.FX.61502635	ACTIVE	12/07/2023
PHNR.FO.61509171	ACTIVE	12/07/2023
PHWH.FX.61488380	ACTIVE	12/07/2023
PHWH.FX.61502629	ACTIVE	12/07/2023
PHWH.FX.61483253	ACTIVE	12/11/2023
PHWH.FX.61447674	ACTIVE	12/13/2023
PHWH.FX.61453249	ACTIVE	12/15/2023
PHHC.FX.61481285	ACTIVE	12/19/2023
DRCS.FX.61509519	ACTIVE	12/20/2023
DRSD.FX.61469494	ACTIVE	12/20/2023
DRSD.FX.61515830	ACTIVE	12/20/2023
PHNR.FO.61508311	ACTIVE	12/20/2023
PHNR.FO.61508585	ACTIVE	12/20/2023
PHWH.FX.61496698	ACTIVE	12/20/2023
PHWH.FX.61508298	ACTIVE	12/20/2023
PHWH.FX.61515840	ACTIVE	12/20/2023
PHHC.FX.61487961	ACTIVE	12/22/2023

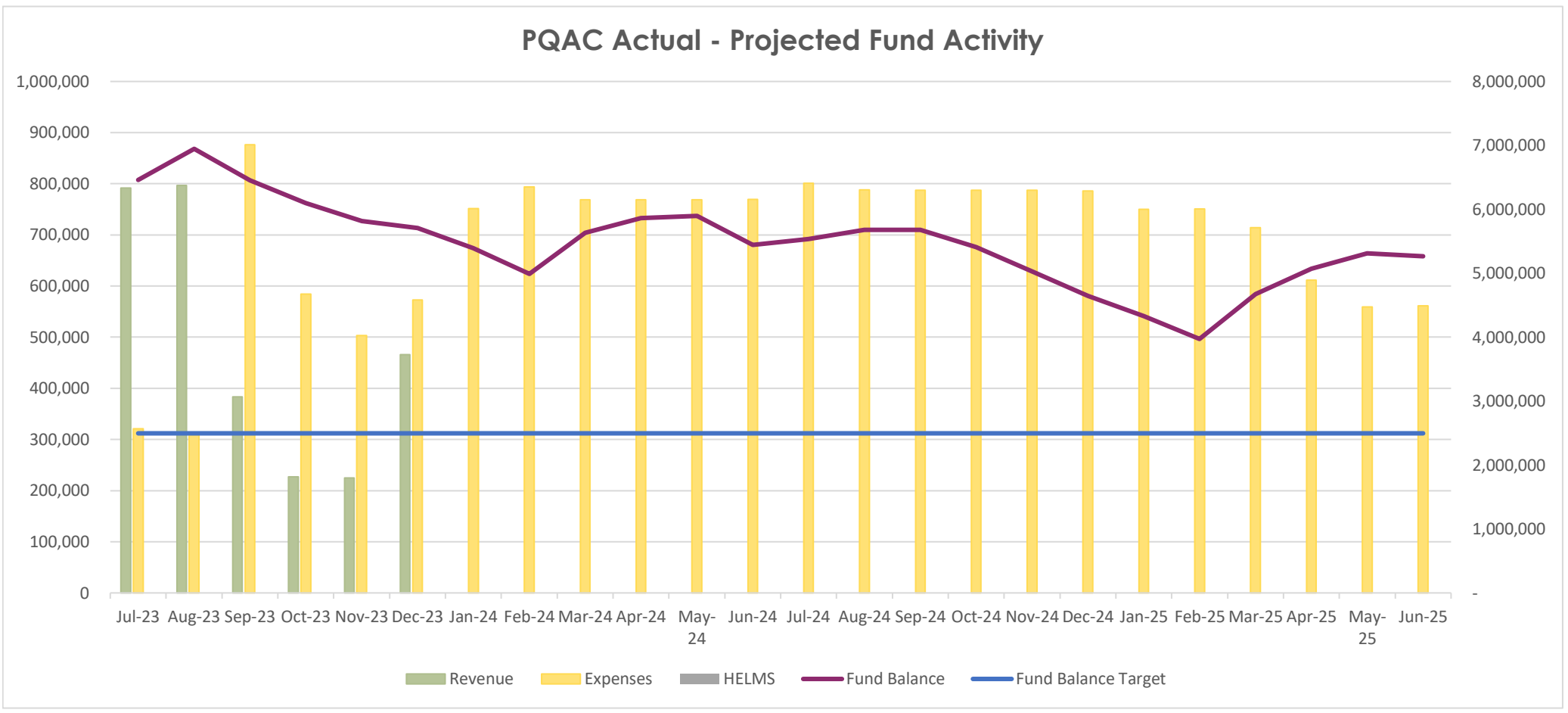
Credential #	Status	Expiration Date
PHNR.FO.61371300	CLOSED	12/02/2023
DRSD.FX.61436469	CLOSED	12/04/2023
PHAR.CF.60960888	CLOSED	12/04/2023
PHAR.CF.00004301	CLOSED	12/04/2023
PHAR.CF.00004351	CLOSED	12/04/2023
PHAR.CF.00059070	CLOSED	12/05/2023
PHWH.FX.60895097	CLOSED	12/05/2023
PHAR.CF.60099730	CLOSED	12/06/2023
PHAR.CF.00003705	CLOSED	12/06/2023
PHWH.FX.60821905	CLOSED	12/06/2023
PHNR.FO.61016607	CLOSED	12/08/2023
PHAR.CF.00003258	CLOSED	12/10/2023
DRCS.FX.00003828	CLOSED	12/13/2023
PHAR.CF.60003333	CLOSED	12/13/2023
PHWH.FX.60907364	CLOSED	12/13/2023
PHAR.CF.00000059	CLOSED	12/14/2023
PHAR.CF.00004295	CLOSED	12/14/2023
PHHC.FX.61163864	CLOSED	12/20/2023
PHNR.FO.61310389	CLOSED	12/20/2023
DRSD.FX.60438551	CLOSED	12/29/2023
PHMF.FX.60269968	CLOSED	12/29/2023
PHNR.FO.60798674	CLOSED	12/29/2023
PHWH.FX.60906113	CLOSED	12/29/2023
PHWH.FX.61403332	CLOSED	12/31/2023

Pharmacy Quality Assurance Commission
2023-25 Budget and Fund Balance Overview
For the period July 1, 2023 through December 31, 2023

Health Professions Account Beginning Fund Balance on July 1, 2023	**5,988,767**
Revenue To Date	2,889,043
23-25 HELMS Assessment To Date	194,727
Expenses To Date	3,971,718
Health Professions Account Fund Balance as of December 31, 2023	**4,711,365**

REVENUE	Est. Revenue	Actual Revenue	Variance	Variance %
To Date	3,523,997	2,889,043	(634,954)	82.0%
Biennium Total	16,979,058			17.02%

EXPENSES	Biennial Budget	Budget To Date	Expenses To Date	Variance To Date	Variance % To Date
Staff Salaries and Benefits	7,152,992	1,835,386	1,700,846	134,540	7.3%
Commission Pay	97,800	24,450	44,480	(20,030)	-81.9%
Professional Service Contracts	20,000	4,167	2,900	1,267	30.4%
Attorney General Support	545,064	136,266	97,091	39,175	28.7%
Goods and Services	62,736	15,684	8,666	7,018	44.7%
Travel	87,816	21,954	24,482	(2,528)	-11.5%
IT Equipment	20,936	10,468	10,263	205	2.0%
WA Recovery Asst. (WRAPP)	171,024	42,756	38,151	4,605	10.8%
Intra-Agency Charges - Discipline	1,670,330	479,259	345,419	133,840	27.9%
Intra-Agency Charges - Credentialing	3,194,376	876,765	773,404	103,361	11.8%
Intra-Agency Charges - Other	953,933	210,054	121,881	88,173	42.0%
TOTAL DIRECT COSTS	**13,977,007**	**3,657,209**	**3,167,583**	**489,626**	**13.4%**
Agency Indirect Costs	2,335,605	610,737	485,228	125,509	20.6%
Division Indirect Costs	1,560,076	407,962	318,906	89,056	21.8%
TOTAL INDIRECT COSTS	**3,895,682**	**1,018,699**	**804,135**	**214,565**	**21.1%**
TOTAL ALL COSTS	**17,872,689**	**4,675,908**	**3,971,718**	**704,190**	**15.1%**



Read this Page Carefully

WA Pharmacy Quality Assurance Commission

~~2023~~2024 General Pharmacy Self-Inspection Worksheet

Attention: Responsible Pharmacy Manager or Equivalent Manager

Washington law holds the responsible pharmacy manager (or equivalent manager) and all pharmacists on duty responsible for ensuring pharmacy compliance with all state and federal laws governing the practice of pharmacy. Failure to complete this annual worksheet and applicable self-inspection worksheet addendums within the month of March and within 30 days of becoming responsible pharmacy manager (as required by WAC 246-945-005) may result in disciplinary action.

Following your self-inspection and completion of the worksheet(s), please review it with your staff pharmacists, ancillary staff and interns, correct any deficiencies noted, sign and date the worksheet(s), and file it so it will be readily available to commission inspectors. **Do not send to the commission office**. You are responsible for ensuring your completed worksheet(s) is available at the time of inspection.

The primary objective of this worksheet, and your self-inspection, is to provide an opportunity to identify and correct areas of non-compliance with state and federal law. (**Note**: Neither the self-inspection nor a commission inspection evaluates your complete compliance with all laws and rules of the practice of pharmacy.) The inspection worksheet also serves as a necessary document used by commission inspectors during an inspection to evaluate a pharmacy's level of compliance.

When a commission inspector discovers an area of non-compliance, they will issue an Inspection Report with Noted Deficiencies. The responsible pharmacy manager (or equivalent manager) must provide a written response (plan of correction) addressing all areas of non-compliance. Identifying and correcting an area of non-compliance prior to a commission inspection, or during an inspection, may eliminate that item from being included as a deficiency on an Inspection Report. Do not assume that you are in compliance with any statement; take the time to personally verify that compliance exists. If you have any questions, please contact your inspector.

A common reason for issuing an Inspection Report with Noted Deficiencies is either not having or not being able to readily retrieve required documents and records. Because commission inspections are unscheduled, it is common for the responsible manager to be absent or unavailable. For this reason, you are asked to provide a list of the specific locations of required documents. Having all required documents and records maintained in a well-organized and readily retrievable manner (a binder is recommended) reduces the chance that you will receive an Inspection Report with Noted Deficiencies.

By answering the questions and referencing the appropriate laws/rules/CFR provided, you can determine whether you are compliant with many of the rules and regulations. If you have corrected any deficiencies, please write "corrected" and the date of correction by the appropriate question. Questions highlighted in **blue** are ~~questions that will be focused on~~common areas of non-compliance observed during routine pharmacy inspections.

Washington State Department of Health

All responsible pharmacy managers (or equivalent managers) of pharmacies **must** complete and sign this self-inspection worksheet within the month of March and within 30 days of becoming responsible pharmacy manager. The form must be available for inspection as required by WAC 246-945-005. **Do not send to the commission office.**

Date ~~responsible pharmacy manager~~ self-inspection worksheet was ~~performed~~completed: Click or tap to enter a date.

Change in responsible pharmacy manager and effective date of change: Click or tap here to enter text. Date: Click or tap to enter a date. (mm/dd/yy)

Print Name of Responsible Pharmacy Manager & License #: Click or tap here to enter text.

Signature of responsible manager: Click or tap here to enter text.

Responsible Pharmacy Manager E-mail: Click or tap here to enter text.

Pharmacy: Click or tap here to enter text. Fax: Click or tap here to enter text. DEA #: Click or tap here to enter text.

Telephone: Click or tap here to enter text. Address: Click or tap here to enter text. Pharmacy License #: Click or tap here to enter text.

Endorsements: ☐ Use of Ancillary Personnel ☐ Dispense Controlled Substances

In Washington State, compounding is defined in RCW 18.64.011(6) and means "**the act of combining two or more ingredients in the preparation of a prescription. Reconstitution and mixing of (a) sterile products according to federal food and drug administration approved labeling does not constitute compounding if prepared pursuant to a prescription and administered immediately or in accordance with package labeling, and (b) nonsterile products according to federal food and drug administration-approved labeling does not constitute compounding if prepared pursuant to a prescription.**"

Please note: If a pharmacy adds flavoring to a commercially available product, it is considered compounding and the non-sterile compounding self-inspection worksheets must also be completed.

Yes	No	
☐	☐	**Does the pharmacy engage in non-sterile compounding of medications?** **If yes,** please complete the ~~2023~~2024 Non-Sterile Compounding Self-Inspection Addendum in addition to the General Pharmacy Self-Inspection Worksheet.
☐	☐	**Does the pharmacy engage in sterile compounding?** **If yes**, you must also complete the ~~2023~~2024 Sterile Compounding Self-Inspection Addendum in addition to the General Pharmacy Self-Inspection Worksheet.

Please answer the following three questions to identify additional required self-inspection forms.		
☐	☐	**Does the pharmacy fill prescriptions for residents of long-term care facilities or hospice programs? (This includes retail/community pharmacies and closed-door long-term care pharmacies, as defined in RCW 18.64.011(4).)** **If yes,** please complete the ~~2023~~2024 Long-Term Care Pharmacy Addendum in addition to the General Pharmacy Self-Inspection Worksheet.
☐	☐	**Is the pharmacy licensed as a hospital pharmacy and/or have HPACs?** **If yes,** please complete the ~~2023~~2024 Hospital and HPAC Pharmacy Self-Inspection Addendum instead of the General Pharmacy Self-Inspection Worksheet.
☐	☐	**Does the pharmacy have an endorsement as a Nuclear Pharmacy?** **If yes,** please complete the ~~2023~~2024 Nuclear Pharmacy Self-Inspection Addendum in addition to the General Pharmacy Self-Inspection Worksheet.

Document and Record Review

Please provide the location of these documents in the pharmacy (be as specific as possible, there can be many filing cabinets and binders). The documentation listed below is required by rule ~~references to~~and must be ~~available~~readily retrievable during inspection~~, by~~. By listing the location of these documents you are also confirming ~~your~~ compliance with the referenced rule.

	Rule Reference
Responsible Pharmacy Manager Self-Inspection Worksheet for last 2 years Location: Click or tap here to enter text.	**WAC 246-945-005(4)(a)** "The responsible pharmacy manager, or equivalent manager, shall sign and date the completed self-inspection worksheet(s), and maintain completed worksheets for two years from the date of completion." **WAC 246-945-005(4)(b)** "When a change in responsible pharmacy manager, or equivalent manager occurs, the new responsible pharmacy manager, or equivalent manager, shall conduct a self-inspection as required under this section. The new responsible pharmacy manager, or equivalent manager, shall sign and date the self-inspection worksheet(s) within thirty days of becoming responsible pharmacy manager, or equivalent manager, and maintain completed worksheets for two years from the date of completion."
Current Biennial Controlled Substance Inventory Location: Click or tap here to enter text.	**WAC 246-945-420(2)** "A facility shall conduct an inventory of controlled substances every two years." **WAC 246-945-420(3)(a)** "Within thirty days of designating a responsible pharmacy manager. The incoming responsible pharmacy manager, or designee, shall conduct a complete controlled substance inventory. **21 CFR 1304.04(h)(1)** "Inventories and records of controlled substances listed in Schedules I and II shall be maintained separately from all of the records of the registrant; and. (2) Inventories and records of controlled substances listed in Schedules III, IV, and V shall be maintained either separately from all other records of the registrant or in such form that the information required is readily retrievable from the ordinary business records of the registrant."
Schedule II Invoices for the last 2 years Location: Click or tap here to enter text.	**WAC 246-945-040(3)(a)** "Every registrant shall keep and maintain inventory records required by 21 CFR Sec. 1304.04. Registrants are also required to keep a record of receipt and distribution of controlled substances. Records shall include: Invoices, orders, receipts, or any other document regardless of how titled, establishing the date, supplier, and quantity of drug received, and the name of the drug;" **WAC 246-945-040(4)** "Credential holders and pharmaceutical firms shall maintain records for Schedule II drugs separately from all other records."

	Rule Reference
Schedule III-V Invoices for the last 2 years Location: Click or tap here to enter text.	**WAC 246-945-040(3)(a)** "Every registrant shall keep and maintain inventory records required by 21 CFR Sec. 1304.04. Registrants are also required to keep a record of receipt and distribution of controlled substances. Records shall include: Invoices, orders, receipts, or any other document regardless of how titled, establishing the date, supplier, and quantity of drug received, and the name of the drug;" **WAC 246-945-040(5)** "Credential holders and pharmaceutical firms may maintain records for Schedule III, IV, and V drugs either separately or in a form that is readily retrievable from the business records of the registrant."
Completed CII order forms (DEA Form 222) and/or finalized CSOS documentation for the last 2 years Location: Click or tap here to enter text.	**WAC 246-945-040(6)** "A federal order form is required for each distribution of a Schedule I or II controlled substance. Credential holders and pharmaceutical firms must keep and make readily available these forms and other records to the commission or its designee." **21 CFR 1305.13(e)** "The purchaser must record on its copy of the DEA Form 222 the number of commercial or bulk containers furnished on each item and the dates on which the containers are received by the purchaser." **21 CFR 1305.22(g)** "When a purchaser receives a shipment, the purchaser must create a record of the quantity of each item received and the date received. The record must be electronically linked to the original order and archived."
Completed loss by theft or destruction forms (DEA Form 106) for the last 2 Years Location: Click or tap here to enter text.	**WAC 246-945-040(3)(c)** "In the event of a significant loss or theft, two copies of DEA 106 (report of theft or loss of controlled substances) must be transmitted to the federal authorities and a copy must be sent to the commission." **21 CFR 1301.76(b)** "The registrant shall notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft. The registrant shall also complete, and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft…."
Power of Attorney for staff authorized to order controlled substances Location: Click or tap here to enter text.	**WAC 246-945-040(1)** "The commission adopts 21 CFR as its own." **21 CFR 1305.05(a)** "A registrant may authorize one or more individuals, whether or not located at his or her registered location, to issue orders for Schedule I and II controlled substances on the registrant's behalf by executing a power of attorney for each such individual, if the power of attorney is retained in the files, with executed Forms 222 where applicable, for the same period as any order bearing the signature of the attorney. The power of attorney must be available for inspection together with other order records."
Ancillary Utilization Plan Location: Click or tap here to enter text.	**WAC 246-945-410(11)(a)** "…A copy of the utilization plan must be maintained in the pharmacy..."
Change of Responsible Pharmacy Manager forms for the last 2 years Location: Click or tap here to enter text.	**WAC 246-945-480(1)** "The outgoing and incoming responsible pharmacy manager must report in writing to the commission a change in a responsible pharmacy manager designation within ten business days of the change." **WAC 246-945-020 (1)** "Unless an alternative standard for a specified record type, form, or format is expressly stated a pharmaceutical firm must maintain and retain records required as evidence of compliance with statutes and rules enforced by the commission in a readily retrievable form and location for at least two years from the date the record was created or received, whichever date is later. **(2)** A pharmaceutical firm must allow the commission, or its designee, access to the pharmaceutical firm's records upon request for the purposes of monitoring compliance with statutes and rules enforced by the commission."

	Rule Reference
Collaborative Drug Therapy Agreement(s) (CDTA), if applicable Location: Click or tap here to enter text.	**WAC 246-945-350(1)** "A pharmacist exercising prescriptive authority in their practice must have a valid CDTA on file with the commission and their practice location." A CDTA must include the elements listed WAC 246-945-350(2) and only valid for two years from the date of signing. (4) Any modification of the written guideline or protocol shall be treated as a new CDTA.
Prescription Records for the last 2 years Location: Click or tap here to enter text.	**WAC 246-945-410(12)** "A facility's paper prescriptions must be maintained in accordance with WAC 246-945-020 and as follows: (a) Paper prescriptions for Schedule II drugs must be maintained as a separate file from other prescriptions. (b) Paper prescriptions for Schedule III, IV, and V drugs must be maintained as a separate file or maintained in a separate file with prescriptions for non-controlled legend drugs as allowed under federal law."

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
General Licensing						
~~☐~~ ☐	~~☐~~ ☐	~~☐~~ ☐	1.	Is the current pharmacy license posted?	**RCW 18.64.043(3)** "It shall be the duty of the owner to immediately notify the commission of any change of location, ownership, or licensure and to keep the license of location or the renewal thereof properly exhibited in said pharmacy."	Click or tap here to enter text.
~~☐~~ ☐	~~☐~~ ☐	~~☐~~ ☐	2.	Are the pharmacist license(s) posted and up to date?	**RCW 18.64.140** "…The current license shall be conspicuously displayed to the public in the pharmacy to which it applies…"	Click or tap here to enter text.
~~☐~~ ☐	~~☐~~ ☐	~~☐~~ ☐	3.	Does the pharmacy have a DEA registration number, is it listed on page 3 of this document?	**WAC 246-945-040(2)** "A separate registration is required for each place of business, as defined in 21 CFR Sec. 1301.12, where controlled substances are manufactured, distributed, or dispensed."	Click or tap here to enter text.
~~☐~~ ☐	~~☐~~ ☐	~~☐~~ ☐	4.	Is the responsible pharmacy manager licensed to practice pharmacy in the State of Washington?	**WAC 246-945-~~332~~310** "Responsible pharmacy manager. The responsible pharmacy manager must be licensed to practice pharmacy in the state of Washington. The responsible pharmacy manager designated by a facility as required under WAC 246-945-410 shall have the authority and responsibility to assure that the area(s) within the facility where drugs are stored, compounded, delivered, or dispensed are operated in compliance with all applicable state and federal statutes and regulations."	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	5.	Are ancillary personnel certification(s) and registration(s) up to date? Please provide documentation of a regular staff roster with credential and expiration date.	**WAC 246-945-205(2)** "To be issued a certification as a pharmacy technician an applicant shall meet the qualifications in RCW 18.64A.020," **WAC 246-945-200(1)** "To become registered as a pharmacy assistant an applicant shall submit an application to the commission that meets the requirements of ~~chapter~~WAC 246-12~~ WAC, Part 2~~-020."	Click or tap here to enter text.
			6.	Pharmacy technician-in-training authority for experiential training.	**WAC 246-945-203(3)** "Before beginning the pharmacy-technician training program the individual shall submit an application to the commission to become certified as a pharmacy assistant. The application must include verification of enrollment in a commission-approved pharmacy-technician education and training program." (2) An individual with a technician in training endorsement may only work in that capacity at those sites identified on the application.	
Facility Standards						
☐	☐	☐	~~6.~~7.	Is the facility appropriately constructed and equipped to protect equipment, records, drugs/devices and other restricted items from unauthorized access?	**WAC 246-945-410(1)** "The facility shall be constructed and equipped with adequate security to protect equipment, records, and supply of drugs, devices, and other restricted sale items from unauthorized access, acquisition, or use."	Click or tap here to enter text.
☐	☐	☐	~~7.~~8.	Is the facility properly equipped?	**WAC 246-945-410(2)** "The facility shall be properly equipped to ensure the safe, clean, and sanitary condition necessary for the proper operation, the safe preparation of prescriptions, and to safeguard product integrity."	Click or tap here to enter text.
☐	☐	☐	~~8.~~9.	Is the facility appropriately staffed?	**WAC 246-945-410(3)** "The facility shall be staffed sufficiently to allow appropriate supervision, operate safely and, if applicable, remain open during posted hours of operation."	Click or tap here to enter text.
☐	☐	☐	~~9.~~10.	Is the facility adequately stocked?	**WAC 246-945-410(4)** "The facility shall be adequately stocked to maintain at all times a representative assortment of drugs in order to meet the pharmaceutical needs of its patients in compliance with WAC 246-945-415."	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	~~10.~~11	Does the facility have a designated responsible pharmacy manager?	**WAC 246-945-410(5)** "The facility shall designate a responsible pharmacy manager: (a) By the date of opening; and (b) Within thirty calendar days of a vacancy."	Click or tap here to enter text.
☐	☐	☐	~~11.~~12	Does each drug dispensed and delivered to patient bear a complete and accurate label?	**WAC 246-945-410(9)** "Each drug dispensed and delivered to a patient must bear a complete and accurate label as required by WAC 246-945-015 through 246-945-018. The information contained on the label shall be supplemented by oral or written information as required by WAC 246-945-325."	Click or tap here to enter text.
☐	☐	☐	~~12.~~13	Are the drug storage areas appropriately secure from unauthorized access?	**WAC 246-945-410 (10)** "Access to the drug storage area located within the facility should be limited to pharmacists unless one of the following applies: (a) A pharmacy intern, or pharmacy ancillary personnel enter under the immediate supervision of a pharmacist; or (b) A pharmacist authorizes temporary access to an individual performing a legitimate nonpharmacy function under the immediate supervision of the pharmacist; or (c) The facility has a policy and procedure restricting access to a health care professional licensed under the chapters specified in RCW 18.130.040, and the actions of the health care professional are within their scope of practice."	Click or tap here to enter text.
☐	☐	☐	~~13.~~14	Is a sign posted in view of patients informing them of generic substitution requirements?	**RCW 69.41.160** "Every pharmacy shall post a sign in a location at the prescription counter that is readily visible to patrons stating, 'Under Washington law, a less expensive interchangeable biological product or equivalent drug may in some cases be substituted for the drug prescribed by your doctor. Such substitution, however, may only be made with the consent of your doctor. Please consult your pharmacist or physician for more information.'"	Click or tap here to enter text.
☐	☐	☐	~~14.~~15	Are refrigerators temperatures maintained between 2-8°C (36-46°F)? **Electronic monitoring is acceptable.**	**WAC 246-945-415(1)**" A pharmacy may deliver filled prescriptions as long as appropriate measures are taken to ensure product integrity and receipt by the patient or patient's agent."	Click or tap here to enter text.
☐	☐	☐	~~15.~~16	Are freezers between -25° & -10°C (-13° & 14°F)?	**WAC 246-945-415(1)** "A pharmacy may deliver filled prescriptions as long as appropriate measures are taken to ensure product integrity and receipt by the patient or patient's agent."	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
Ancillary Personnel						
~~☐~~ ☐	~~☐~~ ☐	~~☐~~ ☐	~~16.~~17	Is the pharmacy adhering to a commission approved Ancillary Utilization Plan?	**RCW 18.64A.060** "No pharmacy licensed in this state shall utilize the services of pharmacy ancillary personnel without approval of the commission. Any pharmacy licensed in this state may apply to the commission for permission to use the services of pharmacy ancillary personnel. The application shall be accompanied by a fee and shall comply with administrative procedures and administrative requirements set pursuant to RCW 43.70.250 and 43.70.280, shall detail the manner and extent to which the pharmacy ancillary personnel would be used and supervised, and shall provide other information in such form as the secretary may require. The commission may approve or reject such applications. In addition, the commission may modify the proposed utilization of pharmacy ancillary personnel and approve the application as modified. Whenever it appears to the commission that pharmacy ancillary personnel are being utilized in a manner inconsistent with the approval granted, the commission may withdraw such approval. In the event a hearing is requested upon the rejection of an application, or upon the withdrawal of approval, a hearing shall be conducted in accordance with chapter 18.64 RCW, as now or hereafter amended, and appeal may be taken in accordance with the administrative procedure act, chapter 34.05 RCW." **WAC 246-945-410(11)** "In accordance with RCW 18.64A.060 prior to utilizing pharmacy ancillary personnel a facility shall submit to the commission a utilization plan for pharmacy technicians and pharmacy assistants: (a) Utilization plan for pharmacy technicians. The application for approval must describe the manner in which the pharmacy technicians will be utilized and supervised, including job descriptions, task analysis or similar type documents that define the duties performed and the conditions under which they are performed, number of positions in each category, as well as other information as may be required by the commission. The commission will be notified of all changes to the utilization plan. A copy of the utilization plan must be	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					maintained in the pharmacy. The utilization plan must comply with WAC 246-945-315 and 246-945-320. (b) Utilization plan for pharmacy assistants. The application for approval shall list the job title or function of the pharmacy assistant and comply with WAC 246-945-315(3)."	
☐	☐	☐	~~17.~~18	Are pharmacy assistants operating within their scope of practice and only completing tasks outlined in the pharmacy's approved ancillary utilization plan?	**RCW 18.64A.060** "... The commission may approve or reject such applications. In addition, the commission may modify the proposed utilization of pharmacy ancillary personnel and approve the application as modified. Whenever it appears to the commission that pharmacy ancillary personnel are being utilized in a manner inconsistent with the approval granted, the commission may withdraw such approval. In the event a hearing is requested upon the rejection of an application, or upon the withdrawal of approval, a hearing shall be conducted in accordance with chapter 18.64 RCW, as now or hereafter amended, and appeal may be taken in accordance with the administrative procedure act, chapter 34.05 RCW." **RCW 18.64A.030** "... (2) 'Pharmacy assistants' may perform, under the supervision of a licensed pharmacist, duties including, but not limited to, typing of prescription labels, filing, refiling, bookkeeping, pricing, stocking, delivery, nonprofessional phone inquiries, and documentation of third-party reimbursements and other such duties and subject to such restrictions as the commission may by rule adopt." **WAC 246-945-315(3**) "A pharmacist may delegate to a pharmacy assistant those functions defined in RCW 18.64A.030 and the following: (a) Prepackage and label drugs for subsequent use in prescription dispensing operations; and (b) Count, pour, and label for individual prescriptions."	Click or tap here to enter text.
☐	☐	☐	~~18.~~19	Are pharmacy technicians operating within their scope of practice and only completing tasks outlined in the pharmacy's approved ancillary utilization plan?	**RCW 18.64A.060** "... The commission may approve or reject such applications. In addition, the commission may modify the proposed utilization of pharmacy ancillary personnel and approve the application as modified. Whenever it appears to the commission that pharmacy ancillary	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					personnel are being utilized in a manner inconsistent with the approval granted, the commission may withdraw such approval. In the event a hearing is requested upon the rejection of an application, or upon the withdrawal of approval, a hearing shall be conducted in accordance with chapter 18.64 RCW, as now or hereafter amended, and appeal may be taken in accordance with the administrative procedure act, chapter 34.05 RCW." **RCW 18.64A.030** "... (1) "Pharmacy technicians" may assist in performing, under the supervision and control of a licensed pharmacist, manipulative, nondiscretionary functions associated with the practice of pharmacy and other such duties and subject to such restrictions as the commission may by rule adopt... ." **WAC 246-945-315(2)** "When delegating a pharmacy function to a pharmacy technician: (a) A pharmacist shall consider the pharmacy technician's scope of practice, education, skill, and experience and take them into account; and (b) A pharmacist will not delegate a pharmacy function that is listed in WAC 246-945-320."	
Recordkeeping						
☐	☐	☐	~~19.~~20	An electronic recordkeeping system is required. Does your record system have the capability to store patient medication records e.g. allergies, idiosyncrasies or chronic conditions, and prescription, refill, transfer, and other information?	**WAC 246-945-417(1)** "A pharmacy shall use an electronic recordkeeping system to establish and store patient medication records, including patient allergies, idiosyncrasies or chronic conditions, and prescription, refill, transfer information, and other information necessary to provide safe and appropriate patient care."	Click or tap here to enter text.
☐	☐	☐	~~20.~~21	~~Does all nonsterile and sterile compounding comply with USP Chapter <825>, if applicable?~~Do pharmacists review and document that refills for controlled substances in Schedules III and IV are correct?	~~**WAC 246-945-100** "Compounding minimum standards. **(1)** All licensees of the commission must comply, at a minimum, with the following chapters of the United States Pharmacopeia (USP) when engaged in compounding nonsterile and sterile products for patient administration or distribution to a licensed practitioner for patient use or administration.... (d) USP General Chapter <825> Radiopharmaceuticals - Preparation, Compounding,~~	~~Click or tap here to enter text.~~

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					~~Dispensing, and Repackaging."~~**RCW 69.50.306 and 21 CFR 1306.22 (f)(3)** "Refilling of prescriptions.(f) As an alternative to the procedures provided by paragraphs (a) through (e) of this section, a computer application may be used for the storage and retrieval of refill information for original paper prescription orders for controlled substances in Schedule III and IV, subject to the following conditions:(3) Documentation of the fact that the refill information entered into the computer each time a pharmacist refills an original paper, fax, or oral prescription order for a Schedule III or IV controlled substance is correct must be provided by the individual pharmacist who makes use of such an application. If such an application provides a hard-copy printout of each day's controlled substance prescription order refill data, that printout shall be verified, dated, and signed by the individual pharmacist who refilled such a prescription order. In lieu of such a printout, the pharmacy shall maintain a bound log book, or separate file, in which each individual pharmacist involved in such dispensing shall sign a statement (in the manner previously described) each day, attesting to the fact that the refill information entered into the computer that day has been reviewed by him and is correct as shown.	
~~☐~~ ☐	~~☐~~ ☐	~~☐~~ ☐	~~21.~~22	Do medications dispensed under ~~and~~an emergency proclamation meet all requirements?	**WAC 246-945-332** "Continuity of care (2) For each medication dispensed under this section, a pharmacist shall: (a) Document the dispensing as a prescription, noting where the information from subsection (1)(a) of this section was obtained; (b) Inform the patient's provider and the pharmacy at which the patient obtains his or her medications of the dispensing as soon as possible following the emergency dispensing; (c) Record the prescription or patient record as an "emergency" prescription."	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	~~22.~~23	Is prescription adaptation in compliance with laws and rules ~~with regard to~~regarding quantity, dosage form, completion of missing information, and documentation in the patient's record?	**WAC 246-945-335** "Prescription adaptation. Upon patient consent, a pharmacist may adapt drugs as specified in this rule, provided that the prescriber has not indicated that adaptation is not permitted. **(1)** Change quantity. A pharmacist may change the quantity of medication prescribed if: (a) The prescribed quantity or package size is not commercially available; (b) The change in quantity is related to a change in dosage form; (c) The change is intended to dispense up to the total amount authorized by the prescriber including refills in accordance with RCW 18.64.520; or (d) The change extends a maintenance drug for the limited quantity necessary to coordinate a patient's refills in a medication synchronization program in accordance with RCW 48.43.096. **(2)** Change dosage form. A pharmacist may change the dosage form of the prescription if it is in the best interest of patient care, so long as the prescriber's directions are also modified to equate to an equivalent amount of drug dispensed as prescribed. **(3)** Complete missing information. A pharmacist may complete missing information on a prescription if there is evidence to support the change. **(4)** Documentation. A pharmacist who adapts a prescription in accordance with these rules must document the adaptation in the patient's record."	Click or tap here to enter text.
☐	☐	☐	~~23.~~24	Are all drug or biologic product substitutions in compliance with ~~the~~ applicable laws and rules?	**WAC 246-945-340** "Prescriptions—Drug product substitutions. **(1)** A pharmacist may substitute a drug or biologic product dispensed pursuant to a prescription if in compliance with applicable laws and rules. **(2)** A pharmacist may substitute a drug product or a biologic product when any of the following applies: (a) The substitution is permitted by RCW 69.41.120; (b) The substitution is permitted by a formulary developed by an interdisciplinary team of an institutional facility; or (c) The substitution is otherwise permitted by law." **(3)** In addition to any other applicable requirements, a pharmacist shall only substitute a drug or a biologic	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					product pursuant to subsection (2)(b) of this section if: (a) An employee or contractor of the institutional facility prescribed the drug or biologic product to be substituted; (b) The interdisciplinary team was composed of a nonpharmacist prescriber listed in RCW 69.41.030 and a pharmacist; and (c) The formulary is readily retrievable by the pharmacist."	
☐	☐	☐	~~24.~~25	Are lawfully prescribed drugs and devices or a therapeutically equivalent drug or device delivered to patients in a timely manner?	**WAC 246-945-415** "Dispensing and delivery of prescription drugs **(2)** Pharmacies have a duty to deliver lawfully prescribed drugs or devices to patients and to distribute drugs and devices approved by the U.S. Food and Drug Administration for restricted distribution by pharmacies, or provide a therapeutically equivalent drug or device in a timely manner consistent with reasonable expectations for filling the prescription, except for the following or substantially similar circumstances: (a) Prescriptions containing an obvious or known error, inadequacies in the instructions, known contraindications, or incompatible prescriptions, or prescriptions requiring action in accordance with WAC 246-945-410(8) or 246-945-335; (b) National or state emergencies or guidelines affecting availability, usage, or supplies of drugs or devices; (c) Lack of specialized equipment or expertise needed to safely produce, store, or dispense drugs or devices, such as certain drug compounding or storage for nuclear medicine; (d) Potentially fraudulent prescriptions; or (e) Unavailability of drug or device despite good faith compliance with WAC 246-945-410(4). **WAC 246-945-415 (3)** Nothing in this section requires pharmacies to deliver a drug or device without payment of their usual and customary or contracted charge."	Click or tap here to enter text.
☐	☐	☐	~~25.~~26	Does the pharmacy provide the patient or agent with a timely alternative, if the lawfully prescribed drug is not in stock, or the prescription cannot be filled?	**WAC 246-945-415 (4)** "If despite good faith compliance with WAC 246-945-410(4), the lawfully prescribed drug or device is not in stock, or the prescription cannot be filled pursuant to subsection (2)(a) of this section, the pharmacy shall provide the patient or agent a timely alternative for appropriate therapy which, consistent with customary	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					pharmacy practice, may include obtaining the drug or device. These alternatives include, but are not limited to: (a) Contact the prescriber to address concerns such as those identified in subsection (2)(a) of this section or to obtain authorization to provide a therapeutically equivalent product; (b) If requested by the patient or their agent, return unfilled lawful prescriptions to the patient or agent; or (c) If requested by the patient or their agent, communicate or transmit, as permitted by law, the original prescription information to a pharmacy of the patient's choice that will fill the prescription in a timely manner." **WAC 246-945-415 (5)** "Engaging in or permitting any of the following shall constitute grounds for discipline or other enforcement actions: (a) Destroy unfilled lawful prescriptions; (b) Refuse to return unfilled lawful prescriptions; (c) Violate a patient's privacy; (d) Discriminate against patients or their agent in a manner prohibited by state or federal laws; and (e) Intimidate or harass a patient."	
☐	☐	☐	~~26.~~27	~~Does the~~If your pharmacy ~~have~~utilizes a ~~secured~~secure delivery area ~~equipped with~~, does the area have adequate security and ~~is this addressed in the pharmacy's policy~~policies and procedures relating to the delivery area?	**WAC 246-945-415 (6)** "Filled prescriptions may be picked up or returned for delivery by authorized personnel when the pharmacy is closed for business if the prescriptions are placed in a secured delivery area outside of the drug storage area. The secured delivery area must be a part of a licensed pharmacy, and equipped with adequate security, including an alarm or comparable monitoring system, to prevent unauthorized entry, theft, or diversion. Access to the secured delivery area must be addressed by the policies and procedures developed by the responsible pharmacy manager."	Click or tap here to enter text.
☐	☐	☐	~~27.~~28	Are all legend drugs dispensed in child-resistant containers, as required by federal law or regulation? (This includes special packaging used such as customized patient medication packages; blister packs, med-minders, etc.)	**WAC 246-945-032 (1)** "All legend drugs shall be dispensed in a child-resistant container as required by federal law or regulation, including 16 CFR, Part 1700, unless: (a) Authorization is received from the prescriber to dispense in a container that is not child-resistant. (b) Authorization is obtained from the patient or a representative of the	Click or tap here to enter text.

Compliant			#			Rule Reference	Notes/Corrective Action
Yes	No	N/A					
				** Best practice recommendation: It is recommended that these authorizations are updated annually. **		patient to dispense in a container that is not child-resistant."	
			~~28.~~29	Do all prescriptions for non-controlled legend drugs ~~have~~include all required elements?		**WAC 246-945-010(3)** "A prescription for a noncontrolled legend drug must include, but is not limited to, the following: (a) Prescriber's name; (b) Name of patient, authorized entity, or animal name and species; (c) Date of issuance; (d) Drug name, strength, and quantity; (e) Directions for use; (f) Number of refills (if any); (g) Instruction on whether or not a therapeutically equivalent generic drug or interchangeable biological product may be substituted, unless substitution is permitted under a prior-consent authorization; (h) Prescriber's manual or electronic signature, or prescriber's authorized agent signature if allowed by law; and (i) If the prescription is written, it must be written on tamper-resistant prescription pad or paper approved by the commission pursuant to RCW 18.64.500."	
☐	☐	☐	28.	a	Prescriber's Name		Click or tap here to enter text.
☐	☐	☐	28.	b	Name of Patient/ Authorized entity/Animal Name and Species		Click or tap here to enter text.
☐	☐	☐	28.	c	Date of Issuance		Click or tap here to enter text.
☐	☐	☐	28.	d	Drug Name, Strength, and quantity		Click or tap here to enter text.
☐	☐	☐	28.	e	Directions for Use		Click or tap here to enter text.
☐	☐	☐	28.	f	Number of Refills		Click or tap here to enter text.
☐	☐	☐	28.	g	Substitution Directions		Click or tap here to enter text.
☐	☐	☐	28.	h	Prescribers Signature		Click or tap here to enter text.
☐	☐	☐	28.	i	If written, on Tamper-resistant Paper		Click or tap here to enter text.
			~~29.~~30	Do all prescriptions for controlled drugs ~~have all~~include additional ~~of the~~ required elements?		**WAC 246-945-010(4)** "A prescription for a controlled substance must include all the information listed in subsection (1) of this section and the following: (a) Patient's address; (b) Dosage form; (c) Prescriber's address; (d) Prescriber's DEA registration number; and (e) Any other requirements listed in 21 CFR, Chapter II."	
☐	☐	☐	29.	a	Patient's address		Click or tap here to enter text.
☐	☐	☐	29.	b	Dosage Form		Click or tap here to enter text.

Compliant			#			Rule Reference	Notes/Corrective Action
Yes	No	N/A					
☐	☐	☐	29.	c	~~Prescriber'~~Prescriber's address		Click or tap here to enter text.
☐	☐	☐	29.	d	Prescriber's DEA number		Click or tap here to enter text.
☐	☐	☐	~~30.~~31		~~Does the~~Do chart ~~order~~orders meet requirements?	**WAC 246-945-010 (5)** "A chart order must meet the requirements of RCW 18.64.550 and any other applicable requirements listed in 21 CFR, Chapter II"	Click or tap here to enter text.
☐	☐	☐	~~31.~~32		Do ~~all~~ emergency prescriptions for Schedule II controlled substances meet ~~the~~ requirements?	**WAC 246-945-010 (6)** "A controlled substance listed in Schedule II can only be dispensed pursuant to a valid prescription in accordance with WAC 246-945-011 unless there is an "emergency." (a) For the purposes of this subsection, an "emergency" exists when the immediate administration of the drug is necessary for proper treatment and no alternative treatment is available, and further, it is not possible for the practitioner to provide a written or electronic prescription for the drug at that time. (b) If a Schedule II drug is dispensed in an emergency, the practitioner must deliver a signed prescription to the dispenser within seven days after authorizing an emergency oral prescription or if delivered by mail it must be postmarked within the seven day period, and further the pharmacist must note on the prescription that it was filled on an emergency basis.	Click or tap here to enter text.
☐	☐	☐	~~32.~~33		Are all ~~emergency~~ controlled substances prescribed orally reduced to a written or electronic prescription?	**WAC 246-945-010 (7)** "A controlled substance listed in Schedule III, IV, or V, can only be dispensed pursuant to a valid prescription in accordance with WAC 246-945-011, or an oral prescription. An oral prescription for a controlled substance listed in Schedule III, IV, or V must be promptly reduced to a written or electronic prescription that complies with WAC 246-945-011."	Click or tap here to enter text.
☐	☐	☐	~~33.~~34		Are all ~~uncontrolled~~noncontrolled legend drugs prescribed orally promptly transcribed to a written or electronic prescription?	**WAC 246-945-010 (8)** "A noncontrolled legend drug can only be dispensed pursuant to a valid prescription in accordance with WAC 246-945-011, or an oral prescription. An oral prescription for a noncontrolled legend drug must be promptly reduced to a written or electronic prescription that complies with WAC 246-945-011."	

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	~~34.~~35	Are all drugs dispensed pursuant to valid prescriptions?	**WAC 246-945-011** "Prescription validity. **(1)** Prior to dispensing and delivering a prescription, a pharmacist shall verify its validity. **(2)** A prescription shall be considered invalid if: (a) At the time of presentation, the prescription shows evidence of alteration, erasure, or addition by any person other than the person who wrote it; (b) The prescription does not contain the required information as provided in WAC 246-945-010; (c) The prescription is expired; or (d) The prescription is for a controlled substance and does not comply with the requirements in RCW 69.50.308. **(3)** A prescription is considered expired when: (a) The prescription is for a controlled substance listed in Schedule II through V and the date of dispensing is more than six months after the prescription's date of issue. (b) The prescription is for a noncontrolled legend drug or OTC's and the date of dispensing is more than twelve months after the prescription's date of issue. [Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075]	Click or tap here to enter text.
☐	☐	☐	~~35.~~36	Do all paper prescriptions contain two lines clearly identified for a practitioner's signature, one that denotes "dispense as written" and the other "substitution permitted"? This is not necessary if substitution is permitted by a prior consent authorization.	**RCW 69.41.120 (1)** "Every drug prescription shall contain an instruction on whether or not a therapeutically equivalent generic drug or interchangeable biological product may be substituted in its place, unless substitution is permitted under a prior-consent authorization. If a written prescription is involved, the prescription must be legible and the form shall have two signature lines at opposite ends on the bottom of the form. Under the line at the right side shall be clearly printed the words "DISPENSE AS WRITTEN." Under the line at the left side shall be clearly printed the words "SUBSTITUTION PERMITTED." The practitioner shall communicate the instructions to the pharmacist by signing the appropriate line. No prescription shall be valid without the signature of the practitioner on one of these lines. In the case of a prescription issued by a practitioner in another state that uses a one-line prescription form or variation thereof, the pharmacist may substitute a therapeutically equivalent generic drug or interchangeable biological product unless	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					otherwise instructed by the practitioner through the use of the words "dispense as written," words of similar meaning, or some other indication."	
☐ ☐	☐ ☐	☐ ☐	~~36.~~37	Are paper prescriptions for controlled substances maintained ~~in appropriate files?~~appropriately?	**WAC 246-945-410(12)** "A facility's paper prescriptions must be maintained in accordance with WAC 246-945-020 and as follows: (a) Paper prescriptions for Schedule II drugs must be maintained as a separate file from other prescriptions. (b) Paper prescriptions for Schedule III, IV, and V drugs must be maintained as a separate file, or maintained in a separate file with prescriptions for noncontrolled legend drugs as allowed under federal law."	Click or tap here to enter text.
☐	☐	☐	~~37.~~38	Are ~~electronic~~paper prescriptions for noncontrolled substances maintained appropriately?	~~**WAC 246-945-417(6)** "Electronic prescriptions for prescription drugs must be maintained by the pharmacy in a system that meets the requirements of 21 CFR Sec. 1311."~~**RCW 69.41.120(4) "**The pharmacist shall retain the file copy of a written or oral prescription for the same period of time specified in RCW 18.64.245 for retention of prescription records."	~~Click or tap here to enter text.~~
☐ ☐	☐ ☐	☐ ☐	~~38.~~39	Are electronic prescriptions maintained appropriately?~~Do the prescription records contain a complete auditable trail?~~	**WAC 246-945-417(~~2~~)** ~~"The electronic recordkeeping system must be capable of real-time retrieval of information pertaining to the ordering, verification, and processing of the~~ **~~6)~~** "Electronic prescriptions for prescription ~~where possible~~drugs must be maintained by the pharmacy in a system that meets the requirements of 21 CFR Sec. 1311."	Click or tap here to enter text.
☐ ☐	☐ ☐	☐ ☐	~~39.~~40	Do the prescription records contain a complete auditable trail?~~Does the electronic recordkeeping system include security features to protect confidentiality and integrity of patient records?~~	**WAC 246-945-417** ~~"Electronic systems for patient medication records, prescriptions, chart orders, and controlled substance records.~~ **~~(3)~~** **(2)** "The electronic recordkeeping system must ~~include security features to protect the confidentiality and integrity~~be capable of ~~patient records including: (a) Safeguards designed to prevent and detect unauthorized access, modification, or manipulation~~real-time retrieval of ~~prescription~~ information ~~and patient medication records; and (b) Functionality that documents any alteration~~pertaining to the ordering, verification, and processing of ~~prescription information after a prescription is dispensed, including~~ the ~~identification of the individual~~	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					~~responsible for the alteration.~~prescription where possible."	
☐ ☐	☐ ☐	☐ ☐	~~40.~~41	Does the electronic recordkeeping system include security features to protect confidentiality and integrity of patient records?~~Do non-controlled substance prescription transfers contain sufficient information and maintain an auditable trail?~~ ~~*See 21 CFR 1306.25 (b) for the requirements for transferring controlled substance prescriptions.~~	**WAC 246-945-~~345~~** "Prescription transfers. … ~~(2)~~ Upon **417** "Electronic systems for patient ~~request, a prescription may be transferred within the limits of state and federal law."~~medication records, prescriptions, chart orders, and controlled substance records. ~~(3) Sufficient information needs to be exchanged in the transfer of a prescription to maintain an auditable trail, and all elements of a valid prescription."~~ ~~(4) Pharmacies sharing a secure real-time database are not required to transfer prescription information for dispensing."~~ ~~(5) Prescriptions must be transferred by electronic means or facsimile, except in emergent situations."~~**(3)** The electronic recordkeeping system must include security features to protect the confidentiality and integrity of patient records including: (a) Safeguards designed to prevent and detect unauthorized access, modification, or manipulation of prescription information and patient medication records; and (b) Functionality that documents any alteration of prescription information after a prescription is dispensed, including the identification of the individual responsible for the alteration.	Click or tap here to enter text.
☐ ☐	☐ ☐	☐ ☐	~~41.~~42	Do non-controlled substance prescription transfers contain sufficient information and maintain an auditable trail? *See 21 CFR 1306.08(e-f) and 21 CFR 1306.25 (b) for the requirements for transferring controlled substance prescriptions.~~Do prescription records properly document partial fills?~~	**WAC 246-945-~~013~~** "Partial filling of prescriptions. **345** "Prescription transfers. … ~~(1)~~ A pharmacist may partially fill a prescription for noncontrolled legend drugs and controlled substances listed in Schedule III through V provided that: (a) The partial fill is requested by the patient or the prescriber; (b) The partial filling is recorded in the same manner as a re-filling; (c) The total quantity dispensed and delivered in all partial fillings must not exceed the total quantity prescribed; and (d) Partial fills for controlled substances listed in Schedule III through V comply with 21 CFR Sec. 1306.23. ~~(2)~~ A pharmacist may partially fill a prescription for a controlled substance listed in Schedule II within the limits	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					~~of RCW 18.64.265, 21 U.S.C. Sec. 829, and 21 CFR Sec. 1306.13, as applicable.~~**(2)** Upon patient request, a prescription may be transferred within the limits of state and federal law." **(3)** Sufficient information needs to be exchanged in the transfer of a prescription to maintain an auditable trail, and all elements of a valid prescription." **(4)** Pharmacies sharing a secure real-time database are not required to transfer prescription information for dispensing." **(5)** Prescriptions must be transferred by electronic means or facsimile, except in emergent situations."	
☐ ~~☐~~ ☐	☐ ~~☐~~ ☐	☐ ~~☐~~ ☐	~~42.~~43	Do prescription records properly document partial fills?~~Does your pharmacy have shared pharmacy services or utilize a central fill?~~	**WAC 246-945-~~425~~013** "~~Pharmacy services~~ Partial filling of prescriptions. **(1)** A pharmacist may ~~be provided off-site at one or more locations. When the services being performed are related to~~partially fill a prescription ~~fulfillment or processing,~~ for noncontrolled legend drugs and controlled substances listed in Schedule III through V provided that: (a) The partial fill is requested by the patient or the ~~pharmacy or pharmacist~~ prescriber; (b) The partial filling is recorded in the same manner as a re-filling; (c) The total quantity dispensed and delivered in all partial fillings must not exceed the total quantity prescribed; and (d) Partial fills for controlled substances listed in Schedule III through V comply with ~~the following: …~~ 21 CFR Sec. 1306.23. ~~**(2)** Central fill shared pharmacy services in accordance with the following conditions: (a) The originating pharmacy shall have written policies and procedures outlining the off-site pharmacy services to be provided by the central fill pharmacy, or the off-site pharmacist or pharmacy technician, and the responsibilities of each party; (b) The parties shall share a secure real-time database or utilize other secure technology, including a private, encrypted connection that allows access by the central pharmacy or off-site pharmacist or pharmacy technician to the information necessary to perform off-site pharmacy services; and (c) A single prescription may be shared by an originating pharmacy and a central fill~~	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					~~pharmacy or off-site pharmacist or pharmacy technician. The fulfillment, processing and delivery of a prescription by one pharmacy for another pursuant to this section will not be construed as the fulfillment of a transferred prescription or as a wholesale distribution."~~**(2)** A pharmacist may partially fill a prescription for a controlled substance listed in Schedule II within the limits of RCW 18.64.265, 21 U.S.C. Sec. 829, and 21 CFR Sec. 1306.13, as applicable.	
☐	☐	☐	~~43.~~44	~~Is an inventory of controlled substances conducted and maintained onsite at a minimum every two years?~~ If your pharmacy utilizes shared pharmacy services or central fill services, are there policies and procedures outlining these services?	~~**WAC 246-945-420(2)** "A facility shall conduct an inventory of controlled substances every two years."~~ ~~-~~**WAC 246-945-425** "Pharmacy services may be provided off-site at one or more locations. When the services being performed are related to prescription fulfillment or processing, the pharmacy or pharmacist must comply with the following: … **(2)** Central fill shared pharmacy services in accordance with the following conditions: (a) The originating pharmacy shall have written policies and procedures outlining the off-site pharmacy services to be provided by the central fill pharmacy, or the off-site pharmacist or pharmacy technician, and the responsibilities of each party; (b) The parties shall share a secure real-time database or utilize other secure technology, including a private, encrypted connection that allows access by the central pharmacy or off-site pharmacist or pharmacy technician to the information necessary to perform off-site pharmacy services; and (c) A single prescription may be shared by an originating pharmacy and a central fill pharmacy or off-site pharmacist or pharmacy technician. The fulfillment, processing and delivery of a prescription by one pharmacy for another pursuant to this section will not be construed as the fulfillment of a transferred prescription or as a wholesale distribution."	Click or tap here to enter text.
☐	☐	☐	~~44.~~45	Is an inventory of controlled substances ~~completed within 30 days of~~conducted and maintained onsite	**WAC 246-945-420(~~3~~2)** "A facility shall conduct ~~its own separate~~an inventory of controlled substances ~~in the following situations: (a) Within thirty days of designating a~~	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
				at a ~~new responsible manager or on the effective date of the addition of a substance to a schedule of controlled substances~~minimum every two years?	~~responsible pharmacy manager. The incoming responsible pharmacy manager, or designee, shall conduct a complete controlled substance~~every two years." This inventory~~. (b) On the effective date of an addition of a substance to a schedule of~~ shall include all controlled substances~~. Each facility that possesses the substance shall take an inventory of the substance~~ "on hand~~, and thereafter, include the substance in each inventory.""~~". ~~See also 21 CFR 1304.~~ 21 CFR 1304.11(a) "Controlled substances shall be deemed to be "on hand" if they are in the possession of or under the control of the registrant, including substances returned by a customer, ordered by a customer but not yet invoiced…" This includes medications in will call.	
☐ ~~☐~~	☐ ~~☐~~	☐ ~~☐~~	~~45.~~46	~~If legend drugs (including~~Is an inventory of controlled substances~~) are dispensed~~ completed within 30 days of a new responsible manager or ~~delivered without a pharmacist on-site, is there~~ the effective date of the addition of a ~~perpetual inventory~~substance to a schedule of controlled substances?	~~**WAC 246-945-420(4)** "A pharmacy that exclusively stores, dispenses or delivers legend drugs, including controlled substances, without a pharmacist on-site shall maintain a perpetual inventory."~~**WAC 246-945-420(3)** "A facility shall conduct its own separate inventory of controlled substances in the following situations: (a) Within thirty days of designating a responsible pharmacy manager. The incoming responsible pharmacy manager, or designee, shall conduct a complete controlled substance inventory. (b) On the effective date of an addition of a substance to a schedule of controlled substances. Each facility that possesses the substance shall take an inventory of the substance on hand, and thereafter, include the substance in each inventory."	Click or tap here to enter text.
☐ ~~☐~~	☐ ~~☐~~	☐ ~~☐~~	~~46.~~47	If ~~prescription~~legend drugs (including controlled substances) are dispensed or delivered without ~~pharmacy ancillary personnel physically~~a pharmacist on-site, is there a perpetual inventory?	**WAC 246-945-420(~~54~~)** "A pharmacy that exclusively stores, dispenses or delivers ~~prescription~~legend drugs, including controlled substances, without ~~pharmacy ancillary personnel physically~~a pharmacist on-site shall maintain a perpetual inventory."	Click or tap here to enter text.
☐ ~~☐~~	☐ ~~☐~~	☐ ~~☐~~	~~47.~~48	If prescription drugs are dispensed or delivered without pharmacy ancillary personnel physically on-site, is there	~~**WAC 246-945-020(1)** "Unless an alternative standard for a specified record type, form, or format is expressly stated a pharmaceutical firm must maintain and retain records~~	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
				a perpetual inventory?~~Are all records readily retrievable for at least two years from the date the record was created or received, whichever is later?~~	~~required as evidence of compliance with statutes and rules enforced by the commission in a readily retrievable form and location for at least two years from the date the record was created or received, whichever date is later."~~ **~~WAC 246-945-001(71)~~** ~~""Readily retrievable" means a record that is kept by automatic data processing systems or other electronic, mechanized, or written recordkeeping systems in such a manner that it can be separated out from all other records in a reasonable time."~~**WAC 246-945-420(5)** "A pharmacy that exclusively stores, dispenses or delivers prescription drugs without pharmacy ancillary personnel physically on-site shall maintain a perpetual inventory."	
☐ ~~☐~~	☐ ~~☐~~	☐ ~~☐~~	~~48.~~49	Are all records readily retrievable for at least two years from the date the record was created or received, whichever is later?~~Does the pharmacy maintain records of all receipt and distribution of controlled substances?~~	**WAC 246-945-020(1)** "Unless an alternative standard for a specified record type, form, or format is expressly stated a pharmaceutical firm must maintain and retain records required as evidence of compliance with statutes and rules enforced by the commission in a readily retrievable form and location for at least two years from the date the record was created or received, whichever date is later." ~~**WAC 246-945-040(3)** "Registrants are also required to keep a record of receipt and distribution of controlled substances. Records shall include: (a) Invoices, orders, receipts, or any other document regardless of how titled, establishing the date, supplier, and quantity of drug received, and the name of the drug; (b) Distribution records, including invoices, or any other document regardless of how titled from wholesalers, manufacturers, or any other entity to which the substances were distributed and prescriptions records for dispensers; … (d) For transfers of controlled substances from one dispenser to another, a record of the transfer must be made at the time of transfer indicating the drug, quantity, date of transfer, who it was transferred to, and from whom. Records must be retained by both the transferee and the transferor. These transfers can only be made in emergencies pursuant to 21 CFR Sec. 1307.11.~~**WAC 246-945-001(71)** ""Readily retrievable" means a record that is kept by automatic data processing systems or other	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					electronic, mechanized, or written recordkeeping systems in such a manner that it can be separated out from all other records in a reasonable time."	
☐ ☐	☐ ☐	☐ ☐	~~49.~~50	~~Are~~Does the pharmacy maintain records of ~~Schedule II drugs maintained separately from~~ all ~~other~~receipt and distribution of controlled ~~substance records~~substances?	**~~WAC 246-945-040(4)~~** ~~"Credential holders and pharmaceutical firms shall maintain records for Schedule II drugs separately from all other records."~~**WAC 246-945-040(3)** "Registrants are also required to keep a record of receipt and distribution of controlled substances. Records shall include: (a) Invoices, orders, receipts, or any other document regardless of how titled, establishing the date, supplier, and quantity of drug received, and the name of the drug; (b) Distribution records, including invoices, or any other document regardless of how titled from wholesalers, manufacturers, or any other entity to which the substances were distributed and prescriptions records for dispensers; … (d) For transfers of controlled substances from one dispenser to another, a record of the transfer must be made at the time of transfer indicating the drug, quantity, date of transfer, who it was transferred to, and from whom. Records must be retained by both the transferee and the transferor. These transfers can only be made in emergencies pursuant to 21 CFR Sec. 1307.11.	Click or tap here to enter text.
☐ ☐	☐ ☐	☐ ☐	~~50.~~51	Are records of Schedule ~~III-V~~II drugs maintained ~~either~~ separately ~~or in a form that is readily retrievable~~ from all other controlled substance records?	**WAC 246-945-040(~~5~~4)** "Credential holders and pharmaceutical firms ~~may~~shall maintain records for Schedule ~~III, IV, and V~~II drugs ~~either~~ separately ~~or in a form that is readily retrievable~~ from ~~the business~~all other records ~~of the registrant~~."	Click or tap here to enter text.
☐ ☐	☐ ☐	☐ ☐	~~51.~~52	~~Does the pharmacy have DEA 222 forms or their electronic equivalent for each acquisition or distribution~~Are records of Schedule ~~I~~III-V drugs maintained either separately or in a form that is readily retrievable from other records?	**WAC 246-945-040(~~6~~5)** ~~"A federal order form is required for each distribution of a Schedule I or II controlled substance.~~ "Credential holders and pharmaceutical firms ~~must keep and make readily available these forms and other~~may maintain records ~~to~~for Schedule III, IV, and V drugs either separately or in a form that is readily retrievable from the ~~commission or its designee~~business records of the registrant."	Click or tap here to enter text.
☐ ☐	☐ ☐	☐ ☐	~~52.~~53	Does the pharmacy have DEA 222 forms or their electronic equivalent for each acquisition or distribution of	**WAC 246-945-040(~~3~~)(~~c~~)** ~~"In the event~~**6)** "A federal order form is required for each distribution of a ~~significant loss~~Schedule I or ~~theft, two copies of DEA 106 (report of~~	Click or tap here to enter text.

Compliant			#			Rule Reference	Notes/Corrective Action
Yes	No	N/A					
					Schedule II drugs?~~Are significant losses or disappearances of controlled substances reported to PQAC, the DEA, and other appropriate authorities?~~	~~theft or loss of~~II controlled ~~substances)~~substance. Credential holders and pharmaceutical firms must ~~be transmitted to the federal authorities and a copy must be sent~~keep and make readily available these forms and other records to the commission or its designee."	
☐ ~~☐~~	☐ ~~☐~~	☐ ~~☐~~	~~53.~~54		Are significant losses or disappearances of controlled substances reported to PQAC, the DEA, and other appropriate authorities?~~Are all records maintained for a minimum of two years or for a time period otherwise required?~~ ~~For example, if a Pharmacy is storing, dispensing, and delivering medications without a pharmacist on-site, it must have adequate visual surveillance of the full pharmacy and retain a high-quality recording for a minimum of thirty calendar days.~~	**WAC 246-945-040(3)(c)** "In the event of a significant loss or theft, two copies of DEA 106 (report of theft or loss of controlled substances) must be transmitted to the federal authorities and a copy must be sent to the commission."~~**WAC 246-945-020(1)** "Unless an alternative standard for a specified record type, form, or format is expressly stated a pharmaceutical firm must maintain and retain records required as evidence of compliance with statutes and rules enforced by the commission in a readily retrievable form and location for at least two years from the date the record was created or received, whichever date is later."~~	Click or tap here to enter text.
Professional Requirements							
Please provide the location or file pathway if policies are maintained in electronic format (be as specific as possible, there can be many filing cabinets and binders).							
			~~54.~~55		Does the pharmacy have policies and procedures in place for the following as applicable?	**WAC 246-945-410(6)** "The facility shall create and implement policies and procedures related to: (a) Purchasing, ordering, storing, compounding, delivering, dispensing, and administering legend drugs, including controlled substances."	
☐ ~~☐~~	☐ ~~☐~~	☐ ~~☐~~	54.	a	Purchasing Location or file pathway:		Click or tap here to enter text.
☐ ~~☐~~	☐ ~~☐~~	☐ ~~☐~~	54.	b	Ordering Location or file pathway:		Click or tap here to enter text.
☐ ~~☐~~	☐ ~~☐~~	☐ ~~☐~~	54.	c	Storing Location or file pathway:		Click or tap here to enter text.
☐ ~~☐~~	☐ ~~☐~~	☐ ~~☐~~	54.	d	Compounding Location or file pathway:		Click or tap here to enter text.

Compliant			#			Rule Reference	Notes/Corrective Action
Yes	No	N/A					
☐	☐	☐	54.	e	Delivering Location or file pathway:		Click or tap here to enter text.
☐	☐	☐	54.	f	Dispensing Location or file pathway:		Click or tap here to enter text.
☐	☐	☐	54.	g	Administration Location or file pathway:		Click or tap here to enter text.
☐	☐	☐	~~55.~~56		Does the pharmacy have a policy in place if a computer system downtime occurs? Location or file pathway:	**WAC 246-945-417(4)** "The pharmacy shall have policies and procedures in place for system downtime. (a) The procedure shall provide for the maintenance of all patient recordkeeping information as required by this chapter. (b) Upon restoration of operation of the electronic recordkeeping system the information placed in the auxiliary recordkeeping procedure shall be entered in each patient's records within two working days, after which the auxiliary records may be destroyed. (c) This section does not require that a permanent dual recordkeeping system be maintained."	Click or tap here to enter text.
☐	☐	☐	~~56.~~57		Do pharmacists perform drug utilization reviews when required?	**WAC 246-945-001(29)** "'Drug utilization review" includes, but is not limited to, the following activities: (a) Evaluation of prescriptions and patient records for known allergies, rational therapy-contraindications, appropriate dose, and route of administration and appropriate directions for use; (b) Evaluation of prescriptions and patient records for duplication of therapy; (c) Evaluation of prescriptions and patient records for interactions between drug-drug, drug-disease, and adverse drug reactions; and (d) Evaluation of prescriptions and patient records for proper utilization, including over- or under-utilization, and optimum therapeutic outcomes." **WAC 246-945-410(8)** "A drug utilization review of each prescription before dispensing and delivery shall occur except in emergent medical situations, or if: (a) The drug is a subsequent dose from a previously reviewed prescription; (b) The prescriber is in the immediate vicinity and controls the drug dispensing process; (c) The medication delivery system is being used to provide access to medications on override and only a quantity sufficient	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					to meet the immediate need of the patient is removed; or (d) Twenty-four hour pharmacy services are not available, and a pharmacist will review all prescriptions added to a patient's profile within six hours of the facility opening."	
☐ ~~☐~~	☐ ~~☐~~	☐ ~~☐~~	~~57.~~58	Do pharmacists perform patient counseling?	**WAC 246-945-325(1)** "The pharmacist shall offer to counsel: (a) Upon the initial fill of a prescription for a new or change of therapy. (b) When the pharmacist using their professional judgment determines counseling is necessary to promote safe and effective use and to facilitate an appropriate therapeutic outcome for that patient."	Click or tap here to enter text.
☐ ~~☐~~	☐ ~~☐~~	☐ ~~☐~~	~~58.~~59	~~Do~~ Are pharmacists ~~that engage in activities~~practicing under a valid and unexpired collaborative drug therapy agreement (CDTA~~) have an unexpired CDTA containing the minimum required elements?~~)?	**WAC 246-945-350 "**Collaborative drug therapy agreements. **(1)** A pharmacist exercising prescriptive authority in their practice must have a valid CDTA on file with the commission and their practice location. **(2)** A CDTA must include: (a) A statement identifying the practitioner authorized to prescribe and the name of each pharmacist who is party to the agreement; (i) The practitioner authorized to prescribe must be in active practice; and (ii) The authority granted must be within the scope of the practitioners' current practice. (b) A statement of the type of prescriptive authority decisions which the pharmacist is authorized to make, which includes: (i) A statement of the types of diseases, drugs, or drug categories involved, and the type of prescriptive authority activity (e.g., modification or initiation of drug therapy) authorized in each case. (ii) A general statement of the training required, procedures, decision criteria, or plan the pharmacist is to follow when making therapeutic decisions, particularly when modification or initiation of drug therapy is involved. (c) A statement of the activities the pharmacist is to follow in the course of exercising prescriptive authority, including: (i) Documentation of decisions made; and (ii) A plan for communication or feedback to the authorizing practitioner concerning specific decisions made. **(3)** A CDTA is only valid for two years from the date of signing.	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					(4) Any modification of the written guideline or protocol shall be treated as a new CDTA."	
☐	☐	☐	~~59.~~60	Is all merchandise in date? Including OTC medications anywhere within the store, not solely behind the counter. *It's advised to perform an inventory check for expired medications while filling out this self- inspection report*	**RCW 69.04.100** "Whenever the director shall find in intrastate commerce an article subject to this chapter which is so adulterated or misbranded that it is unfit or unsafe for human use and its immediate condemnation is required to protect the public health, such article is hereby declared to be a nuisance and the director is hereby authorized forthwith to destroy such article or to render it unsalable for human use." **WAC 246-945-415(1)** "A pharmacy may deliver filled prescriptions as long as appropriate measures are taken to ensure product integrity and receipt by the patient or patient's agent."	Click or tap here to enter text.
☐	☐	☐	~~60.~~61	Does the pharmacy meet the requirements for the return and reuse of medications?	**WAC 246-945-485(1)** "A dispensed drug or prescription device must only be accepted for return and reuse as follows: (a) Noncontrolled legend drugs that have been maintained in the custody and control of the institutional facility, dispensing pharmacy, or their related facilities under common control may be returned and reused if product integrity can be assured. (b) Those that qualify for return under the provisions of chapter 69.70 RCW.	Click or tap here to enter text.
☐	☐	☐	~~61.~~62	Does the pharmacy meet the requirements for return and destruction of medications?	**WAC 246-945-485(2)** "A dispensed drug or prescription device may be accepted for return and destruction if: (a) The dispensed drug or prescription device was dispensed in a manner inconsistent with the prescriber's instructions; (b) The return is in compliance with the Washington state safe medication return program laws and rules, chapters 69.48 RCW and 246-480 WAC; or (c) The return and destruction is in compliance with the facility's policies and procedures	Click or tap here to enter text.
☐	☐	☐	~~62.~~63	Does the pharmacy of a licensed hospital or health care entity possess, distribute, or dispense legend drug samples? Note: Other pharmacies not listed above should mark N/A.	**WAC 246-945-035** "Drug sample prohibitions **(1)** "Except as provided in subsection (2) of this section, a pharmacy shall not possess, distribute or dispense legend drug samples. **(2)** A pharmacy of a licensed hospital or health care entity which receives and distributes drug samples at the request	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					of an authorized practitioner pursuant to RCW 69.45.050 may possess, distribute or dispense legend drug samples."	
~~☐~~ ☐	~~☐~~ ☐	~~☐~~ ☐	~~63.~~64	Are all drugs ready to be dispensed to patients properly labeled and stored, in accordance with federal and state statutes, rules, and regulations?	**RCW 18.64.246(1)** "To every box, bottle, jar, tube or other container of a prescription which is dispensed there shall be fixed a label bearing the name and address of the dispensing pharmacy, the prescription number, the name of the prescriber, the prescriber's directions, the name and strength of the medication, the name of the patient, the date, and the expiration date." **RCW 69.41.050(1)** "To every box, bottle, jar, tube or other container of a legend drug, which is dispensed by a practitioner authorized to prescribe legend drugs, there shall be affixed a label bearing the name of the prescriber, complete directions for use, the name of the drug either by the brand or generic name and strength per unit dose, name of patient and date: PROVIDED, That the practitioner may omit the name and dosage of the drug if he or she determines that his or her patient should not have this information and that, if the drug dispensed is a trial sample in its original package and which is labeled in accordance with federal law or regulation, there need be set forth additionally only the name of the issuing practitioner and the name of the patient." **WAC 246-945-016(1) and (3)** "Prescriptions—Outpatient labels—Minimum requirements. **(1)** All licensees of the commission who dispense legend drugs to outpatients shall affix a label to the prescription container that meets the requirements of RCW 69.41.050 and 18.64.246, and shall also include: (a) Drug quantity; (b) The number of refills remaining, if any; (c) The following statement, "Warning: State or federal law prohibits transfer of this drug to any person other than the person for whom it was prescribed.", except when dispensing to an animal, when a warning sufficient to convey "for veterinary use only" may be used; (d) The name and species of the patient, if a veterinary prescription; and (e) The name of the facility or entity authorized by law to possess a legend drug, if patient is the facility or entity.	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					(3) For the purposes of determining an expiration date as required in RCW 18.64.246, the dispenser shall take the following factors into account: (a) The nature of the drug; (b) The container in which it was packaged by the manufacturer and the expiration date; (c) The characteristics of the patient's container, if the drug is repackaged for dispensing; (d) The expected conditions to which the drug may be exposed; (e) The expected length of time of the course of therapy; and (f) Any other relevant factors."	
☐	☐	☐	~~64.~~65	Does the pharmacy have required policies and procedures for drugs stored outside of the pharmacy?	**WAC 246-945-455(1)** "In order for drugs to be stored in a designated area outside the pharmacy including, but not limited to, floor stock, in an emergency cabinet, in an emergency kit, or as emergency outpatient drug delivery from an emergency department at a registered institutional facility, the following conditions must be met: (a) Drugs stored in such a manner shall remain under the control of, and be routinely monitored by, the supplying pharmacy; (b) The supplying pharmacy shall develop and implement policies and procedures to prevent and detect unauthorized access, document drugs used, returned and wasted, and regular inventory procedures; (c) Access must be limited to health care professionals licensed under the chapters specified in RCW 18.130.040 acting within their scope, and nursing students as provided in WAC 246-945-450; (d) The area is appropriately equipped to ensure security and protection from diversion or tampering; and (e) The facility is able to possess and store drugs."	Click or tap here to enter text.
☐	☐	☐	~~65.~~66	Are prescriptions being refilled in accordance with pharmacy laws and rules?	**WAC 246-945-012** "Prescription refills. **(1)** A prescription for a controlled substance listed in Schedule II cannot be refilled. **(2)** A prescription for a controlled substance listed in Schedule III, IV, or V may be refilled a maximum of five times as indicated by the prescriber. The prescription will expire six months after the date of issue pursuant to WAC 246-945-011 even if there are refills remaining. **(3)** A prescription for a noncontrolled legend drug may be refilled as indicated by the prescriber in accordance with	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					RCW 18.64.520. There is no limit on the number of refills, but the prescription will expire after twelve months from the date of issue pursuant to WAC 246-945-011." **WAC 246-945-330** "Refilling prescriptions. **(1)** A prescription may be refilled when permitted by state and federal law and only as authorized by the prescriber. **(2)** Except as provided in subsection (1) of this section, a pharmacist may renew a prescription for a noncontrolled legend drug one time in a six-month period when an effort has been made to contact the prescriber and they are not available for authorization under the following conditions: (a) The amount dispensed is the quantity on the most recent fill or a thirty-day supply, whichever is less; (b) The refill is requested by the patient or the patients agent; (c) The patient has a chronic medical condition; (d) No changes have been made to the prescription; and (e) The pharmacist communicates the renewal to the prescriber within one business day."	
~~☐~~ ☐	~~☐~~ ☐	~~☐~~ ☐	~~66.~~67	When prescriptions are delivered, does the pharmacy have appropriate measures in place to ensure product integrity?	**WAC 246-945-415(1)** "A pharmacy may deliver filled prescriptions as long as appropriate measures are taken to ensure product integrity and receipt by the patient or patient's agent."	Click or tap here to enter text.
Remote Supervision and Access in the Absence of a Pharmacist						
~~☐~~ ☐	~~☐~~ ☐	~~☐~~ ☐	~~67.~~68	Does the pharmacy store, dispense, or deliver drugs to patients without a pharmacist on site? **If you answered "~~No~~N/A" to question 67, mark questions 68-~~74~~7 N/A.	**WAC 246-945-430(1)** "The following requirements apply to pharmacies storing, dispensing and delivering drugs to patients without a pharmacist on-site and are in addition to applicable state and federal laws applying to pharmacies."	Click or tap here to enter text.
~~☐~~ ☐	~~☐~~ ☐	~~☐~~ ☐	~~68.~~69	Does the pharmacy have full visual surveillance of the pharmacy?	**WAC 246-945-430(2)** "The pharmacy is required to have adequate visual surveillance of the full pharmacy and retain a high quality recording for a minimum of thirty calendar days."	Click or tap here to enter text.
~~☐~~ ☐	~~☐~~ ☐	~~☐~~ ☐	~~69.~~70	Is access to the pharmacy limited and monitored?	**WAC 246-945-430(3)** "Access to a pharmacy by individuals must be limited, authorized, and regularly monitored."	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	~~70.~~71	Does the monitoring system include visual and audio communication?	**WAC 246-945-430(4)** "A visual and audio communication system used to counsel and interact with each patient or patient's caregiver, must be clear, secure, and HIPAA compliant."	Click or tap here to enter text.
☐	☐	☐	~~71.~~72	Does the responsible pharmacy manager or designee perform monthly in-person inspections of the pharmacy?	**WAC 246-945-430(5)** "The responsible pharmacy manager, or designee, shall complete and retain, in accordance with WAC 246-945-005 a monthly in-person inspection of the pharmacy."	Click or tap here to enter text.
☐	☐	☐	~~72.~~73	Can a pharmacist be on-site within 3 hours of an emergency?	**WAC 246-945-430(6)** "A pharmacist must be capable of being on-site at the pharmacy within three hours if an emergency arises."	Click or tap here to enter text.
☐	☐	☐	~~73.~~74	Does the pharmacy close in the event of a surveillance system failure?	**WAC 246-945-430(7)** "The pharmacy must be closed to the public if any component of the surveillance or visual and audio communication system is malfunctioning, and remain closed until system corrections or repairs are completed or a pharmacist is on-site to oversee pharmacy operations."	Click or tap here to enter text.
☐	☐	☐	~~74.~~75	Does the pharmacy maintain a perpetual inventory for legend drugs and controlled substances?	**WAC 246-945-420(4)** "A pharmacy that exclusively stores, dispenses or delivers legend drugs, including controlled substances, without a pharmacist on-site shall maintain a perpetual inventory." **WAC 246-945-420(5)** "A pharmacy that exclusively stores, dispenses or delivers prescription drugs without pharmacy ancillary personnel physically on-site shall maintain a perpetual inventory."	Click or tap here to enter text.

Washington State Department of Health

Read this Page Carefully

Pharmacy Quality Assurance Commission

~~2023~~2024 Health Care Entity (HCE) Self-Inspection Worksheet

Attention: Responsible Pharmacy Manager (or Equivalent Manager)

Washington law holds the responsible pharmacy manager (or equivalent manager) and all pharmacy personnel are responsible for ensuring compliance with all state and federal laws governing the practice of pharmacy. Failure to complete this annual worksheet and applicable self-inspection worksheet addendums within the month of March and within 30 days of becoming responsible pharmacy manager (as required by WAC 246-945-005~~)~~(4)) may result in disciplinary action.

Following your self-inspection and completion of the worksheet(s), please review it with your staff, correct any deficiencies noted, sign and date the worksheet(s), and file it so it will be readily available to commission inspectors. **Do not send to the commission office**. You are responsible for ensuring your completed worksheet(s) is available at the time of inspection.

The primary objective of this worksheet, and your self-inspection, is to provide an opportunity to identify and correct areas of non-compliance with state and federal law. (NOTE: Neither the self-inspection nor a commission inspection evaluates your complete compliance with all laws and rules of the practice of pharmacy.) The inspection worksheet also serves as a necessary document used by commission inspectors during an inspection to evaluate a HCE's level of compliance.

When a commission inspector discovers an area of non-compliance, they will issue an Inspection Report with Noted Deficiencies. The responsible pharmacy manager (or equivalent manager) must provide a written response (plan of correction) addressing all areas of non-compliance. Identifying and correcting an area of non-compliance prior to a commission inspection, or during an inspection, may eliminate that item from being included as a deficiency on an Inspection Report. Do not **assume** compliance with any statement; take the time to personally verify that compliance exists. If you have any questions, please contact your inspector.

A common reason for issuing an Inspection Report with Noted Deficiencies is either not having or not being able to readily retrieve required documents and records. Because commission inspections are unscheduled, it is common for the responsible manager to be absent or unavailable. For this reason, you are asked to provide a list of the specific locations of required documents. Having all required documents and records maintained in a well-organized and readily retrievable manner (a binder is recommended) reduces the chance that you will receive an Inspection Report with Noted Deficiencies.

By answering the questions and referencing the appropriate laws/rules/CFR provided, you can determine whether you are compliant with many of the rules and regulations. If you have corrected any deficiencies, please write corrected and the date of correction by the appropriate question. Questions highlighted in **blue** are ~~questions that will be focused on~~common areas of non-compliance observed during routine HCE inspections.

Health Care Entity (HCE) Self-Inspection Worksheet

All responsible pharmacy managers (or equivalent managers) of HCEs **must** complete and sign this self-inspection worksheet within the month of March and within 30 days of becoming responsible pharmacy manager. The form must be available for inspection as required by WAC 246-945-005. **Do not send to the commission office.**

Date ~~responsible pharmacy manager~~ self-inspection worksheet was ~~performed~~complete: Click or tap to enter a date.

Change in responsible pharmacy manager and effective date of change: Click or tap here to enter text. Date: Click or tap to enter a date.

Print Name of Responsible Pharmacy Manager & License #: Click or tap here to enter text.

Signature of responsible manager: Click or tap here to enter text.

Responsible Pharmacy Manager E-mail: Click or tap here to enter text.

~~Pharmacy~~HCE: Click or tap here to enter text. Fax: Click or tap here to enter text. DEA #: Click or tap here to enter text.

Telephone: Click or tap here to enter text. Address: Click or tap here to enter text. ~~Pharmacy~~HCE License #: Click or tap here to enter text.

Endorsements: ☐ Use of Ancillary Personnel ☐ Dispense Controlled Substances

In Washington State, compounding is defined in RCW 18.64.011(6) and means "**the act of combining two or more ingredients in the preparation of a prescription. Reconstitution and mixing of (a) sterile products according to federal food and drug administration-approved labeling does not constitute compounding if prepared pursuant to a prescription and administered immediately or in accordance with package labeling, and (b) nonsterile products according to federal food and drug administration-approved labeling does not constitute compounding if prepared pursuant to a prescription.**"

Please note: If a pharmacy adds flavoring to a commercially available product, it is considered compounding and the non-sterile compounding self-inspection worksheets must also be completed.

Yes	No	
If you practice or provide any other pharmaceutical services outside of community pharmacy you must answer the following and perform the appropriate self-inspection addendums.		
☐	☐	Do ~~pharmacy~~HCE personnel engage in non-sterile compounding of medications? **If yes, please complete the ~~2021~~2024 Non-Sterile Compounding Self-Inspection Addendum in addition to the Health Care Entity Self-Inspection Worksheet.**
☐	☐	Do ~~pharmacy~~HCE personnel engage in sterile compounding? **If yes, you must also complete the ~~2021~~2024 Sterile Compounding Self-Inspection Addendum. If compounding falls under the 'immediate use exemption' as interpreted by the commission *and* is in the retail/community pharmacy setting then the sterile compounding self-inspection worksheet does not need to be completed.**

Document and Record Review

Please provide the location of these documents in the facility (be as specific as possible, there can be many filing cabinets and binders). The documentation listed below ~~are~~is required by rule ~~references to~~and must be ~~available~~readily retrievable during inspection~~, by~~. By listing the location of these documents, you are also confirming ~~your~~ compliance with the referenced rule.

	Rule Reference
Responsible ~~Pharmacy~~ Manager Self-Inspection Worksheet for last 2 years Location: Click or tap here to enter text.	**WAC 246-945-005(4)(a)** "The responsible pharmacy manager, or equivalent manager, shall sign and date the completed self-inspection worksheet(s), and maintain completed worksheets for two years from the date of completion." **WAC 246-945-005(4)(b)** "When a change in responsible pharmacy manager, or equivalent manager occurs, the new responsible pharmacy manager, or equivalent manager, shall conduct a self-inspection as required under this section. The new responsible pharmacy manager, or equivalent manager, shall sign and date the self-inspection worksheet(s) within thirty days of becoming responsible pharmacy manager, or equivalent manager, and maintain completed worksheets for two years from the date of completion."
Health Care Entity License Location: Click or tap here to enter text.	**RCW 18.64.450(1)** "In order for a health care entity to purchase, administer, dispense, and deliver legend drugs, the health care entity must be licensed by the department."
DEA Registration Location: Click or tap here to enter text.	**WAC 246-945-040(2)** "A separate registration is required for each place of business, as defined in 21 CFR. Sec. 1301.12, where controlled substances are manufactured, distributed, or dispensed."
Current Biennial Controlled Substance Inventory Location: Click or tap here to enter text.	**WAC 246-945-420(2)** "A facility shall conduct an inventory of controlled substances every two years." **WAC 246-945-420(3)(a)** "Within thirty days of designating a responsible pharmacy manager. The incoming responsible pharmacy manager, or designee, shall conduct a complete controlled substance inventory. **(b)** On the effective date of an addition of a substance to a schedule of controlled substances. Each facility that possesses the substance shall take an inventory of the substance on hand, and thereafter, include the substance in each inventory." **21 CFR. 1304.04(h)(1)** "Inventories and records of controlled substances listed in Schedules I and II shall be maintained separately from all of the records of the registrant; and. **(2)** Inventories and records of controlled substances listed in Schedules III, IV, and V

	Rule Reference
	shall be maintained either separately from all other records of the registrant or in such form that the information required is readily retrievable from the ordinary business records of the registrant."
Completed CII order forms (DEA Form 222) and/or finalized CSOS documentation for the last 2 years Location: Click or tap here to enter text.	**WAC 246-945-040(6)** "A federal order form is required for each distribution of a Schedule I or II controlled substance. Credential holders and pharmaceutical firms must keep and make readily available these forms and other records to the commission or its designee." **21 CFR. 1305.13(e**) "The purchaser must record on its copy of the DEA Form 222 the number of commercial or bulk containers furnished on each item and the dates on which the containers are received by the purchaser." **21 CFR. 1305.22(g)** "When a purchaser receives a shipment, the purchaser must create a record of the quantity of each item received and the date received. The record must be electronically linked to the original order and archived."
Schedule II Invoices for the last 2 years Location: Click or tap here to enter text.	**WAC 246-945-040(3)(a)** "Every registrant shall keep and maintain inventory records required by 21 CFR. Sec. 1304.04. Registrants are also required to keep a record of receipt and distribution of controlled substances. Records shall include: Invoices, orders, receipts, or any other document regardless of how titled, establishing the date, supplier, and quantity of drug received, and the name of the drug;" **WAC 246-945-040(4)** "Credential holders and pharmaceutical firms shall maintain records for Schedule II drugs separately from all other records."
Schedule III-V Invoices for the last 2 years Location: Click or tap here to enter text.	**WAC 246-945-040(3)(a)** "Every registrant shall keep and maintain inventory records required by 21 CFR. Sec. 1304.04. Registrants are also required to keep a record of receipt and distribution of controlled substances. Records shall include: Invoices, orders, receipts, or any other document regardless of how titled, establishing the date, supplier, and quantity of drug received, and the name of the drug;" **WAC 246-945-040(5)** "Credential holders and pharmaceutical firms may maintain records for Schedule III, IV, and V drugs either separately or in a form that is readily retrievable from the business records of the registrant."
Completed loss by theft or destruction forms (DEA Form 106) for the last 2 years Location: Click or tap here to enter text.	**WAC 246-945-040(3)(c)** "In the event of a significant loss or theft, two copies of DEA 106 (report of theft or loss of controlled substances) must be transmitted to the federal authorities and a copy must be sent to the commission." **21 CFR. 1301.76(b)** "The registrant shall notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft..."
Power of Attorney for staff authorized to order controlled substances Location: Click or tap here to enter text.	**WAC 246-945-040(1)** "The commission adopts 21 CFR. as its own." **21 CFR. 1305.05(a)** "A registrant may authorize one or more individuals, whether or not located at his or her registered location, to issue orders for Schedule I and II controlled substances on the registrant's behalf by executing a power of attorney for each such individual, if the power of attorney is retained in the files, with executed Forms 222 where applicable, for the same period as any order bearing the signature of the attorney. The power of attorney must be available for inspection together with other order records."
Change of Responsible Pharmacy Manager forms for the last 2 years Location: Click or tap here to enter text.	**WAC 246-945-480(1)** "The outgoing and incoming responsible pharmacy manager must report in writing to the commission a change in a responsible pharmacy manager designation within ten business days of the change." **WAC 246-945-020 (1)** "Unless an alternative standard for a specified record type, form, or format is expressly stated a pharmaceutical firm must maintain and retain records required as evidence of compliance with statutes and rules enforced by the commission in a readily retrievable form and location for at least two years from the date the record was created or received, whichever date is later. **(2)** A pharmaceutical firm must allow the commission, or its designee, access to the pharmaceutical firm's records upon request for the purposes of monitoring compliance with statutes and rules enforced by the commission."
Prescription Records for the last 2 years	**WAC 246-945-410(12)** "A facility's paper prescriptions must be maintained in accordance with WAC 246-945-020 and as follows: **(a)** Paper prescriptions for Schedule II drugs must be maintained as a separate file from other prescriptions.

	Rule Reference
Location: Click or tap here to enter text.	**(b)** Paper prescriptions for Schedule III, IV, and V drugs must be maintained as a separate file or maintained in a separate file with prescriptions for non-controlled legend drugs as allowed under federal law."

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
General Licensing						
☐	☐	☐	1.	Does the Health Care Entity (HCE) have a current license?	**RCW 18.64.450(1)** "In order for a health care entity to purchase, administer, dispense, and deliver legend drugs, the health care entity must be licensed by the department."	Click or tap here to enter text.
☐	☐	☐	2.	Does the HCE have a current DEA registration?	**WAC 246-945-040(2)** "A separate registration is required for each place of business, as defined in 21 CFR. Sec. 1301.12, where controlled substances are manufactured, distributed, or dispensed."	Click or tap here to enter text.
☐	☐	☐	3.	Is the responsible pharmacy manager licensed to practice pharmacy in the State of Washington?	**WAC 246-945-310** "Responsible pharmacy manager. The responsible pharmacy manager must be licensed to practice pharmacy in the state of Washington. The responsible pharmacy manager designated by a facility as required under WAC 246-945-410 shall have the authority and responsibility to assure that the area(s) within the facility where drugs are stored, compounded, delivered, or dispensed are operated in compliance with all applicable state and federal statutes and regulations."	Click or tap here to enter text.
Facility Standards						
☐	☐	☐	4.	Is the facility appropriately constructed and equipped to protect equipment, records, drugs/devices and other restricted items from unauthorized access? **Including samples under the control of the HCE**	**RCW 69.45.040(2)** "Drug samples shall be maintained in a locked area to which access is limited to persons authorized by the manufacturer." **WAC 246-945-410(1)** "The facility shall be constructed and equipped with adequate security to protect equipment, records, and supply of drugs, devices, and other restricted sale items from unauthorized access, acquisition, or use."	Click or tap here to enter text.
☐	☐	☐	5.	Is the facility properly equipped to ensure proper operation,	**WAC 246-945-410(2)** "The facility shall be properly equipped to ensure the safe, clean, and sanitary condition necessary for	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
				prescription preparation, and product integrity?	the proper operation, the safe preparation of prescriptions, and to safeguard product integrity."	
☐	☐	☐	6.	Does the facility have a designated responsible pharmacy manager?	**WAC 246-945-410(5)** "The facility shall designate a responsible pharmacy manager: **(a)** By the date of opening; and **(b)** Within thirty calendar days of a vacancy."	Click or tap here to enter text.
☐	☐	☐	7.	Are the drug storage areas appropriately secure from unauthorized access and are staff working within their scope of practice?	**WAC 246-945-410(10)** "Access to the drug storage area located within the facility should be limited to pharmacists unless one of the following applies: **(a)** A pharmacy intern, or pharmacy ancillary personnel enter under the immediate supervision of a pharmacist; or **(b)** A pharmacist authorizes temporary access to an individual performing a legitimate nonpharmacy function under the immediate supervision of the pharmacist; or **(c)** The facility has a policy and procedure restricting access to a health care professional licensed under the chapters specified in RCW 18.130.040, and the actions of the health care professional are within their scope of practice."	Click or tap here to enter text.
☐	☐	☐	8.	Are medication refrigerator temperatures maintained between 2- 8°C (36-46°F)? ** Electronic monitoring is acceptable. **	**WAC 246-945-410(2)** "The facility shall be properly equipped to ensure the safe, clean, and sanitary condition necessary for the proper operation, the safe preparation of prescriptions, and to safeguard product integrity."	Click or tap here to enter text.
☐	☐	☐	9.	Are medication freezer temperatures maintained between -25°& -10°C (-13° & 14°F) or within acceptable range based on product packaging? ** Electronic monitoring is acceptable. **	**WAC 246-945-410(2)** "The facility shall be properly equipped to ensure the safe, clean, and sanitary condition necessary for the proper operation, the safe preparation of prescriptions, and to safeguard product integrity."	Click or tap here to enter text.
☐	☐	☐	10.	Is drug stock stored under proper conditions (temperature, humidity, light) as recommend by the drug label? **Including samples under the control of the HCE**	**RCW 69.45.040(3)** "Drug samples shall be stored and transported in such a manner as to be free of contamination, deterioration, and adulteration. **(4)** Drug samples shall be stored under conditions of temperature, light, moisture, and ventilation so as to meet the label instructions for each drug."	Click or tap here to enter text.

Compliant			#			Rule Reference	Notes/Corrective Action
Yes	No	N/A					
						WAC 246-945-410(2) "The facility shall be properly equipped to ensure the safe, clean, and sanitary condition necessary for the proper operation, the safe preparation of prescriptions, and to safeguard product integrity."	
☐	☐	☐	11.			**RCW 69.04.100** "Whenever the director shall find in intrastate commerce an article subject to this chapter which is so adulterated or misbranded that it is unfit or unsafe for human use and its immediate condemnation is required to protect the public health, such article is hereby declared to be a nuisance and the director is hereby authorized forthwith to destroy such article or to render it unsalable for human use." **RCW 69.45.040(5)** "Drug samples which have exceeded the expiration date shall be physically separated from other drug samples until disposed of or returned to the manufacturer." **WAC 246-945-410(2)** "The facility shall be properly equipped to ensure the safe, clean, and sanitary condition necessary for the proper operation, the safe preparation of prescriptions, and to safeguard product integrity."	Click or tap here to enter text.
				Is all drug stock in date? **Including OTC medications and samples under the control of the HCE** *It's advised to perform an inventory check for expired medications while filling out this self-inspection worksheet.*			

Policies and Procedures

Please provide the location or file pathway if policies are maintained in electronic format (be as specific as possible, there can be many filing cabinets).

			12.	Does the HCE have policies and procedures in place for the following:		**WAC 246-945-410(6)** "The facility shall create and implement policies and procedures related to: (a) Purchasing, ordering, storing, compounding, delivering, dispensing, and administering legend drugs, including controlled substances."	
☐	☐	☐	12.	a	Purchasing		Click or tap here to enter text.
☐	☐	☐	12.	b	Ordering		Click or tap here to enter text.
☐	☐	☐	12.	c	Storing		Click or tap here to enter text.
☐	☐	☐	12.	d	Compounding		Click or tap here to enter text.
☐	☐	☐	12.	e	Delivering		Click or tap here to enter text.
☐	☐	☐	12.	f	Dispensing		Click or tap here to enter text.
☐	☐	☐	12.	g	Administration		Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	13.	Does the HCE have policies and procedures addressing administration of patient owned medications?	**WAC 246-945-440** "Facilities shall develop written policies and procedures for the administration of patient owned medications."	Click or tap here to enter text.
☐	☐	☐	14.	Does the HCE accept dispensed drugs or prescription devices for return and reuse appropriately?	**WAC 246-945-485(1)** "A dispensed drug or prescription device must only be accepted for return and reuse as follows: **(a)** Noncontrolled legend drugs that have been maintained in the custody and control of the institutional facility, dispensing pharmacy, or their related facilities under common control may be returned and reused if product integrity can be assured. **(b)** Those that qualify for return under the provisions of chapter 69.70 RCW."	Click or tap here to enter text.
☐	☐	☐	15.	Does the HCE accept dispensed drugs or prescription devices for return and destruction appropriately?	**WAC 246-945-485(2)** "A dispensed drug or prescription device may be accepted for return and destruction if: **(a)** The dispensed drug or prescription device was dispensed in a manner inconsistent with the prescriber's instructions; **(b)** The return is in compliance with the Washington state safe medication return program laws and rules, chapters 69.48 RCW and 246-480 WAC; or **(c)** The return and destruction is in compliance with the facility's policies and procedures."	Click or tap here to enter text.
☐	☐	☐	16.	Does the HCE have policies and procedures addressing computer system downtime?	**WAC 246-945-417(7)** "HCEs or HPACs that maintain an electronic record system must be done in accordance with subsections (2) through (7) of this section." **WAC 246-945-417(4)** "The pharmacy shall have policies and procedures in place for system downtime. **(a)** The procedure shall provide for the maintenance of all patient recordkeeping information as required by this chapter. **(b)** Upon restoration of operation of the electronic recordkeeping system the information placed in the auxiliary recordkeeping procedure shall be entered in each patient's records within two working days, after which the auxiliary records may be destroyed. **(c)** This section does not require that a permanent dual recordkeeping system be maintained."	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
Recordkeeping						
☐	☐	☐	17.	Are complete patient medical records maintained in either paper or electronic format?	**WAC 246-945-418** "If an HPAC or HCE does not maintain an electronic recordkeeping system their manual records must contain all information required in WAC 246-945-417."	Click or tap here to enter text.
☐	☐	☐	18.	If applicable, does the HCE maintain electronic record system including patient allergies, idiosyncrasies or chronic conditions, and prescription, refill, transfer information, and other information necessary to provide safe and appropriate patient care?	**WAC 246-945-417(1)** "A pharmacy shall use an electronic recordkeeping system to establish and store patient medication records, including patient allergies, idiosyncrasies or chronic conditions, and prescription, refill, transfer information, and other information necessary to provide safe and appropriate patient care." **WAC 246-945-417(7)** HCEs or HPACs that maintain an electronic record system must be done in accordance with subsections (2) through (7) of this section.	Click or tap here to enter text.
☐	☐	☐	19.	Does the electronic recordkeeping system include security features to protect confidentiality and integrity of patient records?	**WAC 246-945-417(3)** "The electronic recordkeeping system must include security features to protect the confidentiality and integrity of patient records including: **(a)** Safeguards designed to prevent and detect unauthorized access, modification, or manipulation of prescription information and patient medication records; and **(b)** Functionality that documents any alteration of prescription information after a prescription is dispensed, including the identification of the individual responsible for the alteration."	Click or tap here to enter text.
☐	☐	☐	20.	If applicable, does the manual patient medical record system have the capability to store patient medication records e.g. allergies, idiosyncrasies or chronic conditions, and prescription, refill, transfer, and other information as required in WAC 246-945-417?	**WAC 246-945-417(7)** "HCEs or HPACs that maintain an electronic record system must be done in accordance with subsections (2) through (7) of this section." **WAC 246-945-417** "**(1)** A pharmacy shall use an electronic recordkeeping system to establish and store patient medication records, including patient allergies, idiosyncrasies or chronic conditions, and prescription, refill, transfer information, and other information necessary to provide safe and appropriate patient care. **(a)** Systems must prevent auto-population of user identification information. **(b)** Pharmacies that provide off-site pharmacy services without a pharmacist for product fulfillment or prescription processing must track	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					the identity of each individual involved in each step of the off-site pharmacy services. **(2)** The electronic recordkeeping system must be capable of real-time retrieval of information pertaining to the ordering, verification, and processing of the prescription where possible. **(3)** The electronic recordkeeping system must include security features to protect the confidentiality and integrity of patient records including: **(a)** Safeguards designed to prevent and detect unauthorized access, modification, or manipulation of prescription information and patient medication records; and **(b)** Functionality that documents any alteration of prescription information after a prescription is dispensed, including the identification of the individual responsible for the alteration. **(4)** The pharmacy shall have policies and procedures in place for system downtime. **(a)** The procedure shall provide for the maintenance of all patient recordkeeping information as required by this chapter. **(b)** Upon restoration of operation of the electronic recordkeeping system the information placed in the auxiliary recordkeeping procedure shall be entered in each patient's records within two working days, after which the auxiliary records may be destroyed. **(c)** This section does not require that a permanent dual recordkeeping system be maintained. **(5)** The pharmacy shall maintain records in accordance with WAC 246-945-020. **(6)** Electronic prescriptions for prescription drugs must be maintained by the pharmacy in a system that meets the requirements of 21 CFR. Sec. 1311." **WAC 246-945-418** "If an HPAC or HCE does not maintain an electronic recordkeeping system their manual records must contain all information required in WAC 246-945-417. The record system consists of the hard copy of the original prescription and a card or filing procedure that contains all data on new and refill prescriptions for a patient. This data must be organized in such a fashion that information relating to all prescription drugs used by a patient will be reviewed each time a prescription is filled."	

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	21.	Are suitable ~~record~~records of drugs readily retrievable or maintained separately from all other records? **Including drug samples under the control of the HCE**	**RCW 18.64.470** "Every proprietor or manager of a health care entity shall keep readily available a suitable record of drugs, which shall preserve for a period of not less than two years the record of every drug used at such health care entity. The record shall be maintained either separately from all other records of the health care entity or in such form that the information required is readily retrievable from ordinary business records of the health care entity. All recordkeeping requirements for controlled substances must be complied with."	Click or tap here to enter text.
☐	☐	☐	22.	Are all records readily retrievable for at least two years from the date the record was created or received, whichever is later?	**WAC 246-945-020(1)** "Unless an alternative standard for a specified record type, form, or format is expressly stated a pharmaceutical firm must maintain and retain records required as evidence of compliance with statutes and rules enforced by the commission in a readily retrievable form and location for at least two years from the date the record was created or received, whichever date is later." **WAC 246-945-001(7)** ""Readily retrievable" means a record that is kept by automatic data processing systems or other electronic, mechanized, or written recordkeeping systems in such a manner that it can be separated out from all other records in a reasonable time."	Click or tap here to enter text.
Controlled Substances						
☐	☐	☐	23.	Are all controlled substances in the HCE locked and secured to prevent unauthorized access?	**WAC 246-945-040(1)** "The commission adopts 21 CFR. as its own." **21 CFR. 1301.75(a)** "Controlled substances listed in Schedule I shall be stored in a securely locked, substantially constructed cabinet. **(b)** Controlled substances listed in Schedules II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet." **WAC 246-945-410(1)** "The facility shall be constructed and equipped with adequate security to protect equipment, records, and supply of drugs, devices, and other restricted sale items from unauthorized access, acquisition, or use."	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	24.	Does the HCE maintain records of receipt and distribution of all controlled substances?	**WAC 246-945-040(3)** "Registrants are also required to keep a record of receipt and distribution of controlled substances. Records shall include: **(a)** Invoices, orders, receipts, or any other document regardless of how titled, establishing the date, supplier, and quantity of drug received, and the name of the drug; **(b)** Distribution records, including invoices, or any other document regardless of how titled from wholesalers, manufacturers, or any other entity to which the substances were distributed and prescriptions records for dispensers; **(d)** For transfers of controlled substances from one dispenser to another, a record of the transfer must be made at the time of transfer indicating the drug, quantity, date of transfer, who it was transferred to, and from whom. Records must be retained by both the transferee and the transferor. These transfers can only be made in emergencies pursuant to 21 CFR. Sec. 1307.11."	Click or tap here to enter text.
☐	☐	☐	25.	Are records of Schedule II drugs maintained separately from all other controlled substance records?	**WAC 246-945-040(4)** "Credential holders and pharmaceutical firms shall maintain records for Schedule II drugs separately from all other records."	Click or tap here to enter text.
☐	☐	☐	26.	Does the HCE have completed DEA 222 forms or their electronic equivalent for each acquisition or distribution of Schedule II drugs?	**WAC 246-945-040(6)** "A federal order form is required for each distribution of a Schedule I or II controlled substance. Credential holders and pharmaceutical firms must keep and make readily available these forms and other records to the commission or its designee."	Click or tap here to enter text.
☐	☐	☐	27.	Are records of Schedule III-V drugs maintained either separately or in a form that is readily retrievable from other records?	**WAC 246-945-040(5)** "Credential holders and pharmaceutical firms may maintain records for Schedule III, IV, and V drugs either separately or in a form that is readily retrievable from the business records of the registrant." **21 CFR 1304.04(h)(3)** "…Inventories and records of Schedules III, IV, and V controlled substances shall be maintained either separately from all other records of the pharmacy or in such form that the information required is readily retrievable from ordinary business records of the pharmacy."	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	28.	Is an inventory of controlled substances being performed every 2 years? **Including controlled substance samples under the control of the HCE** An inventory of controlled substances must be completed within 30 days of a new responsible pharmacy manager or on the effective date of the addition of a substance to a schedule of controlled substances.	**WAC 246-945-420(2)** "A facility shall conduct an inventory of controlled substances every two years." **WAC 246-945-420(3)(a)** "Within thirty days of designating a responsible pharmacy manager. The incoming responsible pharmacy manager, or designee, shall conduct a complete controlled substance inventory. **(b)** On the effective date of an addition of a substance to a schedule of controlled substances. Each facility that possesses the substance shall take an inventory of the substance on hand, and thereafter, include the substance in each inventory." **21 CFR. 1304.11(a)** "Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location."	Click or tap here to enter text.
☐	☐	☐	29.	Does the HCE have power of attorney forms for ordering schedule II-controlled substances?	**21 CFR. 1305.05(a)** "A registrant may authorize one or more individuals, whether or not located at his or her registered location, to issue orders for Schedule I and II controlled substances on the registrant's behalf by executing a power of attorney for each such individual, if the power of attorney is retained in the files, with executed Forms 222 where applicable, for the same period as any order bearing the signature of the attorney. The power of attorney must be available for inspection together with other order records."	Click or tap here to enter text.
☐	☐	☐	30.	Has the HCE reported significant losses or disappearances of controlled substances to PQAC and the DEA in the previous 24 months?	**21 CFR 1301.76(b)** "The registrant shall notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft." **WAC 246-945-040(3)(c)** "In the event of a significant loss or theft, two copies of DEA 106 (report of theft or loss of controlled substances) must be transmitted to the federal authorities and a copy must be sent to the commission; …"	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
Dispensing – HCEs that do not dispense for use outside the HCE and answer "No" to question 31 may skip question numbers 32-~~47~~41						
☐	☐	☐	31.	Does the HCE dispense prescription medications to patients for at home use?	**RCW 18.64.450(4)** "A health care entity may only administer, dispense, or deliver legend drugs and controlled substances to patients who receive care within the health care entity and in compliance with rules of the commission…"	Click or tap here to enter text.
☐	☐	☐	32.	If HCEs dispense medications without a pharmacist's involvement, are they restricting medications dispensed to a seventy-two (72) hour supply?	**RCW 18.64.450(4)** "…Nothing in this subsection shall prohibit a practitioner, in carrying out his or her licensed responsibilities within a health care entity, from dispensing or delivering to a patient of the health care entity drugs for that patient's personal use in an amount not to exceed seventy-two hours of usage."	Click or tap here to enter text.
☐	☐	☐	33.	Does the HCE have valid prescription records for all drugs dispensed to patients?	**WAC 246-945-410(7)** "Prescription drugs must only be dispensed pursuant to a valid prescription as required by WAC 246-945-011." **WAC 246-945-011(1)** "Prior to dispensing and delivering a prescription, a pharmacist shall verify its validity." **(2)** A prescription shall be considered invalid if: **(a)** At the time of presentation, the prescription shows evidence of alteration, erasure, or addition by any person other than the person who wrote it; **(b)** The prescription does not contain the required information as provided in WAC 246-945-010; **(c)** The prescription is expired; or **(d)** The prescription is for a controlled substance and does not comply with the requirements in RCW 69.50.308. **(3)** A prescription is considered expired when: **(a)** The prescription is for a controlled substance listed in Schedule II through V and the date of dispensing is more than six months after the prescription's date of issue. **(b)** The prescription is for a noncontrolled legend drug or OTC's and the date of dispensing is more than twelve months after the prescription's date of issue."	Click or tap here to enter text.
☐	☐	☐	34.	Are all non-controlled legend drugs prescribed orally promptly transcribed to a written or electronic prescription?	**WAC 246-945-010(8)** "A noncontrolled legend drug can only be dispensed pursuant to a valid prescription in accordance with WAC 246-945-011, or an oral prescription. An oral prescription for a noncontrolled legend drug must be promptly reduced to a written or electronic prescription that complies with WAC 246-945-011."	Click or tap here to enter text.

Compliant			#			Rule Reference	Notes/Corrective Action
Yes	No	N/A					
			35.	Do all prescriptions for non-controlled legend drugs include all required elements?		**WAC 246-945-010(3)** "A prescription for a noncontrolled legend drug must include, but is not limited to, the following: **(a)** Prescriber's name; **(b)** Name of patient, authorized entity, or animal name and species; **(c)** Date of issuance; **(d)** Drug name, strength, and quantity; **(e)** Directions for use; **(f)** Number of refills (if any); **(g)** Instruction on whether or not a therapeutically equivalent generic drug or interchangeable biological product may be substituted, unless substitution is permitted under a prior-consent authorization; **(h)** Prescriber's manual or electronic signature, or prescriber's authorized agent signature if allowed by law; and **(i)** If the prescription is written, it must be written on tamper-resistant prescription pad or paper approved by the commission pursuant to RCW 18.64.500"	
☐	☐	☐	35.	a	Prescriber's Name		Click or tap here to enter text.
☐	☐	☐	35.	b	Name of Patient/ Authorized Entity/Animal Name and Species		Click or tap here to enter text.
☐	☐	☐	35.	c	Date of Issuance		Click or tap here to enter text.
☐	☐	☐	35.	d	Drug Name, Strength, and Quantity		Click or tap here to enter text.
☐	☐	☐	35.	e	Directions for Use		Click or tap here to enter text.
☐	☐	☐	35.	f	Number of Refills		Click or tap here to enter text.
☐	☐	☐	35.	g	Substitution Directions		Click or tap here to enter text.
☐	☐	☐	35.	h	Prescribers Signature		Click or tap here to enter text.
☐	☐	☐	35.	i	If written, on Tamper-Resistant Paper		Click or tap here to enter text.
			36.	Do all prescriptions for controlled substances include additional required elements?		**WAC 246-945-010(4)** "A prescription for a controlled substance must include all the information listed in subsection (1) of this section and the following: **(a)** Patient's address; **(b)** Dosage form; **(c)** Prescriber's address; **(d)** Prescriber's DEA registration number; and **(e)** Any other requirements listed in 21 CFR., Chapter II."	
~~☐~~	~~☐~~	~~☐~~	~~36.~~	~~a~~	~~Elements from Question 38~~		~~Click or tap here to enter text.~~
☐	☐	☐	36.	~~b~~a	Patient's Address		Click or tap here to enter text.
☐	☐	☐	36.	~~c~~b	Dosage Form		Click or tap here to enter text.
☐	☐	☐	36.	~~d~~c	Prescriber's Address		Click or tap here to enter text.
☐	☐	☐	36.	~~e~~d	Prescriber's DEA Number		Click or tap here to enter text.
☐	☐	☐	37.	Are all prescriptions properly labeled and stored, in accordance with federal and state statutes, rules, and regulations?		**RCW 18.64.246(1)** "To every box, bottle, jar, tube or other container of a prescription which is dispensed there shall be fixed a label bearing the name and address of the dispensing pharmacy, the prescription number, the name of the prescriber, the	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
				Includes drug samples under the control of the HCE	prescriber's directions, the name and strength of the medication, the name of the patient, the date, and the expiration date." **RCW 69.41.050(1)** "To every box, bottle, jar, tube or other container of a legend drug, which is dispensed by a practitioner authorized to prescribe legend drugs, there shall be affixed a label bearing the name of the prescriber, complete directions for use, the name of the drug either by the brand or generic name and strength per unit dose, name of patient and date: PROVIDED, That the practitioner may omit the name and dosage of the drug if he or she determines that his or her patient should not have this information and that, if the drug dispensed is a trial sample in its original package and which is labeled in accordance with federal law or regulation, there need be set forth additionally only the name of the issuing practitioner and the name of the patient." **WAC 246-945-016(1) and (3)** "**(1)** All licensees of the commission who dispense legend drugs to outpatients shall affix a label to the prescription container that meets the requirements of RCW 69.41.050 and 18.64.246, and shall also include: **(a)** Drug quantity; **(b)** The number of refills remaining, if any; **(c)** The following statement, "Warning: State or federal law prohibits transfer of this drug to any person other than the person for whom it was prescribed.", except when dispensing to an animal, when a warning sufficient to convey "for veterinary use only" may be used; **(d)** The name and species of the patient, if a veterinary prescription; and **(e)** The name of the facility or entity authorized by law to possess a legend drug, if patient is the facility or entity… **(3)** For the purposes of determining an expiration date as required in RCW 18.64.246, the dispenser shall take the following factors into account: **(a)** The nature of the drug; (b) The container in which it was packaged by the manufacturer and the expiration date; **(c)** The characteristics of the patient's container, if the drug is repackaged for dispensing; **(d)** The expected conditions to which the drug may be exposed; **(e)** The expected length of time of the course of therapy; and **(f)** Any other relevant factors."	
☐	☐	☐	38.	Are all legend drugs dispensed in child-resistant containers, as required by federal law or regulation? (This includes special packaging used such as customized patient medication	**WAC 246-945-032 (1)** "All legend drugs shall be dispensed in a child-resistant container as required by federal law or regulation, including 16 CFR., Part 1700, unless: **(a)** Authorization is received from the prescriber to dispense in a container that is not child-resistant.	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
				packages; blister packs, med-minders, etc.) ** Please see the FAQ on commission website. ** ** Best practice: It is recommended that these authorizations are updated annually. **	**(b)** Authorization is obtained from the patient or a representative of the patient to dispense in a container that is not child-resistant."	
☐	☐	☐	39.	Is supplemental information provided to the patient with each dispensed prescription?	**WAC 246-945-410(9)** "Each drug dispensed and delivered to a patient must bear a complete and accurate label as required by WAC 246-945-015 through 246-945-018. The information contained on the label shall be supplemented by oral or written information as required by WAC 246-945-325." **WAC 246-945-325** **(1)** The pharmacist shall offer to counsel: **(a)** Upon the initial fill of a prescription for a new or change of therapy. **(b)** When the pharmacist using their professional judgment determines counseling is necessary to promote safe and effective use and to facilitate an appropriate therapeutic outcome for that patient. **(2) This does not apply to medications that are administered by a licensed health professional acting within their scope of practice.**	Click or tap here to enter text.
☐	☐	☐	40.	Are electronic prescriptions maintained appropriately?	**WAC 246-945-417(6)** "Electronic prescriptions for prescription drugs must be maintained by the pharmacy in a system that meets the requirements of 21 CFR. Sec. 1311." (7) HCEs or HPACs that maintain an electronic record system must be done in accordance with subsections (2) through (7) of this section.	Click or tap here to enter text.
Pharmacist Professional Requirements						
☐	☐	☐	41.	Unless an exception applies, does the HCE conduct a drug utilization review (DUR) of each prescription before dispensing and delivery? OR	**WAC 246-945-001(29)** "'Drug utilization review" includes, but is not limited to, the following activities: **(a)** Evaluation of prescriptions and patient records for known allergies, rational therapy-contraindications, appropriate dose, and route of administration and appropriate directions for use; **(b)** Evaluation of prescriptions and patient records for duplication of therapy; **(c)** Evaluation of prescriptions and patient records for interactions between drug-drug, drug-disease, and adverse drug reactions; and **(d)** Evaluation	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
				If a pharmacist is involved in the dispensing process, is drug utilization review completed?	of prescriptions and patient records for proper utilization, including over- or under-utilization, and optimum therapeutic outcomes." **WAC 246-945-410(8)** "A drug utilization review of each prescription before dispensing and delivery shall occur **except in emergent medical situations, or if**: **(a)** The drug is a subsequent dose from a previously reviewed prescription; **(b)** The prescriber is in the immediate vicinity and controls the drug dispensing process; **(c)** The medication delivery system is being used to provide access to medications on override and only a quantity sufficient to meet the immediate need of the patient is removed; or **(d)** Twenty-four hour pharmacy services are not available, and a pharmacist will review all prescriptions added to a patient's profile within six hours of the facility opening."	
☐	☐	☐	42.	If a pharmacist is involved in the dispensing process, do pharmacists perform patient counseling?	**WAC 246-945-325(1)** "The pharmacist shall offer to counsel: **(a)** Upon the initial fill of a prescription for a new or change of therapy. **(b)** When the pharmacist using their professional judgment determines counseling is necessary to promote safe and effective use and to facilitate an appropriate therapeutic outcome for that patient."	Click or tap here to enter text.

Read this Page Carefully

WA Pharmacy Quality Assurance Commission
~~2023~~2024 Hospital Pharmacy and HPAC Self-Inspection Worksheet

Attention: Responsible Pharmacy Manager or Equivalent Manager

Washington law holds the responsible manager (or equivalent manager) and all pharmacists on duty responsible for ensuring pharmacy compliance with all state and federal laws governing the practice of pharmacy. Failure to complete this annual worksheet and applicable self-inspection worksheet addendums within the month of March and within 30 days of becoming responsible manager (as required by WAC 246-945-005) may result in disciplinary action.

Following your self-inspection and completion of the worksheet(s), please review it with your staff pharmacists, ancillary staff and interns, correct any deficiencies noted, sign and date the worksheet(s), and file it so it will be readily available to commission inspectors. **Do not send to the commission office**. You are responsible for ensuring your completed worksheet(s) is available at the time of inspection.

The primary objective of this worksheet(s), and your self-inspection, is to provide an opportunity to identify and correct areas of non-compliance with state and federal law. (**Note**: Neither the self-inspection nor a commission inspection evaluates your complete compliance with all laws and rules of the practice of pharmacy.) The inspection worksheet also serves as a necessary document used by commission inspectors during an inspection to evaluate a pharmacy's level of compliance.

When a commission inspector discovers an area(s) of non-compliance, they will issue an **Inspection Report with Noted Deficiencies**. The responsible manager must provide a written response (plan of correction) addressing all areas of non-compliance. Identifying and correcting an area of non-compliance prior to a commission inspection, or during an inspection, may eliminate that item from being included as a deficiency on an Inspection Report. Do not assume that you are in compliance with any statement; take the time to personally verify that compliance exists. If you have any questions, please contact your inspector.

A common reason for issuing an Inspection Report with Noted Deficiencies is either not having or not being able to readily retrieve required documents and records. Because commission inspections are unscheduled, it is common for the responsible manager to be absent or unavailable. For this reason, you are asked to provide a list of the locations of required documents. Having all required documents and records maintained in a well- organized and readily retrievable manner (a binder is recommended) reduces the chance that you will receive an Inspection Report with Noted Deficiencies.

By answering the questions and referencing the appropriate laws/rules/CFR provided, you can determine whether you are compliant with many of the rules and regulations. If you have corrected any deficiencies, please write corrected and the date of correction by the appropriate question.

Questions highlighted in **blue** are ~~questions that will be focused on~~common areas of non-compliance observed during routine pharmacy inspections.

To request this document in another format, call 1-800-525-0127. Deaf or hard of hearing customers, please call 711 (Washington Relay) or email civil.rights@doh.wa.gov.
View translated versions of this statement here.

Washington State Department of Health

~~2023~~2024 Hospital Pharmacy and HPAC Self-Inspection Worksheet

All responsible pharmacy managers (or equivalent managers) of pharmacies **must** complete and sign this self-inspection worksheet within the month of March and within 30 days of becoming responsible pharmacy manager. The form must be available for inspection as required by WAC 246-945-005. **Do not send to the commission office.**

Date responsible pharmacy manager self-inspection was ~~performed~~completed: Click or tap to enter a date.

Change in responsible pharmacy manager and effective date of change: Click or tap here to enter text. Date: Click or tap to enter a date.

Print Name of Responsible Pharmacy Manager & License #: Click or tap here to enter text.

Signature of responsible manager: Click or tap here to enter text.

Responsible Pharmacy Manager E-mail: Click or tap here to enter text.

Pharmacy: Click or tap here to enter text. Fax: Click or tap here to enter text. DEA #: Click or tap here to enter text.

Telephone: Click or tap here to enter text. Address: Click or tap here to enter text. Pharmacy License #: Click or tap here to enter text.

Endorsements: ☐ Use of Ancillary Personnel ☐ Dispense Controlled Substances

In Washington State, compounding is defined in RCW 18.64.011(6) and means "**the act of combining two or more ingredients in the preparation of a prescription. Reconstitution and mixing of (a) sterile products according to federal food and drug administration-approved labeling does not constitute compounding if prepared pursuant to a prescription and administered immediately or in accordance with package labeling, and (b) nonsterile products according to federal food and drug administration-approved labeling does not constitute compounding if prepared pursuant to a prescription.**"

Please note: If a pharmacy adds flavoring to a commercially available product, it is considered compounding and the non-sterile compounding self-inspection worksheets must also be completed.

Yes	No	
☐	☐	Are you a hospital pharmacy? **If yes, you must *only* complete the ~~2023~~2024 Hospital Pharmacy and HPAC Self-Inspection Worksheet, unless you answer yes to any of the following.**
If you practice or provide any other pharmaceutical services outside of community pharmacy you must answer the following and perform the appropriate self-inspection addendums.		
☐	☐	**Does the pharmacy engage in non-sterile compounding of medications?** **If yes,** please complete the ~~2023~~2024 Non-Sterile Compounding Self-Inspection Addendum in addition to the Hospital Pharmacy and HPAC Self-Inspection Worksheet.

☐	☐	**Does the pharmacy engage in sterile compounding?** **If yes**, you must also complete the ~~2023~~2024 Sterile Compounding Self-Inspection Addendum in addition to the Hospital Pharmacy and HPAC Self-Inspection Worksheet.
☐	☐	Do you have an endorsement as a Nuclear Pharmacy? **If yes, you must also complete the ~~2023 Nuclear~~2024 Radiopharmaceuticals Pharmacy Self-Inspection Addendum.**

Document and Record Review

Please provide the location of these documents in the pharmacy (be as specific as possible, there can be many filing cabinets and binders). The documentation listed below are required by rule ~~references to~~and must be ~~available~~readily retrievable during inspection~~, by~~. By listing the location of these documents, **you are also confirming ~~your~~ compliance with the referenced rule.**

	Rule Reference
Schedule III-V Invoices for the last 2 years Location: Click or tap here to enter text.	**WAC 246-945-040(3)(a)** "Every registrant shall keep and maintain inventory records required by 21 CFR Sec. 1304.04. Registrants are also required to keep a record of receipt and distribution of controlled substances. Records shall include: Invoices, orders, receipts, or any other document regardless of how titled, establishing the date, supplier, and quantity of drug received, and the name of the drug;" **WAC 246-945-040(5)** "Credential holders and pharmaceutical firms may maintain records for Schedule III, IV, and V drugs either separately or in a form that is readily retrievable from the business records of the registrant."
Completed CII order forms (DEA Form 222) and/or finalized CSOS documentation for the last 2 years Location: Click or tap here to enter text.	**WAC 246-945-040(6)** "A federal order form is required for each distribution of a Schedule I or II controlled substance. Credential holders and pharmaceutical firms must keep and make readily available these forms and other records to the commission or its designee." **21 CFR 1305.13(e) "**The purchaser must record on its copy of the DEA Form 222 the number of commercial or bulk containers furnished on each item and the dates on which the containers are received by the purchaser." **21 CFR 1305.22(g)** "When a purchaser receives a shipment, the purchaser must create a record of the quantity of each item received and the date received. The record must be electronically linked to the original order and archived."
Completed loss by theft or destruction forms (DEA Form 106) for the last 2 years Location: Click or tap here to enter text.	**WAC 246-945-040(3)(c) "**In the event of a significant loss or theft, two copies of DEA 106 (report of theft or loss of controlled substances) must be transmitted to the federal authorities and a copy must be sent to the commission." **21 CFR 1301.76(b)** "The registrant shall notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft. The registrant shall also complete, and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft."
Power of Attorney for staff authorized to order controlled substances Location: Click or tap here to enter text.	**WAC 246-945-040(1)** "The commission adopts 21 CFR as its own." **21 CFR 1305.05(a)** "A registrant may authorize one or more individuals, whether or not located at his or her registered location, to issue orders for Schedule I and II controlled substances on the registrant's behalf by executing a power of attorney for each such individual, if the power of attorney is retained in the files, with executed Forms 222 where applicable, for the same period as any order bearing the signature of the attorney. The power of attorney must be available for inspection together with other order records."
Ancillary Utilization Plan Location: Click or tap here to enter text.	**WAC 246-945-410(11)(a)** "A copy of the utilization plan must be maintained in the pharmacy."

	Rule Reference
Change of Responsible Pharmacy Manager forms for the last 2 years Location: Click or tap here to enter text.	**WAC 246-945-480** "The outgoing and incoming responsible pharmacy manager must report in writing to the commission a change in a responsible manager designation within ten business days of the change." **WAC 246-945-005(4)(a)** "The responsible pharmacy manager, or equivalent manager, shall sign and date the completed self-inspection worksheet(s), and maintain completed worksheets for two years from the date of completion."
Collaborative Drug Therapy Agreement(s) (CDTA) Location: Click or tap here to enter text.	**WAC 246-945-350(1)** "A pharmacist exercising prescriptive authority in their practice must have a valid CDTA on file with the commission and their practice location."
Prescription Records for the last 2 years Location: Click or tap here to enter text.	**WAC 246-945-410(12)** "A facility's paper prescriptions must be maintained in accordance with WAC 246-945-020 and as follows: (a) Paper prescriptions for Schedule II drugs must be maintained as a separate file from other prescriptions. (b) Paper prescriptions for Schedule III, IV, and V drugs must be maintained as a separate file, or maintained in a separate file with prescriptions for noncontrolled legend drugs as allowed under federal law."

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
General Requirements						
☐	☐	☐	1.	Is the current pharmacy license posted?	**RCW 18.64.043(3)** "It shall be the duty of the owner to immediately notify the commission of any change of location, ownership, or licensure and to keep the license of location or the renewal thereof properly exhibited in said pharmacy."	Click or tap here to enter text.
☐	☐	☐	2.	Are the pharmacist license(s) posted and up to date?	**RCW 18.64.140** "The current license shall be conspicuously displayed to the public in the pharmacy to which it applies."	Click or tap here to enter text.
☐	☐	☐	3.	Does the pharmacy have a DEA registration number, is it listed on page 2 of this document?	**WAC 246-945-040(2)** "A separate registration is required for each place of business, as defined in 21 CFR Sec. 1301.12, where controlled substances are manufactured, distributed, or dispensed.	Click or tap here to enter text.
☐	☐	☐	4.	Is the responsible pharmacy manager licensed to practice pharmacy in the state of Washington?	**WAC 246-945-310 Responsible pharmacy manager.** The responsible pharmacy manager must be licensed to practice pharmacy in the state of Washington. The responsible pharmacy manager designated by a facility as required under WAC 246-945-410 shall have the authority and responsibility to assure that the area(s) within the facility where drugs are stored, compounded, delivered, or dispensed are operated in compliance with all applicable state and federal statutes and regulations.	Click or tap here to enter text.
Facility Standards						
☐	☐	☐	5.	Is the facility appropriately constructed and equipped to protect equipment, records, drugs/devices and other restricted items from unauthorized access?	**WAC 246-945-410(1)** The facility shall be constructed and equipped with adequate security to protect equipment, records, and supply of drugs, devices, and other restricted sale items from unauthorized access, acquisition, or use.	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	6.	Is the pharmacy properly equipped?	**WAC 246-945-410(2)** The facility shall be properly equipped to ensure the safe, clean, and sanitary condition necessary for the proper operation, the safe preparation of prescriptions, and to safeguard product integrity.	Click or tap here to enter text.
☐	☐	☐	7.	Is the pharmacy appropriately staffed?	**WAC 246-945-410(3)** The facility shall be staffed sufficiently to allow appropriate supervision, operate safely and, if applicable, remain open during posted hours of operation.	Click or tap here to enter text.
☐	☐	☐	8.	Is the pharmacy adequately stocked?	**WAC 246-945-410(4)** The facility shall be adequately stocked to maintain at all times a representative assortment of drugs in order to meet the pharmaceutical needs of its patients in compliance with WAC 246-945-415.	Click or tap here to enter text.
☐	☐	☐	9.	Does the pharmacy have a designated responsible pharmacy manager?	**WAC 246-945-410(5)** The facility shall designate a responsible pharmacy manager: (a) By the date of opening; and (b) Within thirty calendar days of a vacancy.	Click or tap here to enter text.
☐	☐	☐	10.	Are the drug storage areas appropriately secure from unauthorized access?	**WAC 246-945-410(10)** Access to the drug storage area located within the facility should be limited to pharmacists unless one of the following applies: (a) A pharmacy intern, or pharmacy ancillary personnel enter under the immediate supervision of a pharmacist; or (b) A pharmacist authorizes temporary access to an individual performing a legitimate nonpharmacy function under the immediate supervision of the pharmacist; or (c) The facility has a policy and procedure restricting access to a health care professional licensed under the chapters specified in RCW 18.130.040, and the actions of the health care professional are within their scope of practice.	Click or tap here to enter text.
☐	☐	☐	11.	Are refrigerators temperatures maintained between 2-8°C (36-46°F)? ** Electronic monitoring is acceptable. **	**WAC 246-945-415(1)** A pharmacy may deliver filled prescriptions as long as appropriate measures are taken to ensure product integrity and receipt by the patient or patient's agent.	Click or tap here to enter text.
☐	☐	☐	12.	Are freezers between -25°& -10°C (-13° & 14°F)?	**WAC 246-945-415(1)** A pharmacy may deliver filled prescriptions as long as appropriate measures are taken to ensure product integrity and receipt by the patient or patient's agent.	Click or tap here to enter text.
Ancillary Personnel						
☐	☐	☐	13.	Are ancillary personnel certification(s) and registration(s) up to date? *Please provide documentation of a regular staff roster with credential and expiration date. *	**WAC 246-945-205(2)** "To be issued a certification as a pharmacy technician an applicant shall meet the qualifications in RCW 18.64A.020," **WAC 246-945-200(1)** "To become registered as a pharmacy assistant an applicant shall submit an application to the commission that meets the requirements of chapter 246-12 WAC, Part 2."	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	14.	Is the pharmacy adhering to a commission approved Ancillary Utilization Plan?	**RCW 18.64A.060** "No pharmacy licensed in this state shall utilize the services of pharmacy ancillary personnel without approval of the commission. Any pharmacy licensed in this state may apply to the commission for permission to use the services of pharmacy ancillary personnel. The application shall be accompanied by a fee and shall comply with administrative procedures and administrative requirements set pursuant to RCW 43.70.250 and 43.70.280, shall detail the manner and extent to which the pharmacy ancillary personnel would be used and supervised, and shall provide other information in such form as the secretary may require. The commission may approve or reject such applications. In addition, the commission may modify the proposed utilization of pharmacy ancillary personnel and approve the application as modified. Whenever it appears to the commission that pharmacy ancillary personnel are being utilized in a manner inconsistent with the approval granted, the commission may withdraw such approval. In the event a hearing is requested upon the rejection of an application, or upon the withdrawal of approval, a hearing shall be conducted in accordance with chapter 18.64 RCW, as now or hereafter amended, and appeal may be taken in accordance with the administrative procedure act, chapter 34.05 RCW." **WAC 246-945-410(11)** "In accordance with RCW 18.64A.060 prior to utilizing pharmacy ancillary personnel a facility shall submit to the commission a utilization plan for pharmacy technicians and pharmacy assistants: (a) Utilization plan for pharmacy technicians. The application for approval must describe the manner in which the pharmacy technicians will be utilized and supervised, including job descriptions, task analysis or similar type documents that define the duties performed and the conditions under which they are performed, number of positions in each category, as well as other information as may be required by the commission. The commission will be notified of all changes to the utilization plan. A copy of the utilization plan must be maintained in the pharmacy. The utilization plan must comply with WAC 246-945-315 and 246-945-320. (b) Utilization plan for pharmacy assistants. The application for approval shall list the job title or function of the pharmacy assistant and comply with WAC 246-945-315(3)."	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	15.	Do pharmacists appropriately delegate functions to ancillary personnel?	**WAC 246-945-315** All delegated pharmacy functions shall be performed under a pharmacist's immediate supervision. A pharmacist, as an adjunct to assist in the immediate supervision of the pharmacy ancillary personnel or intern, may employ technological means to communicate with or observe the pharmacy ancillary personnel or intern. A pharmacist shall make certain all applicable state and federal laws including, but not limited to, confidentiality, are fully observed when employing technological means of communication and observation. If technology is being used to provide immediate supervision of pharmacy ancillary personnel or intern such technology shall be sufficient to provide the personal assistance, direction and approval required to meet the standard of practice for the delegated tasks. (2) When delegating a pharmacy function to a pharmacy technician: (a) A pharmacist shall consider the pharmacy technician's scope of practice, education, skill, and experience and take them into account; and (b) A pharmacist will not delegate a pharmacy function that is listed in WAC 246-945-320. (3) A pharmacist may delegate to a pharmacy assistant those functions defined in RCW 18.64A.030 and the following: (a) Prepackage and label drugs for subsequent use in prescription dispensing operations; and (b) Count, pour, and label for individual prescriptions. **WAC 246-945-317 Tech check tech.** (1) "Verification" as used in this section means the pharmacist has reviewed a patient prescription initiated by an authorized prescriber, has examined the patient's drug profile, and has approved the prescription after taking into account pertinent drug and disease information to ensure the correctness of the prescription for a specific patient. The verification process must generate an audit trail that identifies the pharmacist. The pharmacist who performs the verification of a prescription is responsible for all reports generated by the approval of that prescription. The unit-dose medication fill and check reports are an example. (2) A pharmacist may allow for unit-dose medication checking. Following verification of a prescription by the pharmacist, a technician may check unit-dose medication cassettes filled by another pharmacy technician or pharmacy intern in pharmacies serving facilities licensed under chapter 70.41, 71.12, 71A.20, or 74.42 RCW. No more than a forty-eight-hour supply of drugs may be included in the patient medication cassettes and a licensed health professional must check the drug before administering it to the patient.	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	16.	Does the pharmacy have a copy of the ancillary utilization plan?	**WAC 246-945-410(11)(a)** "A copy of the utilization plan must be maintained in the pharmacy"	Click or tap here to enter text.
☐	☐	☐	17.	Does the pharmacy utilize tech check tech?	**WAC 246-945-317(2)** A pharmacist may allow for unit-dose medication checking. Following verification of a prescription by the pharmacist, a technician may check unit-dose medication cassettes filled by another pharmacy technician or pharmacy intern in pharmacies serving facilities licensed under chapter 70.41, 71.12, 71A.20, or 74.42 RCW. No more than a forty-eight-hour supply of drugs may be included in the patient medication cassettes and a licensed health professional must check the drug before administering it to the patient.	Click or tap here to enter text.
Electronic Recordkeeping Requirements **Please perform appropriate audits on pages 19-20**						
☐	☐	☐	18.	Does your record system have the capability to store patient medication records e.g. allergies, idiosyncrasies or chronic conditions, and prescription, refill, transfer, and other information?	**WAC 246-945-417(1)** "A pharmacy shall use an electronic recordkeeping system to establish and store patient medication records, including patient allergies, idiosyncrasies or chronic conditions, and prescription, refill, transfer information, and other information necessary to provide safe and appropriate patient care."	Click or tap here to enter text.
☐	☐	☐	19.	Are all drugs dispensed only upon a valid order?	**WAC 246-945-410(7)** Prescription drugs must only be dispensed pursuant to a valid prescription as required by WAC 246-945-011. **WAC 246-945-011(5)** A chart order must meet the requirements of RCW 18.64.550 and any other applicable requirements listed in 21 CFR, Chapter II. **RCW 18.64.550(1)** A chart order must be considered a prescription if it contains:(a) The full name of the patient; (b) The date of issuance; (c) The name, strength, and dosage form of the drug prescribed;(d) Directions for use; and (e) An authorized signature:	Click or tap here to enter text.
Policies and Procedures						
☐	☐	☐	20.	Does the pharmacy have policies and procedures adequate to address pharmacy functions?	**WAC 246-945-410(6)** The facility shall create and implement policies and procedures related to: (a) Purchasing, ordering, storing, compounding, delivering, dispensing, and administering legend drugs, including controlled substances. (b) Accuracy of inventory records, patient medical records as related to the administration of controlled substances and legend drugs, and any other records required to be kept by state and federal laws. (c) Adequate security of legend drugs, including controlled sub-stances. (d) Controlling access to legend drugs, including controlled ~~sub-stances~~substances.	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	21.	Do you have a policy addressing system downtime?	**WAC 246-945-417(4)** The pharmacy shall have policies and procedures in place for system downtime.	Click or tap here to enter text.
☐	☐	☐	22.	If providing central fill services, does the pharmacy have policies and procedures outlining off-site pharmacy services?	**WAC 246-945-425(2)(a)** The originating pharmacy shall have written policies and procedures outlining the off-site pharmacy services to be provided by the central fill pharmacy, or the off-site pharmacist or pharmacy technician, and the responsibilities of each party;	Click or tap here to enter text.
☐	☐	☐	23.	Does the pharmacy have policies and procedures for providing emergency discharge medications to patients?	**WAC 246-945-435(1)** The responsible pharmacy manager of a hospital or free standing emergency department may, in collaboration with the appropriate medical staff committee of the hospital, develop policies and procedures to provide discharge medications to patients released from hospital emergency departments during hours when community or outpatient hospital pharmacy services are not available. (2) The policies and procedures in subsection (1) of this section shall: (a) Comply with all requirements of RCW 70.41.480; (b) Ensure all prepackaged medications are affixed with a label that complies with WAC 246-945-018; (c) Require oral or electronically transmitted chart orders be verified by the practitioner in writing within seventy-two hours; (d) The medications distributed as discharge medications are stored in compliance with the laws concerning security and access; and (e) Ensure discharge medications are labeled appropriately. **RCW 70.41.480(2)(b)** "… The director of pharmacy, in collaboration with appropriate hospital medical staff, develops policies and procedures regarding the following: … (b) Assurances that emergency medications to be prepackaged pursuant to this section are prepared by a pharmacist or under the supervision of a pharmacist licensed under chapter 18.64 RCW."	Click or tap here to enter text.
☐	☐	☐	24.	Does the pharmacy have policies and procedures for the use of patient own medications?	**WAC 246-945-440** Facilities shall develop written policies and procedures for the administration of patient owned medications.	Click or tap here to enter text.
☐	☐	☐	25.	Does the pharmacy have policies and procedures for nursing student administration of medications?	**WAC 246-945-450 (1)** Nursing students may be given access privileges to technology used to dispense medications for patient administration as provided for in this section. **WAC 246-945-450 (2)** Nursing students must be enrolled in a nursing program approved by the Washington state nursing care quality assurance commission in accordance with WAC 246-840-510.	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
					WAC 246-945-450(3) A facility that provides a clinical opportunity to nursing students must meet the following to grant access to technology used to dispense medications for patient administration: (a) The facility, in collaboration with the nursing program, shall provide nursing students with orientation and practice experiences that include the demonstration of competency of skills prior to using the dispensing technology; (b) Nursing programs and participating facilities shall provide adequate training for students accessing dispensing technology; (c)The nursing programs and participating facilities shall have policies and procedures for nursing students to provide safe administration of medications; and (d) The nursing program and participating facilities shall develop and have a way of reporting and resolving any nursing student medication errors, adverse events, and alleged diversion.	
☐	☐	☐	26.	Does the pharmacy have required policies and procedures for drugs stored outside of the pharmacy?	**WAC 246-945-455(1)** In order for drugs to be stored in a designated area outside the pharmacy including, but not limited to, floor stock, in an emergency cabinet, in an emergency kit, or as emergency outpatient drug delivery from an emergency department at a registered institutional facility, the following conditions must be met: The supplying pharmacy shall develop and implement policies and procedures to prevent and detect unauthorized access, document drugs used, returned and wasted, and regular inventory procedures; (a) Drugs stored in such a manner shall remain under the control of, and be routinely monitored by, the supplying pharmacy; (b) The supplying pharmacy shall develop and implement policies and procedures to prevent and detect unauthorized access, document drugs used, returned and wasted, and regular inventory procedures; (c) Access must be limited to health care professionals licensed under the chapters specified in RCW 18.130.040 acting within their scope, and nursing students as provided in WAC 246-945-450; (d) The area is appropriately equipped to ensure security and protection from diversion or tampering; and (e) The facility is able to possess and store drugs.	Click or tap here to enter text.

Compliant Yes	Compliant No	Compliant N/A	#			Rule Reference	Notes/Corrective Actions
			27.	Does the pharmacy meet the requirements for:		**WAC 246-945-485** A dispensed drug or prescription device must only be accepted for return and reuse as follows: (a) Noncontrolled legend drugs that have been maintained in the custody and control of the institutional facility, dispensing pharmacy, or their related facilities under common control may be returned and reused if product integrity can be assured. (b) Those that qualify for return under the provisions of chapter 69.70 RCW. (2) A dispensed drug or prescription device may be accepted for return and destruction if: (a) The dispensed drug or prescription device was dispensed in a manner inconsistent with the prescriber's instructions; (b) The return is in compliance with the Washington state safe medication return program laws and rules, chapters 69.48 RCW and 246-480 WAC; or (c) The return and destruction is in compliance with the facility's policies and procedures	
☐	☐	☐	27.	a)	return and destruction of medications?		Click or tap here to enter text.
☐	☐	☐	27.	b)	the return and reuse of medications?		Click or tap here to enter text.
Drug Distribution and Control							
☐	☐	☐	28.	Does the pharmacy possess, distribute, or dispense legend drug samples?		**WAC 246-945-035(2)** A pharmacy of a licensed hospital or health care entity which receives and distributes drug samples at the request of an authorized practitioner pursuant to RCW 69.45.050 may possess, distribute or dispense legend drug samples.	Click or tap here to enter text.
☐	☐	☐	29.	Are all drug containers in the hospital labeled clearly and adequately to show the drug name and strength?		**WAC 246-945-017(1)** All licensees of the commission who dispense legend drugs to hospital inpatients shall ensure all drug containers are labeled clearly, legibly and adequately to show the drug's name (generic and/or trade) and strength, when applicable.	Click or tap here to enter text.
☐	☐	☐	30.	Does the pharmacy dispense investigational drugs? *If no, skip to question. 32*		**WAC 246-945-445(1)** The responsible pharmacy manager or their designee is responsible for the storage, distribution, and control of approved investigational drugs used in an institutional facility. The pharmacy shall be responsible for maintaining and providing information on approved investigational drugs.	Click or tap here to enter text.
☐	☐	☐	31.	Are investigational drugs properly labeled and stored only for use under explicit directions from principal investigators?		**WAC 246-945-445(2)** Under the explicit direction of the authorized principal investigator, coinvestigator(s), or per study protocol requirements, investigational drugs must be properly labeled and stored for use. An appropriate medical staff committee, institution review board, or equivalent committee, shall approve the use of such drugs.	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	32.	Are all drug stock and devices in date and fit for use?	**RCW 69.04.100** Whenever the Pharmacy Quality Assurance commission shall find in intrastate commerce an article subject to this chapter which is so adulterated or misbranded that it is unfit or unsafe for human use and its immediate condemnation is required to protect the public health, such article is hereby declared to be a nuisance and the director is hereby authorized forthwith to destroy such article or to render it unsalable for human use. **WAC 246-945-415(1)** A pharmacy may deliver filled prescriptions as long as appropriate measures are taken to ensure product integrity and receipt by the patient or patient's agent.	Click or tap here to enter text.
Controlled Substance Accountability						
☐	☐	☐	33.	Are procedures established for effective accountability of controlled substances?	**WAC 246-945-040(1)** The commission adopts 21 CFR as its own. **21 CFR 1301.71** All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances.	Click or tap here to enter text.
☐	☐	☐	34.	Does the pharmacy have a biennial controlled substance inventory completed within the last 2 years?	**21 CFR 1304.11** Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location. **WAC 246-945-420(2)** A facility shall conduct an inventory of controlled substances every two years.	Click or tap here to enter text.
☐	☐	☐	35.	Does the pharmacy maintain records of all receipt and distribution of controlled substances?	**WAC 246-945-040(3)** Registrants are also required to keep a record of receipt and distribution of controlled substances. Records shall include: (a) Invoices, orders, receipts, or any other document regardless of how titled, establishing the date, supplier, and quantity of drug received, and the name of the drug; (b) Distribution records, including invoices, or any other document regardless of how titled from wholesalers, manufacturers, or any other entity to which the substances were distributed and prescriptions records for dispensers; (d) For transfers of controlled substances from one dispenser to another, a record of the transfer must be made at the time of transfer indicating the drug, quantity, date of transfer, who it was transferred to, and from whom. Records must be retained by both the transferee and the transferor. These transfers can only be made in emergencies pursuant to 21 CFR Sec. 1307.11.	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	36.	Are records of Schedule II drugs maintained separately from all other controlled substance records?	**WAC 246-945-040(4)** Credential holders and pharmaceutical firms shall maintain records for Schedule II drugs separately from all other records.	Click or tap here to enter text.
☐	☐	☐	37.	Are records of Schedule III-V drugs maintained either separately or in a form that is readily retrievable from other records?	**WAC 246-945-040(5)** Credential holders and pharmaceutical firms may maintain records for Schedule III, IV, and V drugs either separately or in a form that is readily retrievable from the business records of the registrant.	Click or tap here to enter text.
☐	☐	☐	38.	Does the pharmacy have DEA 222 forms or their electronic equivalent for each acquisition or distribution of Schedule II drugs?	**WAC 246-945-040(6)** A federal order form is required for each distribution of a Schedule I or II controlled substance. Credential holders and pharmaceutical firms must keep and make readily available these forms and other records to the commission or its designee.	Click or tap here to enter text.
☐	☐	☐	39.	Are significant losses or disappearances of controlled substances reported to PQAC, the DEA, the CEO of the hospital, and other appropriate authorities?	**WAC 246-945-040(3)(c)** In the event of a significant loss or theft, two copies of DEA 106 (report of theft or loss of controlled substances) must be transmitted to the federal authorities and a copy must be sent to the commission.	Click or tap here to enter text.
Remote Supervision and Access in the Absence of a Pharmacist						
☐	☐	☐	40.	Does the pharmacy store, dispense, or deliver drugs to patients without a pharmacist on site?	**WAC 246-945-430(1)** The following requirements apply to pharmacies storing, dispensing and delivering drugs to patients without a pharmacist on-site and are in addition to applicable state and federal laws applying to pharmacies.	Click or tap here to enter text.
☐	☐	☐	41.	Does the pharmacy have full visual surveillance of the pharmacy?	**WAC 246-945-430(2)** The pharmacy is required to have adequate visual surveillance of the full pharmacy and retain a high-quality recording for a minimum of thirty calendar days.	Click or tap here to enter text.
☐	☐	☐	42.	Is access to the pharmacy limited and monitored?	**WAC 246-945-430(3)** Access to a pharmacy by individuals must be limited, authorized, and regularly monitored.	Click or tap here to enter text.
☐	☐	☐	43.	Does the monitoring system include visual and audio communication?	**WAC 246-945-430(4)** A visual and audio communication system used to counsel and interact with each patient or patient's caregiver, must be clear, secure, and HIPAA compliant.	Click or tap here to enter text.
☐	☐	☐	44.	Does the responsible pharmacy manager or designee perform monthly in-person inspections of the pharmacy?	**WAC 246-945-430(5)** The responsible pharmacy manager, or designee, shall complete and retain, in accordance with WAC 246-945-005 a monthly in-person inspection of the pharmacy.	Click or tap here to enter text.
☐	☐	☐	45.	Can a pharmacist be on-site within 3 hours of an emergency?	**WAC 246-945-430(6)** A pharmacist must be capable of being on-site at the pharmacy within three hours if an emergency arises.	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	46.	Does the pharmacy close in the event of a surveillance system failure?	**WAC 246-945-430(7)** The pharmacy must be closed to the public if any component of the surveillance or visual and audio communication system is malfunctioning, and remain closed until system corrections or repairs are completed or a pharmacist is on-site to oversee pharmacy operations.	Click or tap here to enter text.
☐	☐	☐	47.	Does the pharmacy maintain a perpetual inventory for legend drugs and controlled substances?	**WAC 246-945-420(4)** A pharmacy that exclusively stores, dispenses or delivers legend drugs, including controlled substances, without a pharmacist on-site shall maintain a perpetual inventory.	Click or tap here to enter text.
☐	☐	☐	48.	When 24-hour services are not available does the pharmacist perform retrospective drug utilization review of orders within six hours of being open?	**WAC 246-945-510(8)(d)** A drug utilization review of each prescription before dispensing and delivery shall occur except in emergent medical situations, or if: Twenty-four hour pharmacy services are not available, and a pharmacist will review all prescriptions added to a patient's profile within six hours of the facility opening.	Click or tap here to enter text.
Outpatient Dispensing						
If the pharmacy provides outpatient dispensing services other than emergency prepackaged medications please complete the General Pharmacy Self-Inspection form in addition to the Hospital Pharmacy Self-Inspection form.						
☐	☐	☐	49.	Does the pharmacy dispense emergency outpatient prepackaged medications?	**RCW 70.41.480(1)** "... It is the intent of the legislature to accomplish this objective by allowing practitioners with prescriptive authority to prescribe limited amounts of prepackaged emergency medications to patients being discharged from hospital emergency departments when access to community or outpatient hospital pharmacy services is not otherwise available."	Click or tap here to enter text.
☐	☐	☐	50.	Does the pharmacy maintain a list of approved medications to be prepackaged and delivered?	**RCW 70.41.480(2)(a)** "… The director of pharmacy, in collaboration with appropriate hospital medical staff, develops policies and procedures regarding the following: … (a) Development of a list, preapproved by the pharmacy director, of the types of emergency medications to be prepackaged and distributed."	Click or tap here to enter text.
☐	☐	☐	51.	Does the pharmacy maintain records of prepackaged medications?	**WAC 246-945-018** Prepackage medications dispensed pursuant to RCW 70.41.480, medications dispensed in unit dose form, medications dispensed by a pharmacy to a long-term care facility must include a label with the following information: (1) Drug name; (2) Drug strength; (3) Expiration date in accordance with WAC 246-945-016(3);	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
					(4) The manufacturer's name and lot number, if not maintained in a separate record; and (5) The identity of the pharmacist or provider responsible for the prepackaging, if not maintained in a separate record.	
☐	☐	☐	52.	Are there criteria for when emergency prepackaged medications can be prescribed and dispensed?	**RCW 70.41.480(2)(c)** "… The director of pharmacy, in collaboration with appropriate hospital medical staff, develops policies and procedures regarding the following: … (c) Development of specific criteria under which emergency prepackaged medications may be prescribed and distributed consistent with the limitations of this section;"	Click or tap here to enter text.
☐	☐	☐	53.	Does the pharmacy abide by the supply limitations?	**RCW 70.41.480(2)(f)** "… The director of pharmacy, in collaboration with appropriate hospital medical staff, develops policies and procedures regarding the following: … (d) Establishment of a limit of no more than a forty-eight hour supply of emergency medication as the maximum to be dispensed to a patient, except when community or hospital pharmacy services will not be available within forty-eight hours. In no case may the policy allow a supply exceeding ninety-six hours be dispensed;"	Click or tap here to enter text.
☐	☐	☐	54.	Are prepackaged medications labeled appropriately for outpatient dispensing?	**WAC 246-945-016(1**) All licensees of the commission who dispense legend drugs to outpatients shall affix a label to the prescription container that meets the requirements of RCW 69.41.050 and 18.64.246, and shall also include: (a) Drug quantity; (b) The number of refills remaining, if any; (c) The following statement, "Warning: State or federal law prohibits transfer of this drug to any person other than the person for whom it was prescribed." **RCW 69.41.050(1)** To every box, bottle, jar, tube or other container of a legend drug, which is dispensed by a practitioner authorized to prescribe legend drugs, there shall be affixed a label bearing the name of the prescriber, complete directions for use, the name of the drug either by the brand or generic name and strength per unit dose, name of patient and date: PROVIDED, That the practitioner may omit the name and dosage of the drug if he or she determines that his or her patient should not have this information and that, if the drug dispensed is a trial sample in its original package and which is labeled in accordance with federal law or regulation, there need be set forth additionally only the name of the issuing practitioner and the name of the patient.	Click or tap here to enter text.

Compliant Yes	Compliant No	Compliant N/A	#		Rule Reference	Notes/Corrective Actions
					RCW 18.64.246 To every box, bottle, jar, tube or other container of a prescription which is dispensed there shall be fixed a label bearing the name and address of the dispensing pharmacy, the prescription number, the name of the prescriber, the prescriber's directions, the name and strength of the medication, the name of the patient, the date, and the expiration date. The security of the cover or cap on every bottle or jar shall meet safety standards adopted by the commission.	
Other Areas of Non-Compliance **The commission and its inspectors reserve the right to note areas of non-compliance not specifically identified above on this self-inspection form. If an inspector identifies an issue of non-compliance they will note it in the section below and it will be included on the inspection report.**						
Hospital Pharmacy Associated Clinics (HPACs)						
☐	☐	☐	1.	Are there clinics owned, operated, or under common control of the hospital listed as HPACs on the hospital pharmacy license? *If no, you *do not* need to answer the remaining questions.	**WAC 246-945-233(1)** A parent hospital pharmacy may add or delete a hospital pharmacy associated clinic (HPAC) to a hospital pharmacy license at any time in compliance with WAC 246-945-230(2) (a), (b), and (d).	Click or tap here to enter text.
HPAC Responsible Manager Requirements **Rule Reference for HPAC Questions**						
WAC 246-945-233 The HPAC must designate a responsible pharmacy manager and notify the commission of changes. **Policies and procedures regarding HPACs may be incorporated into the overarching hospital pharmacy required policies and procedures.						
☐	☐	☐	2.	Are procedures established for the procurement, distribution, and maintenance of a system of accountability for drugs, IV solutions, chemicals, and biologicals related to the practice of pharmacy identified for HPACs?	**WAC 246-945-410(6)** The facility shall create and implement policies and procedures related to: (a) Purchasing, ordering, storing, compounding, delivering, dispensing, and administering legend drugs, including controlled substances. (b) Accuracy of inventory records, patient medical records as related to the administration of controlled substances and legend drugs, and any other records required to be kept by state and federal laws. (c) Adequate security of legend drugs, including controlled substances. (d) Controlling access to legend drugs, including controlled substances.	Click or tap here to enter text.
☐	☐	☐	3.	Are drugs located in HPACs properly stored and secured?	**WAC 246-945-410(2)** The facility shall be properly equipped to ensure the safe, clean, and sanitary condition necessary for the proper operation, the safe preparation of prescriptions, and to safeguard product integrity.	Click or tap here to enter text.

Compliant			#			Rule Reference	Notes/Corrective Actions
Yes	No	N/A					
☐	☐	☐	4.		Are significant losses or disappearances of controlled substances reported to PQAC, the DEA, the CEO of the hospital, and other appropriate authorities?	**WAC 246-945-040(3)(c**) In the event of a significant loss or theft, two copies of DEA 106 (report of theft or loss of controlled substances) must be transmitted to the federal authorities and a copy must be sent to the commission.	Click or tap here to enter text.
Facility Standards							
☐	☐	☐	5.		Do the HPACs have sufficient space and equipment for secure, environmentally controlled storage of drugs and other pharmaceutical supplies?	**WAC 246-945-410(2)** The facility shall be properly equipped to ensure the safe, clean, and sanitary condition necessary for the proper operation, the safe preparation of prescriptions, and to safeguard product integrity.	Click or tap here to enter text.
☐	☐	☐	6.		Are all medication areas in the HPAC locked and secured to prevent unauthorized access?	**WAC 246-945-410(1)** The facility shall be constructed and equipped with adequate security to protect equipment, records, and supply of drugs, devices, and other restricted sale items from unauthorized access, acquisition, or use.	Click or tap here to enter text.
☐	☐	☐	7.		If the hospital pharmacy dispenses patient-specific drugs to an HPAC licensed under the parent hospital pharmacy, is the prescription/order information recorded in the patients' medical record?"	**WAC 246-945-415 Dispensing and delivery of prescription drugs (8)** A licensed hospital pharmacy dispensing appropriately labeled, patient specific drugs to a HPAC licensed under the parent hospital pharmacy may do so only pursuant to a valid prescription and prescription information is authenticated in the medical record of the patient to whom the legend drug or controlled substance will be provided according to policy and procedures of the parent hospital pharmacy.	Click or tap here to enter text.
HPAC Drug Transfer and Control							
			8.		Do labels for medications dispensed to HPAC patients include:	**RCW 18.64.246(1)** To every box, bottle, jar, tube or other container of a prescription which is dispensed there shall be fixed a label bearing the name and address of the dispensing pharmacy, the prescription number, the name of the prescriber, the prescriber's directions, the name and strength of the medication, the name of the patient, the date, and the expiration date. The security of the cover or cap on every bottle or jar shall meet safety standards adopted by the commission. At the prescriber's request, the name and strength of the medication need not be shown. If the prescription is for a combination medication product, the generic names of the medications combined or the trade name used by the manufacturer or distributor for the product shall be noted on the label. The identification of the licensed	
☐	☐	☐	8.	a	Name of prescriber		Click or tap here to enter text.

Compliant			#			Rule Reference	Notes/Corrective Actions
Yes	No	N/A					
☐	☐	☐	8.	b	Directions for use	pharmacist responsible for each dispensing of medication must either be recorded in the pharmacy's record system or on the prescription label. This section shall not apply to the dispensing of medications to in-patients in hospitals. **RCW 69.41.050(1)** To every box, bottle, jar, tube or other container of a legend drug, which is dispensed by a practitioner authorized to prescribe legend drugs, there shall be affixed a label bearing the name of the prescriber, complete directions for use, the name of the drug either by the brand or generic name and strength per unit dose, name of patient and date: PROVIDED, That the practitioner may omit the name and dosage of the drug if he or she determines that his or her patient should not have this information and that, if the drug dispensed is a trial sample in its original package and which is labeled in accordance with federal law or regulation, there need be set forth additionally only the name of the issuing practitioner and the name of the patient. **WAC 246-945-016** All licensees of the commission who dispense legend drugs to outpatients shall affix a label to the prescription container that meets the requirements of RCW 69.41.050 and 18.64.246, and shall also include: (a) Drug quantity; (b) The number of refills remaining, if any; (c) The following statement, "Warning: State or federal law prohibits transfer of this drug to any person other than the person for whom it was prescribed.", except when dispensing to an animal, when a warning sufficient to convey "for veterinary use only" may be used; (d) The name and species of the patient, if a veterinary prescription; and (e) The name of the facility or entity authorized by law to possess a legend drug, if patient is the facility or entity.	Click or tap here to enter text.
☐	☐	☐	8.	c	Brand or Generic Drug name and strength per dose		Click or tap here to enter text.
☐	☐	☐	8.	d	Name of patient, and		Click or tap here to enter text.
☐	☐	☐	8.	e	Date		Click or tap here to enter text.
Records							
			9.	For *automated* patient record systems: Do patient records include all required information?		**WAC 246-945-417(2)** The electronic recordkeeping system must be capable of real-time retrieval of information pertaining to the ordering, verification, and processing of the prescription where possible. (3) The electronic recordkeeping system must include security features to protect the confidentiality and integrity of patient records including: (a) Safeguards designed to prevent and detect unauthorized access, modification, or manipulation of prescription information and patient medication records; and	
☐	☐	☐	9.	a	Patient full name and address		Click or tap here to enter text.
☐	☐	☐	9.	b	Serial number assigned to each new prescription		Click or tap here to enter text.

Compliant			#			Rule Reference	Notes/Corrective Actions
Yes	No	N/A					
☐	☐	☐	9.	c	Date of all instances of dispensing a drug	(b) Functionality that documents any alteration of prescription information after a prescription is dispensed, including the identification of the individual responsible for the alteration. (4) The pharmacy shall have policies and procedures in place for system downtime. (a) The procedure shall provide for the maintenance of all patient recordkeeping information as required by this chapter. (b) Upon restoration of operation of the electronic recordkeeping system the information placed in the auxiliary recordkeeping procedure shall be entered in each patient's records within two working days, after which the auxiliary records may be destroyed. (c) This section does not require that a permanent dual record-keeping system be maintained. (5) The pharmacy shall maintain records in accordance with WAC 246-945-020. (6) Electronic prescriptions for prescription drugs must be maintained by the pharmacy in a system that meets the requirements of 21 CFR Sec. 1311. (7) HCEs or HPACs that maintain an electronic record system must be done in accordance with subsections (2) through (7) of this section.	Click or tap here to enter text.
☐	☐	☐	9.	d	The identification of the dispenser who filled the prescription		Click or tap here to enter text.
☐	☐	☐	9.	e	Name, strength, dosage form, and quantity of drug dispensed		Click or tap here to enter text.
☐	☐	☐	9.	f	Prescriber's name address, and DEA number where required.		Click or tap here to enter text.
☐	☐	☐	9.	g	Any refill instructions by the prescriber		Click or tap here to enter text.
☐	☐	☐	9.	h	Complete directions for use of the drug, which prohibits use of "as directed"		Click or tap here to enter text.
☐	☐	☐	9.	i	Authorization for other than child-resistant containers, if applicable.		Click or tap here to enter text.
☐	☐	☐	10.		Are allergies and chronic conditions identified in patient records?	**WAC 246-945-417(1)** A pharmacy shall use an electronic recordkeeping system to establish and store patient medication records, including patient allergies, idiosyncrasies or chronic conditions, and prescription, refill, transfer information, and other information necessary to provide safe and appropriate patient care. **WAC 246-945-418** If an HPAC or HCE does not maintain an electronic recordkeeping system their manual records must contain all information required in WAC 246-945-417. The record system consists of the hard copy of the original prescription and a card or filing procedure that contains all data on new and refill prescriptions for a patient. This data must be organized in such a fashion that information relating to all prescription drugs used by a patient will be reviewed each time a prescription is filled.	Click or tap here to enter text.
			11.		For *manual* patient record systems: Do patient records include all required information?	**WAC 246-945-418** If an HPAC or HCE does not maintain an electronic recordkeeping system their manual records must contain all information required in WAC 246-945-417. The	

Compliant Yes	Compliant No	Compliant N/A	#			Rule Reference	Notes/Corrective Actions
☐	☐	☐	11.	a	Patient full name and address	record system consists of the hard copy of the original prescription and a card or filing procedure that contains all data on new and refill prescriptions for a patient. This data must be organized in such a fashion that information relating to all prescription drugs used by a patient will be reviewed each time a prescription is filled.	Click or tap here to enter text.
☐	☐	☐	11.	b	Serial number assigned to each new prescription		Click or tap here to enter text.
☐	☐	☐	11.	c	Date of all instances of dispensing a drug		Click or tap here to enter text.
☐	☐	☐	11.	d	The identification of the dispenser who filled the prescription		Click or tap here to enter text.
☐	☐	☐	11.	e	Name, strength, dosage form, and quantity of drug dispensed		Click or tap here to enter text.
☐	☐	☐	11.	f	Prescriber's name address, and DEA number where required.		Click or tap here to enter text.
Drug Administration							
☐	☐	☐	12.		Is access to the drug storage area of the HPAC limited only to those WA credentialed personnel acting within their scope of practice? *Nursing students acting within their scope of practice can administer medications.*	**WAC 246-945-455(1)(c)** Access must be limited to health care professionals licensed under the chapters specified in RCW 18.130.040 acting within their scope, and nursing students as provided in WAC 246-945-450. **WAC 246-945-317 Tech check tech. (1)** "Verification" as used in this section means the pharmacist has reviewed a patient prescription initiated by an authorized prescriber, has examined the patient's drug profile, and has approved the prescription after taking into account pertinent drug and disease information to ensure the correctness of the prescription for a specific patient. The verification process must generate an audit trail that identifies the pharmacist. The pharmacist who performs the verification of a prescription is responsible for all reports generated by the approval of that prescription. The unit-dose medication fill and check reports are an example. (2) A pharmacist may allow for unit-dose medication checking. Following verification of a prescription by the pharmacist, a technician may check unit-dose medication cassettes filled by another pharmacy technician or pharmacy intern in pharmacies serving facilities licensed under chapter 70.41, 71.12, 71A.20, or 74.42 RCW. No more than a forty-eight hour supply of drugs may be included in the patient medication cassettes and a licensed health professional must check the drug before administering it to the patient.	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
☐	☐	☐	13.	Are all drugs in an HPAC dispensed only upon a valid order or a practitioner?	**WAC 246-945-410(7)** Prescription drugs must only be dispensed pursuant to a valid prescription as required by WAC 246-945-011. **WAC 246-945-011(5)** A chart order must meet the requirements of RCW 18.64.550 and any other applicable requirements listed in 21 CFR, Chapter II. **RCW 18.64.550(1)** A chart order must be considered a prescription if it contains: (a) The full name of the patient; (b) The date of issuance; (c) The name, strength, and dosage form of the drug prescribed; (d) Directions for use; and (e) An authorized signature.	Click or tap here to enter text.

6.1. 2024 PQAC Master Calendar Approval

CMT Calls: Wednesday: Or call in (audio only) +1 564-999-2000,,799859196# United States, Olympia Phone Conference ID: 799 859 196#		**PANEL A** **1. Huey** **2. Teri** **3. Patrick (Chair)** **4.** Vacant **5. Judy**	**PANEL B** **6. Craig** **7. Hawkins (Chair)** **8. Matthew** **9. Stephanie** **10. Bonnie**	**PANEL C** **11. William** **12. Jerrie** **13. Uyen (Chair)** **14. Kenneth** **15. Ann**
Date	**Time**	**Activity**	**Who**	**Location**
January 3, 2024	12:00-1:30 pm	CMT	Panel A	Teams
Janaury 5, 2024	12:00-1:00 pm	Weekly Legislative Call	PQAC	Zoom
January 10, 2024	12:00-1:30 pm	CMT	Panel B	Teams
January 12, 2024	12:00-1:00 pm	Weekly Legislative Call	PQAC	Zoom
January 17, 2024	12:00-1:30 pm	CMT	Panel C	Teams
January 19, 2024	12:00-1:00 pm	Weekly Legislative Call	PQAC	Zoom
January 24, 2024	12:00-1:30 pm	CMT	Panel A	Teams
January 24, 2024	TBD	Legislative Day	WSPA	TBD
January 26, 2024	12:00-1:00 pm	Weekly Legislative Call	PQAC	Zoom and L&I, 7273 Linderson Way SW
February 1, 2024	9:00-3:00 pm	Business Meeting	PQAC	Zoom and L&I, 7273 Linderson Way SW
February 2, 2024	8:00-9:00 am	CMT	Panel B	TBD and Teams
February 2, 2024	12:00-1:00 pm	Weekly Legislative Call	PQAC	Zoom and L&I, 7273 Linderson Way SW
February 7, 2024	12:00-1:30 pm	CMT	Panel C	Teams
February 9, 2024	12:00-1:00 pm	Weekly Legislative Call	PQAC	Zoom and L&I, 7273 Linderson Way SW
Feburary 11-13, 2024	TBD	Nt'l Assoc. of Chain Drug Stores Regional Meeting	PQAC	Bonita Springs, FL
February 14, 2024	12:00-1:30 pm	CMT	Panel A	Teams
February 16, 2024	12:00-1:00 pm	Weekly Legislative Call	PQAC	Zoom and L&I, 7273 Linderson Way SW
Feburary 19, 2024	TBD	Legislative Day - Community	WSPA	TBD
February 21, 2024	12:00-1:30 pm	CMT	Panel B	Teams
February 23, 2024	12:00-1:00 pm	Weekly Legislative Call	PQAC	Zoom and L&I, 7273 Linderson Way SW
February 28, 2024	12:00-1:30 pm	CMT	Panel C	Teams
March 1, 2024	12:00-1:00 pm	Weekly Legislative Call	PQAC	Zoom and L&I, 7273 Linderson Way SW
March 7, 2024	9:00-3:00 pm	Business Meeting	PQAC	Zoom and L&I, 7273 Linderson Way SW
March 8, 2024	8:00-9:00 am	CMT	Panel A	TBD and Teams
March 8, 2024	9:00-1:00 pm	Business Meeting	PQAC	Zoom and L&I, 7273 Linderson Way SW
March 13, 2024	12:00-1:30 pm	CMT	Panel B	Teams
March 15, 2024	12:00-1:00 pm	Weekly Legislative Call	PQAC	Zoom and L&I, 7273 Linderson Way SW
March 20, 2024	12:00-1:30 pm	CMT	Panel C	Teams
March 27, 2024	12:00-1:30 pm	CMT	Panel A	Teams
April 3, 2024	12:00-1:30 pm	CMT	Panel B	Teams
April 10, 2024	12:00-1:30 pm	CMT	Panel C	Teams
April 16-19, 2024	TBD	Academy of Managed Care Pharmacy's Nt'l Meeting	PQAC	New Orleans, LA
April 17, 2024	12:00-1:30 pm	CMT	Panel A	Teams
April 24, 2024	12:00-1:30 pm	CMT	Panel B	Teams
April 27-30, 2024	TBD	Nt'l Assoc. of Chain Drug Stores' Annual Meeting	PQAC	Palm Beach, FL
May 2, 2024	9:00-3:00 pm	Business Meeting	PQAC	Zoom and ESD113, 6005 Tyee Dr SW
May 3, 2024	8:00-9:00 am	CMT	Panel C	Teams
May 3, 2024	9:00-1:00 pm	Business Meeting	PQAC	Zoom and ESD113, 6005 Tyee Dr SW
May 8, 2024	12:00-1:30 pm	CMT	Panel A	Teams
May 15, 2024	12:00-1:30 pm	CMT	Panel B	Teams

CMT Calls: Wednesday: Or call in (audio only) +1 564-999-2000,,799859196# United States, Olympia Phone Conference ID: 799 859 196#		**PANEL A** **1. Huey** **2. Teri** **3. Patrick (Chair)** **4.** Vacant **5. Judy**	**PANEL B** **6. Craig** **7. Hawkins (Chair)** **8. Matthew** **9. Stephanie** **10. Bonnie**	**PANEL C** **11. William** **12. Jerrie** **13. Uyen (Chair)** **14. Kenneth** **15. Ann**
May 15-17, 2024	TBD	Nt'l Assoc. of Boards of Pharmacy's 120th Annual Meeting	PQAC	Fort Worth, TX
May 22, 2024	12:00-1:30 pm	CMT	Panel C	Teams
May 29, 2024	12:00-1:30 pm	CMT	Panel A	Teams
May 30-June 2, 2024	TBD	WSPA's Northwest Pharmacy Convention	PQAC	Coeur D'Alene, ID
June 5, 2024	12:00-1:30 pm	CMT	Panel B	Teams
June 12, 2024	12:00-1:30 pm	CMT	Panel C	Teams
June 19, 2024	12:00-1:30 pm	CMT	Panel A	Teams
June 27, 2024	9:00-3:00 pm	Business Meeting	PQAC	Zoom and ESD113, 6005 Tyee Dr SW
June 28, 2024	8:00-9:00 am	CMT	Panel B	TBD and Teams
June 28, 2024	9:00-1:00 pm	Business Meeting	PQAC	Zoom and ESD113, 6005 Tyee Dr SW
July 3, 2024	12:00-1:30 pm	CMT	Panel C	Teams
July 10, 2024	12:00-1:30 pm	CMT	Panel A	Teams
July 24, 2024	12:00-1:30 pm	CMT	Panel B	Teams
July 31, 2024	12:00-1:30 pm	CMT	Panel C	Teams
August 7, 2024	12:00-1:30 pm	CMT	Panel A	Teams
August 14, 2024	12:00-1:30 pm	CMT	Panel B	Teams
August 22, 2024	9:00-3:00 pm	Business Meeting	PQAC	Zoom and L&I, 7273 Linderson Way SW
August 23, 2024	8:00-9:00 am	CMT	Panel C	TBD and Teams
August 23, 2024	9:00-1:00 pm	Business Meeting	PQAC	Zoom and L&I, 7273 Linderson Way SW
August 28, 2024	12:00-1:30 pm	CMT	Panel A	Teams
September 4, 2024	12:00-1:30 pm	CMT	Panel B	Teams
September 11, 2024	12:00-1:30 pm	CMT	Panel C	Teams
September 18, 2024	12:00-1:30 pm	CMT	Panel A	Teams
September 25, 2024	12:00-1:30 pm	CMT	Panel B	Teams
October 2, 2024	12:00-1:30 pm	CMT	Panel C	Teams
October 7-8, 2024	TBD	American Society of Health Systems Pharmacists (ASHP)'s Conference for Pharmacy Leaders	PQAC	Chicago, IL
October 10, 2024	9:00-3:00 pm	Business Meeting	PQAC	Zoom and L&I, 7273 Linderson Way SW
October 11, 2024	8:00-9:00 am	CMT	Panel A	TBD and Teams
October 11, 2024	9:00-1:00 pm	Business Meeting	PQAC	Zoom and L&I, 7273 Linderson Way SW
October 16, 2024	12:00-1:30 pm	CMT	Panel B	Teams
October 20-23, 2024	TBD	AMCP Nexus 2024	PQAC	Las Vegas, NV
October 20-24, 2024	TBD	National Association of Boards of Pharmacy District 6, 7, & 8 Meeting	PQAC	Albequerque, NM
October 23, 2024	12:00-1:30 pm	CMT	Panel C	Teams
October 30, 2024	12:00-1:30 pm	CMT	Panel A	Teams
November 6, 2024	12:00-1:30 pm	CMT	Panel B	Teams
November 7, 2024	TBD	2024 ASCP Annual Meeting and Exhibition	PQAC	Aurora, CO
November 13, 2024	12:00-1:30 pm	CMT	Panel C	Teams
November 20, 2024	12:00-1:30 pm	CMT	Panel A	Teams
November 27, 2024	12:00-1:30 pm	CMT	Panel B	Teams
December 4, 2024	12:00-1:30 pm	CMT	Panel C	Teams
December 8-12, 2024	TBD	ASHSP's Midyear Clinical	PQAC	New Orleans, LA

CMT Calls: Wednesday: Or call in (audio only) +1 564-999-2000,,799859196# United States, Olympia Phone Conference ID: 799 859 196#		**PANEL A** **1. Huey** **2. Teri** **3. Patrick (Chair)** **4.** Vacant **5. Judy**	**PANEL B** **6. Craig** **7. Hawkins (Chair)** **8. Matthew** **9. Stephanie** **10. Bonnie**	**PANEL C** **11. William** **12. Jerrie** **13. Uyen (Chair)** **14. Kenneth** **15. Ann**
December 12, 2024	9:00-3:00 pm	Business Meeting	PQAC	Zoom and L&I, 7273 Linderson Way SW
December 13, 2024	8:00-9:00 am	CMT	Panel A	TBD and Teams
December 13, 2024	9:00-1:00 pm	Business Meeting	PQAC	Zoom and L&I, 7273 Linderson Way SW
December 18, 2024	12:00-1:30 pm	CMT	Panel B	Teams
December 25, 2024	Cancelled (holiday)	CMT	Panel C	Teams

WAC 246-945-345 Prescription transfers. (1) Subsections (2) through (~~5~~6) of this section apply to the transfer of prescription information for noncontrolled drugs. The transfer of controlled substance prescription information must conform to the requirements of 21 C.F.R. Sec. 1306.08 and Sec. 1306.25.

(2) Upon request by a patient or authorized representative of a patient ~~request~~, a prescription ~~may~~ shall be transferred within the limits of state and federal law.

(3) Facilities shall fulfill prescription transfer requests at the time of request to the transferred individual's or individual's authorized representative's requested facility.

(~~3~~4) Sufficient information needs to be exchanged in the transfer of a prescription to maintain an auditable trail, and all elements of a valid prescription.

(~~4~~5) Pharmacies sharing a secure real-time database are not required to transfer prescription information for dispensing.

(~~5~~6) Prescriptions must be transferred by electronic means or facsimile, except in emergent situations.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470,

18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-345, filed 6/1/20, effective 7/1/20.]

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: December 08, 2023
TIME: 8:42 AM

WSR 24-01-021

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: Naloxone nasal spray as over-the-counter status**.** In March 2023, the United States Food and Drug Administration (FDA) approved the first 4 mg naloxone hydrochloride nasal spray as an over-the-counter (OTC) drug and has approved other naloxone nasal sprays since that time. Naloxone is an opioid antagonist used for the emergency treatment of known or suspected opioid overdose. Currently, WAC 246-945-030 incorporates the 39th edition of the Approved Drug Products with Therapeutic Equivalence Evaluations, or "Orange Book," which has naloxone listed as a prescription drug. The Pharmacy Quality Assurance Commission (commission) considers the ongoing opioid epidemic to be a public health emergency in Washington state. In order to combat this epidemic in Washington, the commission is amending WAC 246-945-030 and adding a new section, WAC 246-945-034, classifying the 3mg and 4mg naloxone hydrochoride nasal spray as approved by the FDA for OTC distribution as an OTC drug in Washington state.

The timeline for the availability of naloxone nasal spray is set by the manufacturers, although some are already available. This emergency rule prepares Washington state for the moment that the drug becomes available by manufacturers. The proposed new section of chapter 246-945 WAC would also allow for expansion of different formularies if the FDA makes further changes. This preparation would allow for a faster release of the drug throughout the state, meaning this life saving drug would be in the hands of Washingtonians faster. Increasing patient access to the drug is critical to reduce opioid overdoses.

This emergency rule filing allows for the 3mg and 4mg dosage versions of naloxone spray to be prescribed as over-the-counter products. The previous emergency rule filing on this topic, filed as WSR 23-17-059 on August 11, 2023, only allowed the 4 mg nasal spray under the brand name Narcan to be prescribed as an OTC product, but the FDA broadened the classification of allowed naloxone products since that previous filing.

Citation of rules affected by this order:

New: WAC 246-945-034
Repealed: None
Amended: WAC 246-945-030
Suspended: None

Statutory authority for adoption: RCW 18.64.005

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 this rule is necessary for the preservation of public health, safety, and general welfare. The opioid epidemic is a public health emergency which requires the use of the emergency rulemaking process. Observing the time requirements of notice and opportunity to comment upon adoption of a permanent rule would be contrary to the public interest. This rule would increase access to this lifesaving drug faster, which would help relieve some stress on affected communities in Washington state and attempt to reduce opioid overdoses.

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	1	Amended	1	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	0	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	1	Repealed	0

Date Adopted: December 8, 2023	**Signature:** 
Name: Kenneth Kenyon, PharmD, BCPS	
Title: Pharmacy Quality Assurance Commission Chair	

EXPEDITED RULE MAKING

CR-105 (December 2017)
(Implements RCW 34.05.353)

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OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: October 23, 2023
TIME: 1:49 PM

WSR 23-22-035

Agency: Department of Health – Pharmacy Quality Assurance Commission

Title of rule and other identifying information: (describe subject) Updating reference to United States Pharmacopeia (USP) General Chapters 795 and 797. The Pharmacy Quality Assurance Commission (commission) is proposing a revision to WAC 246-945-100, Compounding minimum standards, to update the rule to the most recent version of the USP – National Formulary <795> and <797>.

Purpose of the proposal and its anticipated effects, including any changes in existing rules: The proposed rule amends WAC 246-945-100 to update the rule to the most recent versions of the USP <795> and <797>. USP <795> and <797> were adopted into rule by reference effective on July 1, 2020. Since then, USP <795> and <797> have been updated.

Reasons supporting proposal: The existing reference in WAC 246-945-100 does not account for changes made to USP <795> and <797> that are official as of November 1, 2023 by USP. The proposed rule updates the references to the most recent versions. The proposed rule language qualifies for expedited rulemaking under RCW 34.05.353(1)(b) as the language incorporates by reference national standards without material change.

Statutory authority for adoption: RCW 18.64.005

Statute being implemented: RCW 18.64.005 and 18.64.270

Is rule necessary because of a:

Federal Law?	☐ Yes	☒ No
Federal Court Decision?	☐ Yes	☒ No
State Court Decision?	☐ Yes	☒ No

If yes, CITATION:

Name of proponent: (person or organization)

☐ Private
☐ Public
☒ Governmental

Name of agency personnel responsible for:

	Name	Office Location	Phone
Drafting:	Haleigh Mauldin	111 Israel Rd SE, Tumwater WA 98501	360-890-0720
Implementation:	Haleigh Mauldin	111 Israel Rd SE, Tumwater WA 98501	360-890-0720
Enforcement:	Marlee O'Neill	111 Israel Rd SE, Tumwater WA 98501	360-480-9180

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters: None

Expedited Adoption - Which of the following criteria was used by the agency to file this notice:

☐ Relates only to internal governmental operations that are not subject to violation by a person;

☒ Adopts or incorporates by reference without material change federal statutes or regulations, Washington state statutes, rules of other Washington state agencies, shoreline master programs other than those programs governing shorelines of statewide significance, or, as referenced by Washington state law, national consensus codes that generally establish industry standards, if the material adopted or incorporated regulates the same subject matter and conduct as the adopting or incorporating rule;

☐ Corrects typographical errors, make address or name changes, or clarify language of a rule without changing its effect;

☐ Content is explicitly and specifically dictated by statute;

☐ Have been the subject of negotiated rule making, pilot rule making, or some other process that involved substantial participation by interested parties before the development of the proposed rule; or

☐ Is being amended after a review under RCW 34.05.328.

Expedited Repeal - Which of the following criteria was used by the agency to file notice:

☐ The statute on which the rule is based has been repealed and has not been replaced by another statute providing statutory authority for the rule;

☐ The statute on which the rule is based has been declared unconstitutional by a court with jurisdiction, there is a final judgment, and no statute has been enacted to replace the unconstitutional statute;

☐ The rule is no longer necessary because of changed circumstances; or

☐ Other rules of the agency or of another agency govern the same activity as the rule, making the rule redundant.

Explanation of the reason the agency believes the expedited rule-making process is appropriate pursuant to RCW 34.05.353(4): The proposed amendments adopt by reference, without material change, the most recent version of the national standard, USP <795> and USP <797>. The national standard is adopted by reference in exiting rule. The proposed amendments update the rule to the most recent version of the national standard.

NOTICE

THIS RULE IS BEING PROPOSED UNDER AN EXPEDITED RULE-MAKING PROCESS THAT WILL ELIMINATE THE NEED FOR THE AGENCY TO HOLD PUBLIC HEARINGS, PREPARE A SMALL BUSINESS ECONOMIC IMPACT STATEMENT, OR PROVIDE RESPONSES TO THE CRITERIA FOR A SIGNIFICANT LEGISLATIVE RULE. IF YOU OBJECT TO THIS USE OF THE EXPEDITED RULE-MAKING PROCESS, YOU MUST EXPRESS YOUR OBJECTIONS IN WRITING AND THEY MUST BE SENT TO

Name: Haleigh Mauldin

Agency: Pharmacy Quality Assurance Commission

Address: PO Box 47852 Olympia WA 98504-7852

Phone: 360-890-0720

Fax: N/A

Email: PharmacyRules@doh.wa.gov

Other: https://fortress.wa.gov/doh/policyreview

AND RECEIVED BY (date) 1/2/2024

Date: October 23, 2023 **Name:** Kenneth Kenyon, PharmD, BCPS **Title:** Pharmacy Quality Assurance Commission	**Signature:** 

AMENDATORY SECTION (Amending WSR 20-12-072, filed 6/1/20, effective 7/1/20)

WAC 246-945-100 Compounding minimum standards. (1) All licensees of the commission must comply, at a minimum, with the following chapters of the United States Pharmacopeia (USP) when engaged in compounding nonsterile and sterile products for patient administration or distribution to a licensed practitioner for patient use or administration:

(a) USP General Chapter <795> Pharmaceutical Compounding - Nonsterile Preparations, official as of November 1, 2023;

(b) USP General Chapter <797> Pharmaceutical Compounding - Sterile Preparations, official as of November 1, 2023;

(c) USP General Chapter <800> Hazardous Drugs - Handling in Healthcare Settings; and

(d) USP General Chapter <825> Radiopharmaceuticals - Preparation, Compounding, Dispensing, and Repackaging.

(2) Copies of the USP General Chapters listed in subsection (1) of this section are available for public inspection at the commission's office at Department of Health, Town Center 2, 111 Israel Road S.E., Tumwater, WA 98501. Requestors may also contact USP directly to obtain copies.

EXPEDITED RULE MAKING

CR-105 (December 2017)
(Implements RCW 34.05.353)

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: November 20, 2023
TIME: 5:41 PM

WSR 23-23-153

Agency: Department of Health - Pharmacy Quality Assurance Commission

Title of rule and other identifying information: Citation and technical changes to pharmacy rules in chapter 246-945 WAC. The Pharmacy Quality Assurance Commission (commission) is considering amending WAC 246-945-001, 246-945-011, 246-945-014, 246-945-018, 246-945-063, 246-945-156, 246-945-170, 246-945-173, 246-945-175, 246-945-200, 246-945-217, 246-945-230, 246-945-417, and 246-945-590 to remove and replace citations to rules that have been repealed and make general grammatical and technical corrections.

Purpose of the proposal and its anticipated effects, including any changes in existing rules: The commission completed rulemaking in 2020, consolidating multiple chapters of rules that regulate the practice of pharmacy into one chapter, chapter 246-945 WAC. This proposal will remove citations to repealed WAC chapters, update citations to the current governing WAC chapter or specific rule(s) and make general grammatical corrections without making any material changes.

Reasons supporting proposal: Following the rules consolidation project that resulted in the creation of chapter 246-945 WAC in 2020, the commission discovered a number of cross-references that are now outdated. The Secretary also finalized updated fees for commission licensees since that time and updates are now needed to correct all fee rule references.

Statutory authority for adoption: RCW 18.64.005

Statute being implemented: RCW 18.64.005

Is rule necessary because of a:

Federal Law?	☐ Yes	☒ No
Federal Court Decision?	☐ Yes	☒ No
State Court Decision?	☐ Yes	☒ No

If yes, CITATION:

Name of proponent: (person or organization) Washington State Pharmacy Quality Assurance Commission

☐ Private
☐ Public
☒ Governmental

Name of agency personnel responsible for:

	Name	Office Location	Phone
Drafting:	Joshua Munroe	111 Israel Rd SE, Tumwater, WA 98501	360-502-5058
Implementation:	Joshua Munroe	111 Israel Rd SE, Tumwater, WA 98501	360-502-5058
Enforcement:	Joshua Munroe	111 Israel Rd SE, Tumwater, WA 98501	360-502-5058

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters: None.

Expedited Adoption - Which of the following criteria was used by the agency to file this notice:

☐ Relates only to internal governmental operations that are not subject to violation by a person;

☐ Adopts or incorporates by reference without material change federal statutes or regulations, Washington state statutes, rules of other Washington state agencies, shoreline master programs other than those programs governing shorelines of statewide significance, or, as referenced by Washington state law, national consensus codes that generally establish industry standards, if the material adopted or incorporated regulates the same subject matter and conduct as the adopting or incorporating rule;

☒ Corrects typographical errors, make address or name changes, or clarify language of a rule without changing its effect;

☐ Content is explicitly and specifically dictated by statute;

☐ Have been the subject of negotiated rule making, pilot rule making, or some other process that involved substantial participation by interested parties before the development of the proposed rule; or

☐ Is being amended after a review under RCW 34.05.328.

Expedited Repeal - Which of the following criteria was used by the agency to file notice:

☐ The statute on which the rule is based has been repealed and has not been replaced by another statute providing statutory authority for the rule;

☐ The statute on which the rule is based has been declared unconstitutional by a court with jurisdiction, there is a final judgment, and no statute has been enacted to replace the unconstitutional statute;

☐ The rule is no longer necessary because of changed circumstances; or

☐ Other rules of the agency or of another agency govern the same activity as the rule, making the rule redundant.

Explanation of the reason the agency believes the expedited rule-making process is appropriate pursuant to RCW 34.05.353(4): The commission believes the expedited rulemaking process is appropriate as the proposed rules fall under RCW 34.05.353(1)(c) since they "correct typographical errors... and clarify language of a rule without changing its effect." The updating of references from older repealed sections of rule to the current active sections of rule does not represent a substantive change to any regulation under the commission's jurisdiction.

NOTICE

THIS RULE IS BEING PROPOSED UNDER AN EXPEDITED RULE-MAKING PROCESS THAT WILL ELIMINATE THE NEED FOR THE AGENCY TO HOLD PUBLIC HEARINGS, PREPARE A SMALL BUSINESS ECONOMIC IMPACT STATEMENT, OR PROVIDE RESPONSES TO THE CRITERIA FOR A SIGNIFICANT LEGISLATIVE RULE. IF YOU OBJECT TO THIS USE OF THE EXPEDITED RULE-MAKING PROCESS, YOU MUST EXPRESS YOUR OBJECTIONS IN WRITING AND THEY MUST BE SENT TO

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AND RECEIVED BY (date) 1/22/2024

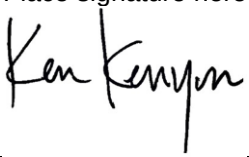
Date: November 20, 2023

Name: Kenneth Kenyon, PharmD, BCPS

Title: Pharmacy Quality Assurance Commission Chair

Signature:

Place signature here



AMENDATORY SECTION (Amending WSR 20-12-072, filed 6/1/20, effective 7/1/20)

WAC 246-945-001 Definitions. The definitions in chapters 18.64 and 18.64A RCW and those in this section apply throughout this chapter unless otherwise stated.

(1) "ACPE" means accreditation council for pharmacy education.

(2) "Active ingredient" means any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of humans or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in that drug product in a modified form intended to furnish the specified activity or effect.

(3) "Adulterated" refers to a drug that was produced and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with WAC 246-945-550 as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.

(4) "Animal control agency" means any agency authorized by law to euthanize or destroy animals; to sedate animals prior to euthanasia or to engage in chemical capture of animals.

(5) "Approved legend drugs" means any legend drug approved by the commission for use by registered humane societies or animal control agencies for the sole purpose of sedating animals prior to euthanasia, when necessary, and for use in chemical capture programs.

(6) "Audit trail" means all materials and documents required for the entire process of filling a prescription, which shall be sufficient to document or reconstruct the origin of the prescription, and authorization of subsequent modifications of that prescription.

(7) "Blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

(8) "Blood component" means that part of the blood separated by physical or mechanical means.

(9) "Central fill pharmacy" means a pharmacy contracting with an originating pharmacy, or having the same owner as an originating pharmacy, that provides centralized prescription filling on behalf of the originating pharmacy pursuant to these rules.

(10) "Chemical capture program" means wildlife management programs registered under RCW 69.41.080 and 69.50.320 to use approved legend drugs and controlled substance for chemical capture. Chemical capture includes immobilization of individual animals in order for the animals to be moved, treated, examined, or for other legitimate purposes.

(11) "Collaborative drug therapy agreement" or "CDTA" means a written guideline or protocol previously established and approved by a practitioner authorized to prescribe drugs that enables a pharmacist to exercise prescriptive authority.

(12) "Controlled substances" has the same meaning as RCW 69.50.101.

(13) "Controlled substance wholesaler" means a wholesaler licensed under RCW 18.64.046 to possess and sell controlled substances to a licensed pharmacy or other legally licensed or authorized person.

(14) "Commission" means the pharmacy quality assurance commission.

(15) "Counterfeit" means a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor.

(16) "CPE" means continuing pharmacy education accredited by the ACPE.

(17) "Consultation" means:

(a) A communication or deliberation between a pharmacist and a patient, a patient's agent, or a patient's health care provider in which the pharmacist uses professional judgment to provide advice about drug therapy.

(b) A method by which the pharmacist meets patient information requirements as set forth in WAC 246-945-325.

(18) "Credential" means a license, certification, or registration under the chapters specified in RCW 18.130.040 issued to a person to practice a regulated health care profession. Whether the credential is a license, certification, or registration is determined by the law regulating the profession.

(19) "DEA" means the United States Drug Enforcement Administration.

(20) "Delegated tasks" means tasks that are performed pursuant to a pharmacist's direction, without the exercise of the pharmacy ancillary personnel's own judgment and discretion, and which do not require the pharmacy ancillary personnel's to exercise the independent professional judgment that is the foundation of the practice of the profession of pharmacy.

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

(22) "Dose" means the amount of drug to be administered at one time.

(23) "Drug(s) of concern" are those drugs identified by the commission as demonstrating a potential for abuse by all professionals licensed to prescribe, dispense, or administer such substances in this state.

(24) "Drug price advertising" means the dissemination of nonpromotional information pertaining to the prices of legend or prescription drugs.

(25) "Drug product" means a finished dosage form (e.g., tablet, capsule, solution) that contains an active drug ingredient generally, but not necessarily, in association with inactive ingredients. The term also includes a finished dosage form that does not contain an active ingredient but is intended to be used as a placebo.

(26) "Drug sample" means a unit of prescription drug that is not intended to be sold and is intended to promote the sale of the drug.

(27) "Drug standard and information sources" means industry recognized reference and resources.

(28) "Drug storage area" means an area where legend drugs, controlled substances, or other restricted items are stored, compounded, or dispensed.

(29) "Drug utilization review" includes, but is not limited to, the following activities:

(a) Evaluation of prescriptions and patient records for known allergies, rational therapy-contraindications, appropriate dose, and route of administration and appropriate directions for use;

(b) Evaluation of prescriptions and patient records for duplication of therapy;

(c) Evaluation of prescriptions and patient records for interactions between drug-drug, drug-food, drug-disease, and adverse drug reactions; and

(d) Evaluation of prescriptions and patient records for proper utilization, including over- or under-utilization, and optimum therapeutic outcomes.

(30) "Electronic means" means an electronic device used to send, receive, ((~~and/~~)) or store prescription information, including computers, facsimile machines, etc.

(31) "Electronic signature" means an electronic sound, symbol, or process attached to or logically associated with a contract or other record and executed or adopted by a person with the intent to sign the record.

(32) "Enrolled student" means a student who has accepted an offer of admission in writing and the student has made the appropriate deposit securing admission to an accredited school or college of pharmacy.

(33) "Equivalent manager" means an individual authorized to act on behalf of a pharmaceutical firm not licensed as a pharmacy to serve as the primary contact for the department and is responsible for managing the facility operations which includes, but is not limited to, actively involved in and aware of the daily operations of the facility.

(34) "Export wholesaler" means any wholesaler authorized by the commission to export legend drugs and nonprescription (OTC) drugs to foreign countries.

(35) "FDA" – United States Food and Drug Administration.

(36) "Full-line wholesaler" means a drug wholesale distributor that is licensed under RCW 18.64.046 to possess and sell legend drugs, controlled substance and nonprescription drugs to a licensed pharmacy or other legally licensed or authorized person.

(37) "FPGEC" means foreign pharmacy graduate examination committee.

(38) "FPGEE" means foreign pharmacy graduate equivalency examination.

(39) "Generic substitution" means the act of switching between a branded drug and its therapeutically equivalent generic version.

(40) "HIPAA" means Health Insurance Portability and Accountability Act.

(41) "Hospital" means any institution licensed under chapter 70.41 or 71.12 RCW or designated under RCW 72.23.020.

(42) "Hospital pharmacy" means that portion of a hospital licensed under RCW 18.64.043 which is engaged in the manufacture, production, preparation, dispensing, sale, or distribution of drugs, components, biologicals, chemicals, devices and other materials used in the diagnosis and treatment of injury, illness and diseases.

(43) "Hospital pharmacy associated clinic" or "HPAC" means an individual practitioner's office or multipractitioner clinic owned, operated, or under common control of a parent hospital or health system,

where the physical address of the office or clinic is identified on a hospital pharmacy license.

(44) "Immediate supervision" means supervision by a pharmacist who is immediately available at all times the delegated tasks are being performed; who is aware of delegated tasks being performed; and who provides personal assistance, direction and approval throughout the time the delegated tasks are being performed.

(a) "Immediately available" means the pharmacist and pharmacy ancillary personnel or interns are on the same physical premises, or if not, technology is used to enable real time, two-way communications between the pharmacist and ((~~technician(s)~~)) pharmacy ancillary personnel and interns.

(b) Use of technology: A pharmacist, as an adjunct to assist in the immediate supervision of the pharmacy ancillary personnel or intern, may employ technological means to communicate with or observe the pharmacy ancillary personnel or intern. A pharmacist shall make certain all applicable state and federal laws including, but not limited to, confidentiality, are fully observed when employing technological means of communication and observation. If technology is being used to provide immediate supervision of pharmacy ancillary personnel or intern such technology shall be sufficient to provide the personal assistance, direction and approval required to meet the standard of practice for the delegated tasks.

(45) "Inoperable" means a credential status indicating that an individual cannot practice because he or she is not actively participating or enrolled in a required training program when this condition is a requirement of the credential. Inoperable status is not the result of enforcement action. The health care professional can resume practice when appropriately enrolled in a required training program and the credential is reactivated.

(46) "Internal test assessment" means, but is not limited to, conducting those tests of quality assurance necessary to ensure the integrity of the test.

(47) "Investigational drug" means any article drug that has an investigational drug application (INDA) that has been approved by the FDA.

(48) "Key party" means immediate family members and others who would be reasonably expected to play a significant role in the health care decisions of the patient or client and includes, but is not limited to, the spouse, domestic partner, sibling, parent, child, guardian and person authorized to make health care decisions of the patient or client.

(49) "Law enforcement" means any general or limited authority Washington peace officer or federal law enforcement officer or tribal officer.

(50) "License transfer" means the process used by licensed pharmacists to transfer their existing pharmacist license to Washington using NABP's Electronic Licensure Transfer Program® (e-LTP™).

(51) "Lot" means a batch or a specific identified portion of a batch having uniform character and quality within specified limits, or in the case of a drug product produced by continuous process, it is a specific identified amount produced in a unit of time or quantity in a manner that assures it is having uniform character and quality within specified limits.

(52) "Manual signature" means a printed or wet signature.

(53) "Misbranded" applies to all drugs the package or label of which bears any statement, design or device regarding such article or the ingredients or substances contained therein which is false or misleading in any particular way, and drug product which is falsely branded as to the state, territory or country in which it is manufactured or produced.

(54) "NABP" means the National Association of Boards of Pharmacy.

(55) "NDC" means National Drug Code.

(56) "Nuclear pharmacy" means a pharmacy providing radiopharmaceutical services.

(57) "Nuclear pharmacist" means a pharmacist licensed under RCW 18.64.080 who holds an endorsement that meets the requirements of WAC 246-945-180.

(58) "Originating pharmacy" means a pharmacy that receives a prescription from a patient, the patient's agent, or a prescriber, outsources prescription filling or processing functions to another pharmacy, and ultimately dispenses the prescription drug or device to the patient or the patient's agent. This does not include pharmacies engaged in shared pharmacy services in accordance with RCW 18.64.570.

(59) "Over-the-counter drugs" or "OTC" means "nonlegend" or "nonprescription" drugs, and any drugs which may be lawfully sold without a prescription.

(60) "Over-the-counter only wholesaler" means any wholesaler licensed under RCW 18.64.046 to possess and sell OTC drugs to any outlets credentialed for resale.

(61) "Pharmaceutical firm" means a business engaged in the dispensing, delivering, distributing, manufacturing, or wholesaling of prescription drugs or devices within or into Washington state.

(62) "Pharmacy intern" means a person who is registered with the commission under RCW 18.64.080(3) as a pharmacy intern.

(63) "Pharmacy services" means any services provided that meet the definition of the practice of pharmacy, RCW 18.64.011.

(64) "Plan of correction" is a proposal devised by the applicant or credential holder that includes specific corrective actions that must be taken to correct identified unresolved deficiencies with time frames to complete them.

(65) "Precursor drugs" as defined in chapter 69.43 RCW.

(66) "Prescription drug" means any drug, including any biological product required by federal statute or regulation to be dispensed only by a prescription, including finished dosage forms and bulk drug substances subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act.

(67) "Protocol" means a written set of procedures, steps or guidance.

(68) "Radiopharmaceutical service" means, but is not limited to:

(a) The preparing, compounding, dispensing, labeling, and delivery of radiopharmaceuticals;

(b) The participation in radiopharmaceutical selection and radiopharmaceutical utilization reviews;

(c) The proper and safe storage and distribution of radiopharmaceuticals;

(d) The maintenance of radiopharmaceutical quality assurance;

(e) The responsibility for advising, where necessary or where regulated, of therapeutic values, hazards and use of radiopharmaceuticals; or

(f) The offering or performing of those acts, services, operations or transactions necessary in the conduct, operation management and control of a nuclear pharmacy.

(69) "Radiopharmaceutical" means any substance defined as a drug in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any nonradioactive reagent kit or nuclide generator which is intended to be used in the preparation of any such substance but does not include drugs such as carbon-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides. The term "radioactive drug" includes a "radioactive biological product."

(70) "Radiopharmaceutical quality assurance" means, but is not limited to, the performance of appropriate chemical, biological and physical tests on radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals, including internal test assessment authentication of product history and the keeping of proper records.

(71) "Readily retrievable" means a record that is kept by automatic data processing systems or other electronic, mechanized, or written recordkeeping systems in such a manner that it can be separated out from all other records in a reasonable time.

(72) "Reverse distributor" means a pharmaceutical wholesaler that receives drugs for destruction, return credit, or otherwise disposes of drugs received from a registrant that holds a credential to dispense or possess drugs.

(73) "Secretary" means the secretary of the Washington state department of health.

(74) "Strength" means:

(a) The concentration of the drug product; ((~~and/~~)) or

(b) The potency, that is, the therapeutic activity of the drug product as indicated by appropriate laboratory tests or by adequately developed and controlled clinical data.

(75) "U.S. jurisdiction" means a state of the United States, the District of Columbia, the Commonwealth of Puerto Rico, or a territory or insular possession subject to the jurisdiction of the United States.

(76) "USP" means the United States Pharmacopeia.

(77) "Therapeutic substitution" means the act of dispensing an alternative drug that is believed to be therapeutically similar but may be chemically different, in a different category, or with different pharmacokinetic properties. This substitution is based on the premise that the substituted drug will provide similar clinical efficacy, desired outcome, and safety profile.

(78) "TOEFL iBT" means an internet based test which measures the ability to use and understand English. It evaluates the combined use of reading, listening, speaking and writing skills.

(79) "Virtual manufacturer" means an individual or facility that sells his or her own prescription drugs, but never physically possesses the drugs.

(80) "Virtual wholesaler" means an individual or facility that sells a prescription drug ((~~and/~~)) or device, but never physically possesses the product.

(81) "Wholesale distribution" means distribution of prescription drugs to persons other than a consumer or patient, but does not include:

(a) The sale, purchase, or trade of a drug, an offer to sell, purchase or trade a drug, or the dispensing of a drug pursuant to a prescription;

(b) The lawful distribution of drug samples by manufacturers' representatives or distributors' representatives;

(c) The sale, purchase, or trade of blood and blood components intended for transfusion;

(d) Intracompany sales, being defined as any transaction or transfer between any division, subsidiary, parent ((~~and/~~)) or affiliated, or related company under the common ownership and control of a corporate entity, unless such transfer occurs between a wholesale distributor and a health care entity or practitioner; or

(e) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons, for purposes of this section, "emergency medical reasons" includes transfers of prescription drugs by retail pharmacy to another retail pharmacy or practitioner to alleviate a temporary shortage, except that the gross dollar value of such transfers shall not exceed five percent of the total prescription drug sale revenue of either the transferor or transferee pharmacy during any ((~~twelve~~)) 12 consecutive month period.

AMENDATORY SECTION (Amending WSR 20-12-072, filed 6/1/20, effective 7/1/20)

WAC 246-945-011 Prescription validity. (1) Prior to dispensing and delivering a prescription, a pharmacist shall verify its validity.

(2) A prescription shall be considered invalid if:

(a) At the time of presentation, the prescription shows evidence of alteration, erasure, or addition by any person other than the person who wrote it;

(b) The prescription does not contain the required information as provided in WAC 246-945-010;

(c) The prescription is expired; or

(d) The prescription is for a controlled substance and does not comply with the requirements in RCW 69.50.308.

(3) A prescription is considered expired when:

(a) The prescription is for a controlled substance listed in Schedule II through V and the date of dispensing is more than six months after the prescription's date of issue.

(b) The prescription is for a noncontrolled legend drug or ((~~OTC's~~)) OTC and the date of dispensing is more than ((~~twelve~~)) 12 months after the prescription's date of issue.

AMENDATORY SECTION (Amending WSR 21-17-062, filed 8/11/21, effective 9/11/21)

WAC 246-945-014 Electronic prescribing mandate waiver. (1) A practitioner may submit an attestation to the department for a waiver from the electronic prescribing mandate in RCW 69.50.312, if the practitioner is experiencing an economic hardship, technological limitations not reasonably in the control of the practitioner, or other ex-

ceptional circumstance. A practitioner does not need to submit a waiver if exempted from the mandate under RCW 69.50.312 (2)(a) through (j). A practitioner must submit an attestation for the waiver using forms provided by the department. The department shall deem the waiver granted upon submission of an attestation and the practitioner will be deemed exempt under RCW 69.50.312 (2)(k).

(2) A practitioner who has submitted an attestation for a waiver from the mandate in RCW 69.50.312 is exempt from the electronic prescribing mandate for the calendar year in which the attestation is signed, beginning with the effective date of this section.

(a) For economic hardship and ((~~technical~~)) technological limitations, a practitioner may attest to the need for a waiver up to three times, giving the practitioner three years to come into compliance with the mandate.

(b) There is no limit on the number of other exceptional circumstance waivers under subsection (3)(c) of this section that a practitioner can submit.

(3) A practitioner required to electronically prescribe under RCW 69.50.312 may submit an attestation for a waiver from this mandate due to:

(a) Economic hardship in the following circumstances:

(i) A bankruptcy in the previous year or submitted an attestation for a waiver under this chapter due to a bankruptcy in the previous year;

(ii) Opening a new practice after January 1, 2020;

(iii) Intent to discontinue operating in Washington prior to December 31, 2022; or

(iv) Operating a low-income clinic, that is defined as a clinic serving a minimum of ((~~thirty~~)) 30 percent medicaid patients.

(b) Technological limitations outside the control of the practitioner if the practitioner is in the process of transitioning to an electronic prescription system.

(c) Other exceptional circumstances include:

(i) The practitioner is providing services at a free clinic;

(ii) The practitioner generates fewer than ((~~one hundred~~)) 100 prescriptions of Schedules II through V drugs in a one-year period, including both new and refill prescriptions;

(iii) The practitioner is located in an area without sufficient internet access to comply with the e-prescribing mandate; or

(iv) Unforeseen circumstances that stress the practitioner or health care system in such a way that compliance is not possible. Examples may include, but are not limited to, natural disasters, widespread health care emergencies, unforeseeable barriers to electronic prescribing, or unforeseen events that result in a statewide emergency.

(4) The department may audit waiver attestations submitted by a practitioner to determine compliance with this chapter. Knowingly submitting a false attestation is grounds for disciplinary action against a practitioner's license by the appropriate disciplinary authority as well as fines pursuant to RCW 69.50.312(5).

AMENDATORY SECTION (Amending WSR 20-12-072, filed 6/1/20, effective 7/1/20)

WAC 246-945-018 Prescriptions—Labeling—Prepackage medications. Prepackage medications dispensed pursuant to RCW 70.41.480, medications dispensed in unit dose form, and medications dispensed by a pharmacy to a long-term care facility must include a label with the following information:

(1) Drug name;

(2) Drug strength;

(3) Expiration date in accordance with WAC 246-945-016(3);

(4) The manufacturer's name and lot number, if not maintained in a separate record; and

(5) The identity of the pharmacist or provider responsible for the prepackaging, if not maintained in a separate record.

AMENDATORY SECTION (Amending WSR 20-12-072, filed 6/1/20, effective 7/1/20)

WAC 246-945-063 Precursor definitions. The definitions in this section apply to WAC 246-945-065 through 246-945-088.

(1) "((~~Registered~~)) Restricted product" means any nonprescription product containing any detectable quantity of ephedrine, pseudoephedrine, and phenylpropanolamine or their salts or isomers, or salts of isomers.

(2) "Retailer" means a pharmacy licensed by, or shopkeeper or itinerant vendor registered with, the department of health under chapter 18.64 RCW that sells, dispenses, or otherwise provides restricted products to purchasers.

(3) "Sale" means the transfer, selling, or otherwise furnishing of any restricted product to any person.

AMENDATORY SECTION (Amending WSR 20-12-072, filed 6/1/20, effective 7/1/20)

WAC 246-945-156 Pharmacy intern—Temporary practice permit. (1) An individual that holds a pharmacy intern registration in another U.S jurisdiction, that has registration standards substantially equivalent to Washington, may request a temporary practice permit if:

(a) The applicant is not subject to denial of a credential or issuance of a conditional or restricted credential in any state;

(b) Does not have a criminal record in Washington state;

(c) The applicant's fingerprint-based national background check results are pending; and

(d) The applicant meets WAC 246-945-155 (1)(a) or (b).

(2) To request a temporary practice permit, the pharmacy intern applicant shall submit a written request for a temporary practice permit, and any applicable fees in accordance with ((~~chapter 246-907~~)) WAC 246-945-990 through 246-945-992.

(3) A temporary practice permit expires:

(a) When the pharmacy intern registration is issued;

(b) When a notice of decision on the pharmacy intern registration application is mailed to the applicant; or

(c) Ninety days after the temporary practice permit is issued. The applicant may obtain a one-time extension of up to ((~~ninety~~)) 90 days with approval of the commission.

AMENDATORY SECTION (Amending WSR 20-12-072, filed 6/1/20, effective 7/1/20)

WAC 246-945-170 Pharmacist licensure by license transfer—Temporary practice permits. (1) An individual who holds an active pharmacist license, in good standing, issued by another U.S. jurisdiction may apply for a pharmacist license in Washington by license transfer. In addition to the completion of the commission's application, the applicant must:

(a) File for license transfer using the NABP eLTP process; and

(b) Take and pass the approved jurisprudence examination.

(2) A temporary practice permit to practice pharmacy may be issued to an applicant for a pharmacist license by license transfer if the applicant meets all of the requirements and qualifications in subsection (1) of this section, and the following criteria are met:

(a) The applicant is not subject to denial of a credential or issuance of a conditional or restricted credential in any U.S. jurisdiction;

(b) Does not have a criminal record in Washington state;

(c) The applicant's fingerprint-based national background check results are pending; and

(d) To request a temporary practice permit, the applicant shall submit a written request for a temporary practice permit, and pay the applicable fees in accordance with ((~~chapter 246-907~~)) WAC 246-945-990 through 246-945-992.

(3) A temporary practice permit expires:

(a) When the pharmacist license is issued;

(b) When a notice of decision on the pharmacist license application is mailed to the applicant; or

(c) One hundred eighty days after the temporary practice permit is issued. The applicant may obtain a one-time extension of ((~~one hundred eighty~~)) 180 days with approval of the commission.

(4) A temporary practice permit holder cannot qualify as a responsible pharmacy manager.

AMENDATORY SECTION (Amending WSR 20-12-072, filed 6/1/20, effective 7/1/20)

WAC 246-945-173 Expired pharmacist license. To return to active status a pharmacist with an expired license shall pay the applicable fees in accordance with ((~~chapter 246-907~~)) WAC 246-945-990 through 246-945-992 and:

(1) If the pharmacist license has been expired for less than three years the pharmacist shall meet the requirements of ((~~chapter 246-12 WAC, Part 2~~)) WAC 246-12-040 and ((~~fifteen~~)) 15 CPE hours per year the license has been expired.

(2) If the pharmacist license has been expired for three years or more, and the pharmacist holds an active credential in another U.S. jurisdiction, and is in good standing, the pharmacist shall:

(a) Meet the requirements ((~~in chapter 246-12 WAC, Part 2~~)) of WAC 246-12-040;

(b) Provide certification of an active pharmacist license which includes:

(i) Name and license number;

(ii) Issue and expiration date; and

(iii) Verification that the license has not been the subject of final or pending disciplinary action.

(c) Submit verification of current active pharmacy practice from another U.S. jurisdiction; and

(d) Take and pass the commission approved jurisprudence examination.

(3) If a pharmacist license has been expired for three years or more, and the pharmacist has not been in active practice in another U.S. jurisdiction, the pharmacist shall:

(a) Meet the requirements of ((~~chapter 246-12 WAC, Part 2~~)) WAC 246-12-040;

(b) Serve an internship of ((~~three hundred~~)) 300 hours in compliance with WAC 246-945-163; and

(c) Take and pass the commission approved jurisprudence and licensure examinations.

AMENDATORY SECTION (Amending WSR 20-12-072, filed 6/1/20, effective 7/1/20)

WAC 246-945-175 Inactive pharmacist license. (1) A pharmacist may obtain an inactive license by meeting the requirements of WAC 246-12-090 and RCW 18.64.140.

(2) An inactive license can be renewed in accordance with ((~~chapter 246-12~~)) WAC 246-12-100 and by paying the applicable fees in accordance with WAC 246-945-990 through 246-945-992.

(3) If a license is inactive for three years or less, to return to active status a pharmacist shall meet the requirements of ((~~chapter 246-12 WAC, Part 4~~)) WAC 246-12-110.

(4) If a license is inactive for more than three years, and the pharmacist has been in active practice in another U.S. jurisdiction, to return to active status the pharmacist must:

(a) Provide certification of an active pharmacist license which includes:

(i) Name and license number;

(ii) Issue and expiration date; and

(iii) Verification that the license has not been the subject of final or pending disciplinary action.

(b) Submit verification of current active pharmacy from another U.S. jurisdiction;

(c) Meet the requirements of ((~~chapter 246-12 WAC, Part 4~~)) WAC 246-12-110; and

(d) Take and pass the commission approved jurisprudence examination.

(5) If a pharmacist license has been inactive for more than three years, and the pharmacist has not been in active practice in another U.S. jurisdiction, to return to active status, the pharmacist shall comply with the requirements of WAC 246-945-173(3).

AMENDATORY SECTION (Amending WSR 23-09-062, filed 4/18/23, effective 5/19/23)

WAC 246-945-200 Pharmacy assistants. (1) To become registered as a pharmacy assistant an applicant shall submit an application to the commission that meets the requirements of WAC 246-12-020.

(2) The supervising pharmacist, shall instruct the pharmacy assistant regarding their scope of practice.

(3) To renew a registration a pharmacy assistant shall submit an application to the commission with the applicable fees in accordance with WAC 246-945-990 through 246-945-992.

AMENDATORY SECTION (Amending WSR 20-12-072, filed 6/1/20, effective 7/1/20)

WAC 246-945-217 Expired pharmacy technician certification. To return to active status a pharmacy technician with an expired certification shall pay the applicable fees in accordance with ((~~chapter 246-907~~)) WAC 246-945-990 through 246-945-992, and:

(1) If a pharmacy technician's certification has expired for five years or less, the pharmacy technician shall meet the requirements of ((~~chapter 246-12 WAC, Part 2~~)) WAC 246-12-040.

(2) If the pharmacy technician's certification has expired for over five years and they have not been in active practice in another U.S. jurisdiction, the pharmacy technician shall:

(a) Complete the requirements for certification under WAC 246-945-205; and

(b) Meet the requirements of ((~~chapter 246-12 WAC, Part 2~~)) WAC 246-12-040.

(3) If the pharmacy technician's certification has expired for over five years and they have been in an active practice in another U.S. jurisdiction with duties that are substantially equivalent to a pharmacy technician in Washington state, the pharmacy technician shall:

(a) Submit verification of current active pharmacy practice in another U.S. jurisdiction; and

(b) Meet the requirements of ((~~chapter 246-12 WAC, Part 2~~)) WAC 246-12-040.

AMENDATORY SECTION (Amending WSR 20-12-072, filed 6/1/20, effective 7/1/20)

WAC 246-945-230 General information, change of location, ownership or new construction. (1) The definitions in this subsection apply throughout WAC 246-945-230 through 246-945-247 unless otherwise specified:

(a) "License" includes "licensing," "licensure," "certificate," "certification," and "registration."

(b) "Facility" includes pharmacies, nonresident pharmacies, health care entities, hospital pharmacy associated clinics, wholesalers, and manufacturers.

(2) The commission shall license a facility that:

(a) Submits a completed application for the license applied for on forms provided by the commission;

(b) Pays the applicable fees in accordance with ((~~chapter 246-907~~)) WAC 246-945-990 through 246-945-992. This fee will not be prorated under any circumstances;

(c) Undergoes an inspection by the commission if the facility is located in Washington pursuant to WAC 246-945-005 that results in either no deficiencies or an approved plan of correction; and

(d) Obtains a controlled substances registration from the commission and is registered with the DEA if the facility intends to possess or distribute controlled substances.

(3) Once an initial license is issued, a licensed facility must:

(a) Notify the commission and pay a facility inspection fee in lieu of paying an ((~~original~~)) initial license fee for modifications or remodels. A modification or remodel of a pharmacy location includes changes to a previously approved area, room or pharmacy building which result in changes in the pharmacy that affects security, square footage, access to drugs, compounding or necessitates temporary relocation of pharmacy services.

(b) Submit a new application on forms provided by the commission and pay the ((~~original~~)) initial license fee as established in ((~~chapter 246-907~~)) WAC 246-945-990 through 246-945-992 if the facility changes location to a different address. If located in Washington, a facility may not relocate prior to the inspection of the new premises.

(c) Notify the commission and pay the ((~~original~~)) initial license fee in accordance with ((~~chapter 246-907~~)) WAC 246-945-990 through 246-945-992 whenever there is a change of ownership. Change in ownership includes changes in business or organizational structure such as a change from sole proprietorship to a corporation, or a change of more than ((~~fifty~~)) 50 percent ownership in a corporation.

(i) Upon receipt of a change of ownership application and fees, the purchaser may begin operations prior to the issuance of a new pharmacy license only when the purchaser and seller have a written power of attorney agreement. This agreement shall delineate that violations during the pending application process shall be the sole responsibility of the seller.

(ii) This agreement shall be provided to the commission upon request.

(d) Notify the commission within ((~~thirty~~)) 30 days of any changes to the information provided on their application.

(e) Notify the commission of any changes in their responsible pharmacy manager in accordance with WAC 246-945-480, if a responsible pharmacy manager is required for initial licensure.

(f) Renew their license in accordance with ((~~chapter 246-907~~)) WAC 246-945-990 through 246-945-992.

(4) A license is issued to a location and is not transferable.

AMENDATORY SECTION (Amending WSR 20-12-072, filed 6/1/20, effective 7/1/20)

WAC 246-945-417 Electronic systems for patient medication records, prescriptions, chart orders, and controlled substance records. (1) A pharmacy shall use an electronic recordkeeping system to establish and store patient medication records, including patient allergies, idiosyncrasies or chronic conditions, and prescription, refill, transfer information, and other information necessary to provide safe and appropriate patient care.

(a) Systems must prevent auto-population of user identification information.

(b) Pharmacies that provide off-site pharmacy services without a pharmacist for product fulfillment or prescription processing must track the identity of each individual involved in each step of the off-site pharmacy services.

(2) The electronic recordkeeping system must be capable of real-time retrieval of information pertaining to the ordering, verification, and processing of the prescription where possible.

(3) The electronic recordkeeping system must include security features to protect the confidentiality and integrity of patient records including:

(a) Safeguards designed to prevent and detect unauthorized access, modification, or manipulation of prescription information and patient medication records; and

(b) Functionality that documents any alteration of prescription information after a prescription is dispensed, including the identification of the individual responsible for the alteration.

(4) The pharmacy shall have policies and procedures in place for system downtime.

(a) The procedure shall provide for the maintenance of all patient recordkeeping information as required by this chapter.

(b) Upon restoration of operation of the electronic recordkeeping system the information placed in the auxiliary recordkeeping procedure shall be entered in each patient's records within two working days, after which the auxiliary records may be destroyed.

(c) This section does not require that a permanent dual recordkeeping system be maintained.

(5) The pharmacy shall maintain records in accordance with WAC 246-945-020.

(6) Electronic prescriptions for prescription drugs must be maintained by the pharmacy in a system that meets the requirements of 21 C.F.R. Sec. 1311.

(7) HCEs or HPACs that maintain an electronic record system must be done in accordance with subsections ((~~(2)~~)) (1) through ((~~(7)~~)) (6) of this section.

AMENDATORY SECTION (Amending WSR 20-12-072, filed 6/1/20, effective 7/1/20)

WAC 246-945-590 Wholesaler—Policies and procedures. Wholesalers shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, transport, and shipping and wholesale distribution of drugs, including policies and procedures for identifying, recording, and reporting losses or thefts and for correcting all errors and inaccuracies in inventories. Wholesalers shall include the following in their written policies and procedures:

(1) A procedure to be followed for handling recalls and withdrawals of drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to:

(a) Any action initiated at the request of FDA or any other federal, state, or local law enforcement or other government agency, including the commission; or

(b) Any volunteer action by the manufacturer to remove defective or potentially defective drugs from the market.

(2) A procedure to ensure that wholesalers prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of a strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.

(3) A procedure to ensure that any outdated drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed in accordance with federal and state laws, including all necessary documentation and the appropriate witnessing. This procedure shall provide for written documentation of the disposition of outdated drugs.

(4) A procedure for the destruction of outdated drugs in accordance with federal and state laws.

(5) A procedure for the disposing and destruction of containers, labels, and packaging to ensure that the containers, labels, and packaging cannot be used in counterfeiting activities, including all necessary documentation, and the appropriate witnessing of the destruction of any labels, packaging, immediate containers, or containers in accordance with all applicable federal and state requirements.

(6) A procedure for identifying, investigating, and reporting significant drug inventory discrepancies involving counterfeit, suspect of being counterfeit, contraband, or suspect of being contraband, in the inventory and reporting of such discrepancies ((~~as required to the FDA, commission and/or appropriate federal or state agency~~)) to the FDA, commission, and, as applicable, the DEA upon discovery of such discrepancies.

(7) A procedure for reporting criminal or suspected criminal activities involving the inventory of drug(s) as required to the commission, FDA, and if applicable, DEA.

(8) Procedures addressing:

(a) The design and operation of the suspicious order monitoring and reporting system;

(b) Mandatory annual training for staff responsible for identifying and reporting suspicious orders and potential diversion activities. Such training must include the following:

(i) The wholesaler's suspicious order monitoring system;

(ii) The process to collect all relevant information on customers in accordance with WAC ((~~246-960-330~~)) 246-945-585; and

(iii) The requirement and process for submission of suspicious order and information on customers who engage in potential diversion activities.

(9) A procedure for timely responding to customers who submit purchase orders for patients with emergent needs.

Department of Health
Pharmacy Quality Assurance Commission

Policy Statement

Revised – 12/05/22

Title:	Extension Process for Pharmacy Intern Renewal Limitation	*Number:* P013
References:	RCW 18.64.005; RCW 18.64.080; WAC 246-945-155	
Contact:	Marlee B. O'Neill, Executive Director	
Phone:	(360) 236-4946	
Email:	wspqac@doh.wa.gov	
Effective Date:	February 1, 2024	
Supersedes:	N/A	
Approved By:	Ken Kenyon, PharmD, BCPS Pharmacy Quality Assurance Commission Chair	

This policy statement establishes the approach of the Pharmacy Quality Assurance Commission (commission) to grant renewal extensions to pharmacy interns who have reached the renewal limitation set in WAC 246-945-155(3).

RCW 18.64.080(3) states all registrations issued to pharmacy interns shall be valid for a period to be determined by the commission, but in no instance shall the registration be valid if the individual is no longer making timely progress toward graduation.

Chapter 246-945 WAC, the Commission's new rules chapter, went into effect on July 1, 2020. It replaced all former requirements, including those of pharmacy intern registrations. The new rule states that pharmacy intern registrations may be renewed twice following issuance. Issued registrations are valid for two years (WAC 246-945-990). Each registrant may therefore hold an active pharmacy intern registration for a total of approximately six years.

The commission is aware that due to unforeseen circumstances, pharmacy interns are not always able to complete their internship hours prior to their registration expiring after having held it for six years. The commission authorized rulemaking to explore extending the two-time renewal limit. However, while rulemaking is in progress, the commission will consider requests from pharmacy interns to allow them to renew their registration beyond six years if the commission determines there is good cause to do so. "Good cause" includes, but is not limited

to, a serious health issue or needing to care for a family member with a serious health issue. Pharmacy interns must still meet all other requirements in RCW 18.64.080 and WAC 246-945-155.

To request an extension, a pharmacy intern must email WSPQAC@doh.wa.gov with the following information:

- Name;
- Intern registration number;
- Intern registration expiration date;
- Explanation of the reason for the request; and,
- Documentation for how the intern meets all other requirements of RCW 18.64.080 and WAC 246-945-155.

The commission will make every effort to timely process these requests; however, requestors should assume that these requests take up to 60 days to process.

Finally, the Commission has begun to engage in rulemaking to consider amending WAC 246-945-155 in order to, among other things, convert this policy statement into rule.

Department of Health
Pharmacy Quality Assurance Commission

Policy Statement

Revised – 12/05/22

Title:	Temporary Practice Permits for Military Spouse Pharmacy Interns	*Number:* P011
References:	RCW 18.64.080(3); RCW 16.340.020; WAC 246-945-155; WAC 246-945-156	
Contact:	Marlee B. O'Neill, Executive Director	
Phone:	(360) 236-4946	
Email:	wspqac@doh.wa.gov	
Effective Date:	February 1, 2024	
Supersedes:	N/A	
Approved By:	Ken Kenyon, PharmD, BCPS Pharmacy Quality Assurance Commission Chair	

As of February 1, 2024, the Pharmacy Quality Assurance Commission (commission) will issue *temporary* pharmacy intern practice permits for 180 days to applicants who are spouses of military personnel and who meet the criteria in RCW 18.340.020(1)(a).

RCW 18.64.080(3) allows all pharmacy intern licenses to be valid for a period to be determined by the commission, but in no instance shall the certificate be valid if the individual is no longer making timely progress toward graduation. In accordance with WAC 246-945-155, individuals are required to register with the commission as a pharmacy intern before beginning pharmacy practice experiences in Washington. Additionally, WAC 246-945-156(3) states that pharmacy intern temporary practice permits will expire ninety days after the permit is issued and the applicant may obtain a one-time extension of up to ninety days with approval of the commission.

House Bill 1009 - Concerning Military Spouse Employment (Chapter 165, Laws of 2023) went into effect on July 23, 2023. Section 4 of the bill took effective on October 1, 2023, and requires the Commission to issue temporary practice permits for a minimum of 180 days to applicants who are spouses of military personnel subject to a military transfer, and who are licensed, certified, or registered in another state to perform professional services in that state.

The pharmacy intern license is the only temporary practice permit for spouses of military personnel issued by the Commission that is not currently issued for a minimum of 180 days. Based on the implementation of House Bill 1009, the Commission will issue pharmacy intern temporary practice permits for 180 days to applicants who are spouses of military personnel and who meet the criteria in RCW 18.340.020(1)(a), by February 1, 2024.

Finally, the Commission has begun to engage in rulemaking to consider amending WAC 246-945-155 and WAC 246-945-156 to, among other things, convert this policy statement into rule.