PROPOSED RULE MAKING

CR-102 (December 2017)
(Implements RCW 34.05.320)
Do **NOT** use for expedited rule making

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: April 05, 2021
TIME: 9:50 AM

WSR 21-08-059

Agency: Department of Health and Pharmacy Quality Assurance Commission

☒ **Original Notice**

☐ **Supplemental Notice to WSR**

☐ **Continuance of WSR**

☒ **Preproposal Statement of Inquiry was filed as WSR** 21-04-051 **; or**

☐ **Expedited Rule Making--Proposed notice was filed as WSR ; or**

☐ **Proposal is exempt under RCW 34.05.310(4) or 34.05.330(1).**

☐ **Proposal is exempt under RCW .**

Title of rule and other identifying information: (describe subject) WAC 246-945-014, Electronic prescribing mandate waiver. The Pharmacy Quality Assurance Commission (commission) and the Department of Health (department) are jointly proposing a new section of rule to outline the electronic prescribing mandate, exceptions allowing a waiver, and related waiver process as required by Substitute Senate Bill (SSB) 5380 passed during the 2019 legislative session.

Hearing location(s):

Date:	**Time:**	**Location:** (be specific)	**Comment:**
06/04/2021	9:30 am	In response to the coronavirus disease 2019 (COVID-19) public health emergency, the Department of Health and the Pharmacy Quality Assurance Commission will not provide a physical location for this hearing to promote social distancing and the safety of the citizens of Washington State. A virtual public hearing, without a physical meeting space, will be held instead. To access the meeting: Please register for this meeting and join from your computer, tablet or smartphone. https://attendee.gotowebinar.com/register/3088602240482857744 You can also dial in using your phone. United States: +1 (631) 992-3221 Access Code: 902-027-067 New to GoToMeeting? Get the app now and be ready when your first meeting starts: https://global.gotomeeting.com/install/541045301	N/A

Date of intended adoption: 06/04/2021 (Note: This is **NOT** the **effective** date)

Submit written comments to:

Name: Cori Tarzwell
Address: PO Box 47990, Olympia, WA 98504
Email: https://fortress.wa.gov/doh/policyreview
Fax: N/A
Other: cori.tarzwell@doh.wa.gov
By (date) 05/28/2021

Assistance for persons with disabilities:

Contact Cori Tarzwell
Phone: 360-236-4981
Fax: N/A
TTY: 711
Email: cori.tarzwell@doh.wa.gov
Other:
By (date) 05/28/2021

Purpose of the proposal and its anticipated effects, including any changes in existing rules: SSB 5380, Section 16, requires all providers prescribing controlled substances Schedules II-V, and refills for Schedules III-V, to transmit those prescriptions electronically. The law also provides for exceptions to this mandate and directs the department to create a waiver for practitioners who cannot comply with the mandate due to economic hardship, technological limitations, or other exceptional circumstances. The proposed rules implement the requirements of the bill by creating a waiver and clarifying what qualifies as an economic hardship, technological limitation, or exceptional circumstance.

The intent of the underlying statute is to ensure prescriptions and refills for controlled substances in Schedules II-V are transmitted electronically whenever possible; however, the statute acknowledges challenges to electronic prescribing. The proposed rule clarifies what economic hardships, technological limitations, or exceptional circumstances qualify a provider for a waiver of electronic prescribing.

The requirement to electronically prescribe goes into effect January 1, 2021. However, due to the COVID-19 pandemic, the Secretary of Health (Secretary) issued a waiver for all providers until September 30, 2021. Should it be necessary, the Secretary may consider extending that waiver until such a time that compliance is deemed possible.

Reasons supporting proposal: SSB 5380, Section 16, requires all providers prescribing controlled substances Schedules II-V, and refills for Schedules III-V, to transmit those prescriptions electronically. The law also provides for exceptions to this mandate and directs the department to create a waiver for practitioners who cannot comply with the mandate due to economic hardship, technological limitations, or other exceptional circumstances. Through discussion with stakeholders, it was determined rules are necessary to clarify what is an economic or technological hardship, or exceptional circumstance. The final proposed rules were drafted with stakeholder feedback to create a waiver program that provides necessary guidance to licensees, allows for relatively easy compliance, and results in immediate access to a waiver if a licensee request one.

Statutory authority for adoption: RCW 69.50.312; SSB 5380 (chapter 314, Laws of 2019)

Statute being implemented: RCW 69.50.312; SSB 5380 (chapter 314, Laws of 2019)

Is rule necessary because of a:

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

If yes, CITATION:

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters: N/A

Name of proponent: (person or organization) Washington State Department of Health and the Pharmacy Quality Assurance Commission.

☐ Private
☐ Public
☒ Governmental

Name of agency personnel responsible for:

	Name	Office Location	Phone
Drafting:	Cori Tarzwell	111 Israel Rd SE, Olympia, WA 98504	360-236-4981
Implementation:	Lauren Lyles	111 Israel Rd SE, Olympia, WA 98504	360-236-4853
Enforcement:	Lauren Lyles	111 Israel Rd SE, Olympia, WA 98504	360-236-4853

Is a school district fiscal impact statement required under RCW 28A.305.135? ☐ Yes ☒ No

If yes, insert statement here:

The public may obtain a copy of the school district fiscal impact statement by contacting:

Name:
Address:
Phone:
Fax:
TTY:
Email:
Other:

Is a cost-benefit analysis required under RCW 34.05.328?

☒ Yes: A preliminary cost-benefit analysis may be obtained by contacting:

Name: Cori Tarzwell
Address: PO Box 47990, Olympia, WA 98504
Phone: 360-236-4981
Fax: N/A
TTY: 711
Email: cori.tarzwell@doh.wa.gov
Other:

☐ No: Please explain:

Regulatory Fairness Act Cost Considerations for a Small Business Economic Impact Statement:

This rule proposal, or portions of the proposal, **may be exempt** from requirements of the Regulatory Fairness Act (see chapter 19.85 RCW). Please check the box for any applicable exemption(s):

☐ This rule proposal, or portions of the proposal, is exempt under RCW 19.85.061 because this rule making is being adopted solely to conform and/or comply with federal statute or regulations. Please cite the specific federal statute or regulation this rule is being adopted to conform or comply with, and describe the consequences to the state if the rule is not adopted.

Citation and description:

☐ This rule proposal, or portions of the proposal, is exempt because the agency has completed the pilot rule process defined by RCW 34.05.313 before filing the notice of this proposed rule.

☐ This rule proposal, or portions of the proposal, is exempt under the provisions of RCW 15.65.570(2) because it was adopted by a referendum.

☐ This rule proposal, or portions of the proposal, is exempt under RCW 19.85.025(3). Check all that apply:

- ☐ RCW 34.05.310 (4)(b) (Internal government operations)
- ☐ RCW 34.05.310 (4)(c) (Incorporation by reference)
- ☐ RCW 34.05.310 (4)(d) (Correct or clarify language)
- ☐ RCW 34.05.310 (4)(e) (Dictated by statute)
- ☐ RCW 34.05.310 (4)(f) (Set or adjust fees)
- ☐ RCW 34.05.310 (4)(g) ((i) Relating to agency hearings; or (ii) process requirements for applying to an agency for a license or permit)

☐ This rule proposal, or portions of the proposal, is exempt under RCW .

Explanation of exemptions, if necessary:

COMPLETE THIS SECTION ONLY IF NO EXEMPTION APPLIES

If the proposed rule is **not exempt**, does it impose more-than-minor costs (as defined by RCW 19.85.020(2)) on businesses?

☒ No Briefly summarize the agency's analysis showing how costs were calculated. The proposed costs to comply with these rules are minimal and apply directly to health care providers with prescribing authority for controlled substances Schedules II-V and refills for controlled substances Schedules III-V. The only cost is assumed to be completing an attestation and submitting it to the proper disciplining authority at the department. It is assumed that this can be done by staff at any level and would take less than 30 minutes per year.

☐ Yes Calculations show the rule proposal likely imposes more-than-minor cost to businesses, and a small business economic impact statement is required. Insert statement here:

The public may obtain a copy of the small business economic impact statement or the detailed cost calculations by contacting:

Name:
Address:
Phone:
Fax:
TTY:
Email:
Other:

Date: April 5, 2021	**Signature:** 
Name: Jessica Todorovich for Umair A. Shah, MD, MPH /Tim Lynch	
Title: Chief of Staff for Secretary of Health/ Pharmacy Quality Assurance Commission Chair	

NEW SECTION

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 exceptional 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 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, 2021; or

(iv) Operating a low-income clinic, that is defined as a clinic serving a minimum of thirty 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.

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

(ii) The practitioner generates fewer than one hundred 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. 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).

From: Appriss Health
To: Jamie Weimer; DOH WSPQAC; Miller, Joanne (DOH)
Cc: kmccormick@appriss.com; tmiracle@apprisshealth.com; Accountspecialist@appriss.com; tnadrich@apprisshealth.com
Subject: Washington NPLEx Dashboard Report - Apr 2021
Date: Saturday, May 1, 2021 9:25:23 AM
Attachments: WA_PHARMACY_TRX_REPORT_04012021.csv

External Email

MONTHLY PROGRAM ADMINISTRATOR'S DASHBOARD

5 Logins - 0 Searches - 0 Report Queries - 34 Active Watches - 0 Active Watch Hits

NEW USERS THIS MONTH

New Users = 0

Total Accounts = 139

Active Users = 3

TOP USAGE AGENCIES

TOP USERS BY USAGE

TOP AGENCIES BY ACTIVE WATCHES

1. NW HIDTA (75)
2. ICE - King County (11)

TRANSACTION SUMMARY STATISTICS (2021)

	JAN	FEB	MAR	APR	TOTAL
PURCHASES	58,504	51,943	70,640	82,986	**264,073**
BLOCKS	2,433	2,301	2,931	3,933	**11,598**
GRAMS SOLD	130,934	117,632	165,200	197,654	**611,420**
BOXES SOLD	66,771	59,470	79,346	92,123	**297,710**
GRAMS BLOCKED	6,569	7,011	8,009	11,356	**32,945**
BOXES BLOCKED	2,700	2,897	3,183	4,360	**13,140**
AVG GRAMS PER BOX BLOCKED	2.43	2.42	2.52	2.60	**2.49**

PHARMACY PARTICIPATION STATISTICS (Apr 2021)

Enabled Pharmacies	998
Pharmacies Submitting a Transaction	951
Pharmacies Logging in Without a Transaction	1
Inactive Pharmacies	46
Pharmacy Participation for Apr	95.39%

DISCLAIMER: This is an automated report meant to give you a quick snapshot of the NPLEx system in your state. The statistics listed in this report are only meant to be a general overview and not necessarily the exact final numbers. Prior to releasing any statistics mentioned in this report, we highly recommend that you verify the numbers with your NPLEx customer relationship manager. For questions or issues, please contact kmccormick@appriss.com.

Credential #	Status	First Issuance Date	Effective Date	Expiration Date
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PHMF.FX.61148943	ACTIVE	04/06/2021	04/06/2021	09/30/2021
PHNR.FO.61121313	ACTIVE	04/07/2021	04/07/2021	05/31/2022
PHWH.FX.61163852	ACTIVE	04/07/2021	04/07/2021	09/30/2021
PHAR.CF.61097970	ACTIVE	04/09/2021	04/09/2021	05/31/2022
PHNR.FO.61167124	ACTIVE	04/09/2021	04/09/2021	05/31/2022
PHNR.FO.61166637	ACTIVE	04/09/2021	04/09/2021	05/31/2022
PHNR.FO.61160844	ACTIVE	04/09/2021	04/09/2021	05/31/2022
PHHC.FX.61162638	ACTIVE	04/12/2021	04/12/2021	09/30/2021
PHMF.FX.61154188	ACTIVE	04/12/2021	04/12/2021	09/30/2021
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PHAR.CF.61117009	ACTIVE	04/13/2021	04/13/2021	05/31/2022
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PHNR.FO.61169192	ACTIVE	04/19/2021	04/19/2021	05/31/2022
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PHHC.FX.61173233	ACTIVE	05/24/2021	05/24/2021	09/30/2021

Credential #	Status	First Issuance Date	Effective Date	Expiration Date

No Closures to report

Updated HCE Self-Inspection Worksheet now available for review and additional comments

In order to obtain additional input from stakeholders, the commission is requesting further public comments on the HCE self-inspection worksheet required in Chapter 246-945 WAC.

You may access the **updated version** of the HCE self-inspection sheet here. Please take the time to review and provide input.

The timeline for submission of comments is May 24, 2021 to midnight June 7, 2021.

When submitting comments, please ensure your email includes the following information:

SUBJECT LINE:

> **Public Comments – HCE Self-Inspection Worksheet**

BODY OF THE EMAIL:

> **HCE self-inspection worksheet**
> **Section of the self-inspection worksheet**
> **Page Number**
> **Question number**
> **Clear and succinct comment**

Utilizing the format above, please submit your email to: **PharmacyRules@doh.wa.gov**

Additional Information:

There is no requirement to complete the HCE self-inspection worksheet at this time and there will not be until it is finalized by the commission.

The commission will be communicating primarily through their GovDelivery listserv, so please subscribe to the commission's GovDelivery channel by following this link: https://public.govdelivery.com/accounts/WADOH/subscriber/new.

For more information on the deadlines for all other self-inspection worksheets, please see this previous GovDelivery notice.

Read this Page Carefully

WA Pharmacy Quality Assurance Commission

2021 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 or 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 during routine pharmacy inspections.

All responsible pharmacy managers (or equivalent managers) of pharmacies **must** complete and sign this self-inspection worksheet within the month of March or 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 inspection was performed: 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." 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.

- Reconstitution and mixing of **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.
- Reconstitution and mixing of **nonsterile** products according to federal food and drug administration-approved labeling does not constitute compounding if prepared pursuant to a prescription.

(NEW) 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.

Yes	No	
☐	☐	**Does the pharmacy engage in non-sterile compounding of medications?** **If yes,** please complete the 2021 Non-Sterile Compounding Self-Inspection Addendum in addition to the General Pharmacy Self-Inspection Worksheet.

Yes	No	
☐	☐	**Does the pharmacy engage in sterile compounding?** **If yes,** you must also complete the 2021 Sterile Compounding Self-Inspection Addendum. (NEW) 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.
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 2021 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 2021 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 2021 Nuclear Pharmacy Self-Inspection Addendum in addition to the General Pharmacy Self-Inspection Worksheet.

Document and Record Review

Where are the following items located inside 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 be available during inspection, 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."

	Rule Reference
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 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(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."
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."
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** "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	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					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."	
☐	☐	☐	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 246-12 WAC, Part 2."	Click or tap here to enter text.
Facility Standards						
☐	☐	☐	6	**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	**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	**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	**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.
☐	☐	☐	10	**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.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	11	**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	**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	**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	**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	**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	**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	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					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)."	
☐	☐	☐	17	**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.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	18	**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 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."	Click or tap here to enter text.
Recordkeeping						
☐	☐	☐	19	**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.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	20	**Does all nonsterile and sterile compounding comply with USP Chapter <825>, if applicable?**	**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, Dispensing, and Repackaging."	Click or tap here to enter text.
☐	☐	☐	21	**Do medications dispensed under and 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.
☐	☐	☐	22	**Is prescription adaptation in compliance with laws and rules with regard to 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	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					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."	
☐	☐	☐	23	**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 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."	Click or tap here to enter text.
☐	☐	☐	24	**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	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					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."	
☐	☐	☐	25	**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 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)	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					Discriminate against patients or their agent in a manner prohibited by state or federal laws; and (e) Intimidate or harass a patient."	
☐	☐	☐	26	**Does the pharmacy have a secured delivery area equipped with adequate security and is this addressed in the pharmacy's policy and procedures?**	**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**	**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.)** **** Best practice recommendation: It is recommended that these authorizations are updated annually. ****	**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 patient to dispense in a container that is not child-resistant."	Click or tap here to enter text.
☐	☐	☐	28	**Do all prescriptions for non-controlled legend drugs have 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	Click or tap here to enter text.

Compliant			#			Rule Reference	Notes/Corrective Action
Yes	No	N/A					
						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	**Do all prescriptions for controlled drugs have all 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."	Click or tap here to enter text.
☐	☐	☐	29	**a**	**Patient's address**		Click or tap here to enter text.
☐	☐	☐	29	**b**	**Dosage Form**		Click or tap here to enter text.
☐	☐	☐	29	**c**	**Prescriber' address**		Click or tap here to enter text.
☐	☐	☐	29	**d**	**Prescriber's DEA number**		Click or tap here to enter text.
☐	☐	☐	30	**Does the chart order 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.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	31	**Do all emergency prescriptions for controlled substances meet the requirements?** **Are all emergency controlled substances prescribed orally reduced to a written or electronic prescription?**	**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. **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.
☐	☐	☐	32	**Are all uncontrolled 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.
☐	☐	☐	33	**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-	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					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]	
☐	☐	☐	34	**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 otherwise instructed by the practitioner through the use of the words "dispense as written," words of similar meaning, or some other indication."	Click or tap here to enter text.
☐	☐	☐	35	**Are paper prescriptions maintained in appropriate files?**	**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	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					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."	
☐	☐	☐	36	**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."	Click or tap here to enter text.
☐	☐	☐	37	**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 prescription where possible."	Click or tap here to enter text.
☐	☐	☐	38	**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)** 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.
☐	☐	☐	39	**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 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."	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	40	**Do prescription records properly document partial fills?**	**WAC 246-945-013** "Partial filling of prescriptions. **(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 of RCW 18.64.265, 21 U.S.C. Sec. 829, and 21 CFR Sec. 1306.13, as applicable.	Click or tap here to enter text.
☐	☐	☐	41	**Does your pharmacy have shared pharmacy services or utilize a central fill?**	**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.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	42	**Is an inventory of controlled substances conducted and maintained onsite at a minimum every two years?**	**WAC 246-945-420(2)** "A facility shall conduct an inventory of controlled substances every two years."	Click or tap here to enter text.
☐	☐	☐	43	**Is an inventory of controlled substances completed within 30 days of a new responsible manager or on the effective date of the addition of a substance to a schedule of controlled substances?**	**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." See also 21 CFR 1304.	Click or tap here to enter text.
☐	☐	☐	44	**If legend drugs (including controlled substances) are dispensed or delivered without a pharmacist on-site, is there a perpetual inventory?**	**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.
☐	☐	☐	45	**If prescription drugs are dispensed or delivered without pharmacy ancillary personnel physically on-site, is there 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.
☐	☐	☐	46	**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(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."	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	47	**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.
☐	☐	☐	48	**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.
☐	☐	☐	49	**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.
☐	☐	☐	50	**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.
☐	☐	☐	51	**Are significant losses or disappearances of controlled substances reported to PQAC, the DEA, 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.

Compliant			#			Rule Reference	Notes/Corrective Action
Yes	No	N/A					
☐	☐	☐	52	**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 246-945-020(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							
☐	☐	☐	53	**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."	Click or tap here to enter text.
☐	☐	☐	53	**a**	**Purchasing**		Click or tap here to enter text.
☐	☐	☐	53	**b**	**Ordering**		Click or tap here to enter text.
☐	☐	☐	53	**c**	**Storing**		Click or tap here to enter text.
☐	☐	☐	53	**d**	**Compounding**		Click or tap here to enter text.
☐	☐	☐	53	**e**	**Delivering**		Click or tap here to enter text.
☐	☐	☐	53	**f**	**Dispensing**		Click or tap here to enter text.
☐	☐	☐	53	**g**	**Administration**		Click or tap here to enter text.
☐	☐	☐	54	**Does the pharmacy have a policy in place if a computer system downtime occurs?**		**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	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					not require that a permanent dual recordkeeping system be maintained."	
☐	☐	☐	55	**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 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."	Click or tap here to enter text.
☐	☐	☐	56	**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.
☐	☐	☐	57	**Do pharmacists that engage in activities under a 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.	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					(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. **(4)** Any modification of the written guideline or protocol shall be treated as a new CDTA."	
☐	☐	☐	58	**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.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	59	**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.
☐	☐	☐	60	**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.
☐	☐	☐	61	**Does the pharmacy possess, distribute, or dispense legend drug samples?**	**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 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.
☐	☐	☐	62	**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,	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					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. **(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."	
☐	☐	☐	63	**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	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					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."	
☐	☐	☐	64	**Are components for compounding that do not have an expiration date from the manufacturer or supplier labeled with:** **The date of receipt** **Assigned a conservative expiration date, that does not exceed 3 years after the receipt** **This date should take into consideration the nature of the component, its degradation mechanism, the packaging/container, and storage conditions.**	**RCW 18.64.270(2)** "Any medicinal products that are compounded for patient administration or distribution to a licensed practitioner for patient use or administration shall, at a minimum, meet the standards of the official United States pharmacopeia as it applies to nonsterile products and sterile administered products." USP 795 Component Selection, Handling, and Storage "For components that do not have expiration dates assigned by the manufacturer or supplier, the compounder shall label the container with the date of receipt and assign a conservative expiration date, not to exceed three years after receipt, to the component based on the nature of the component and its degradation mechanism, the container in which it is packaged, and the storage conditions."	Click or tap here to enter text.
☐	☐	☐	65	**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.	Click or tap here to enter text.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
					(3) A prescription for a noncontrolled legend drug may be refilled as indicated by the prescriber in accordance with 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	**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	**Does the pharmacy store, dispense, or deliver drugs to patients without a pharmacist on site?** ****If you answered "No" to question 67, mark questions 68-74 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	**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.

Compliant			#		Rule Reference	Notes/Corrective Action
Yes	No	N/A				
☐	☐	☐	69	**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.
☐	☐	☐	70	**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	**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	**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	**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	**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.

Commission SBAR Communication

Agenda Item/Title: 4.2 Self-Inspection Worksheet and Updates Regarding new Compounding Law - ACTION

Date SBAR Communication Prepared: 5/27/2021

Reviewer: Lauren Lyles-Stoltz – Executive Director

Link to Action Plan:

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

Situation:

Substitute House Bill (SHB) 1445 passed the legislature this session which changed the definition of compounding to exclude reconstitution. SHB 1445 becomes effective July 25, 2021. Specific exclusions were made for both sterile and nonsterile reconstituted drug products.

Background:

Changes to the General Self-Inspection Worksheet, Hospital Pharmacy and HPAC Self-Inspection Worksheet, and future the Health Care Entity Self-Inspection Worksheet are required to capture these revisions.

Assessment:

There are two areas on the Worksheets which require changes.

The first area which requires change is on Page 2 of the General Self-Inspection Form and the Hospital Pharmacy and HPAC Self-Inspection Form. These worksheets contain a yellow instructional banner defining compounding:

> "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*." This includes what is traditionally considered reconstitution. If a pharmacy reconstitutes medications or adds flavoring, it is considered compounding and the sterile and/or non-sterile compounding self-inspection worksheets must also be completed."

Suggested changes to this language are to strike the second sentence "This includes what is traditionally considered reconstitution" in its entirety. Strike the phrases "reconstitutes medications or" and "sterile and/or" from the third sentence and adding the phrase "to a commercially available product" after the word "flavoring" in the third sentence. 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.

> "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*." ~~This includes what is traditionally considered reconstitution~~. If a pharmacy ~~reconstitutes medications or~~ adds flavoring to a commercially available product, it is considered compounding and the ~~sterile and/or~~ non-sterile compounding self-inspection worksheet must also be completed."

This leaves the final language:

> "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*. If a pharmacy adds flavoring to a commercially available product, it is considered compounding and the non-sterile compounding self-inspection worksheet must also be completed."

The Commission may also wish to consider revising or removing this language as well:

> "(NEW) 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."

Additional language may be considered for addition to the above (NEW) statement to read:

> "The General Self-Inspection Worksheets must still be completed." OR
> "The Hospital and HPAC Self-Inspection Worksheets must still be completed." as applicable.

Further, we recommend adding an additional section immediately following the above proposed language in the yellow banner to provide further clarification to licensees that specifically calls out the revision to the definition of compounding. This language may be omitted from future versions of the Self-Inspection Worksheets once the licensees are aware of the legislative change in the definition.

> "Reconstitution and mixing of 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.
> Reconstitution and mixing of nonsterile products according to federal food and drug administration-approved labeling does not constitute compounding if prepared pursuant to a prescription."

The second area which requires revision is also on Page 2 of the General Self-Inspection Worksheet and the Hospital Pharmacy and HPAC Self-Inspection Worksheet. The General Pharmacy and Hospital/HPAC Self-Inspection Worksheets contain the following question:

> "Does your pharmacy engage in non-sterile compounding or reconstitution of medications?"

Suggested change to this language includes striking the phrase "or reconstitution" from this question to read:

> "Does your pharmacy engage in non-sterile compounding of medications?"

Recommendation:

Motions: This will require a motion from the commission to approve the following:

1. The revised General, Hospital and HPAC Self-Inspection worksheets with the suggested edits as deemed necessary; and

2. Enforcement discretion to waive the requirements to complete sterile and non-sterile self-inspection addendums if only engaging in reconstitution until August 1, 2021. After then the law will be in effect and the enforcement discretion will no longer be needed. SHB 1445 becomes effective July 25, 2021,

staff is suggesting August 1, 2021 to make it easier for licensees to remember the effective date, but this is a soft suggestion. This will address the commenter's consideration during the last commission meeting, which was a request to waive addendum requirements for pharmacies engaging in reconstitution, which will help alleviate some pressures on pharmacy staff and honor the new statute.

Follow-up Action:

The PQAC team will proceed as directed.

Commission SBAR Communication

Agenda Item/Title: OTC Wholesalers Without a Home State License: OTC Wholesaler Licensure and Inspection Requirement In-State vs Out-of-State

Date SBAR Communication Prepared: May 12th, 2021

Reviewer: Lauren Lyles-Stolz, PharmD, Executive Director

Link to Action Plan:

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

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

Wholesalers located outside of Washington State that exclusively distribute over-the-counter (OTC) drugs are often not required to hold a wholesaler license and have therefore not received an inspection from the resident state board of pharmacy. WAC 246-945-246(3) requires that a wholesaler applicant located outside of Washington State provide a copy of the resident state license and a copy of a site inspection conducted by the resident regulatory authority or a third-party inspection program recognized by the Pharmacy Quality Assurance Commission (commission). The commission can consider if any adjustments are needed to WAC 246-945-246(3) to accommodate OTC-only wholesalers.

Background: (Briefly state the pertinent history):

While the old rule (WAC 246-879-070) required OTC-only wholesalers to be licensed as a wholesaler, the rule did not require proof of licensure or a copy of an inspection from the resident state for out-of-state applicants. In the new chapter, WAC 246-945-246 (1)(b) requires "In-state and out-of-state pharmaceutical wholesalers" to be licensed by the commission as a wholesaler. This provision applies to wholesalers distributing prescription and OTC drugs. WAC 246-945-246(3) contains additional requirements for wholesaler applicants located outside of Washington State. Specifically, WAC 246-945-246(3) requires that the out-of-state applicant provide:

> (a) A copy of a site inspection conducted by the regulatory authority in the resident U.S. jurisdiction or third-party inspection program recognized by the commission within the last two years and every two years with the distributor's renewal;
> (b) A copy of the resident state license; and
> (c) A list of licenses, registrations, permits or certificates held in other U.S. jurisdictions.

The 2021 NABP Survey of Law indicates that out of the 50 states, 15 require wholesaler distributors of nonprescription drugs to be licensed. Staff have also received feedback from an applicant that their resident state which does not license nonprescription drug

wholesalers does not offer inspections for OTC-only distributors. PQAC inspectors currently inspect all wholesalers in Washington State, including OTC-only distributors.

There are two third-party inspection programs recognized by the commission: NABP Drug Distributor Accreditation (DDA) (formerly VAWD) and, more recently, National Coalition for Drug Quality & Security (NCDQS). NABP DDA does not offer inspections for OTC-only distributors at this time. The program is primarily focused on prescription drugs and devices; however, if issues are observed during their onsite survey that involve OTC drugs, NABP will collect the information and determine if a violation of state or federal law is occurring in that facility. NCDQS also does not currently inspect OTC-only distributors but have indicated to staff that they would be able to.

Finally, at the April 23rd business meeting, the commission voted to accept a proof of license or evidence that the resident state does not require a license or inspections as well as temporarily defer inspections of OTC wholesalers until a method of inspection is established for both in and out of state OTC wholesalers. The commission can now revisit this topic and determine what, if any, adjustments are needed to accommodate OTC-only distributors.

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

The current rule [specifically WAC 246-945-246(3)(a) and (b)] pose a challenge to out-of-state OTC-only distributors whose resident state does not require licensure or offer inspections.

Since the commission recently recognized NCDQS as a third-party inspection program for wholesalers, commission staff can refer out-of-state OTC-only wholesalers to their services in order to meet the requirements in WAC 246-945-246(3)(a). However, if the resident state does not require OTC-only wholesalers to be licensed they are not able to comply with WAC 246-945-246(3)(b). Additional guidance or rulemaking is needed to accommodate these wholesaler applicants.

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

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

can also submit a formal ask to NABP to consider incorporating future OTC wholesaler inspections in their inspection portfolio.

OPTION 2: Continue current decision of deferring inspection of in-state and out-of-state OTC wholesalers AND accept approval or evidence of a state board that does not require a license or inspections.

OPTION 3: Other actions as determined by the commission.

Commission staff will communicate the commission's decision to licensees, credentialing, and other relevant stakeholder and initiate drafting guidance or rulemaking as applicable.

16. Wholesale Prescription Drug Distributor Licensure Requirements (cont.)

State	Does State Require Wholesale Distributors of Nonprescription Drugs to Be Licensed?	Are Criminal History Record Checks Required for Wholesale Distributors?	Does State Recognize NABP Drug Distributor Accreditation?
Alabama	Yes J	No	Yes
Alaska	No	Yes V	No
Arizona	Yes	No	No
Arkansas	No	No	No
California	No	Yes X	No
Colorado	No	Yes III	Yes
Connecticut	Yes	No	O
Delaware	Yes	Yes	Yes
District of Columbia	Yes	No	No
Florida	No	G	No
Georgia	No	R	No
Guam	—	—	—
Hawaii	No	No	No
Idaho	No Z	Yes III	Yes
Illinois	No	Yes P	No
Indiana	No	Yes	Yes
Iowa	No	Yes V	Yes JJJ
Kansas	Yes	Yes MMM	Yes
Kentucky	No	No	Yes
Louisiana	Yes	OO	No
Maine	No	No GGG	FFF
Maryland	No	Yes III	Yes UU
Massachusetts	No	No	No †
Michigan	No	Yes E	No
Minnesota	Yes	No	Yes II
Mississippi	No	Yes	No
Missouri	No	Yes	No
Montana	No	Yes ZZ	Yes
Nebraska	No	Yes III	Yes
Nevada	No	No GGG	Yes
New Hampshire	No	No	Yes
New Jersey	Yes	No	N
New Mexico	No	Yes	No
New York	No	FF	No
North Carolina	No	Yes	No
North Dakota	No	Yes	Yes YY
Ohio	No	Yes HHH	Yes MM
Oklahoma	No	No	Yes
Oregon	Yes	No CCC	Yes
Pennsylvania	Yes	Yes	No
Puerto Rico	Yes	—	O
Rhode Island	Yes	Yes	Yes MM
South Carolina	No	No	Yes
South Dakota	No	No	Yes
Tennessee	No	Yes	No
Texas	Yes PP	Yes G	No
Utah	No	Yes	Yes N
Vermont	No	No	Yes
Virginia	No	Yes	Yes N
Washington	Yes K	Yes AAA	Yes OOO †
West Virginia	No	No	No
Wisconsin	No	No	No
Wyoming	No	Yes	Yes

Colored text denotes change from 2020 edition.

† Other comments noted in 2020 edition no longer apply.

— Indicates information is not available.

16. Wholesale Prescription Drug Distributor Licensure Requirements (cont.)

Legend

A — Full-service drug wholesaler licensure fees. Nonprescription drug wholesaler licensure fee: $500; renewal fee: $500 (biennial).

B — VAWD (now known as Drug Distributor Accreditation) required for original licensure issuance and renewal.

C — Plus controlled substance registration fee. (AL – $100/yr. CT – $185/yr. Each additional location is $150. ID – $150/yr for registration. MA – $225/yr. NM – $60/yr. NY – $1,200/2 yrs. OH – $100/2 yrs. OR – $100/yr. RI – $100. TN – $40/2 yrs. UT – $100/yr ($78 renewal). VA – $90/yr. For resident wholesale distributors only. WA – $150/yr ($150 renewal). WY – $250/yr.)

D — Varies. Set by Division of Professional Regulation biannually.

E — Unless the facility is organized as an LLC.

F — All drug and medical gas wholesalers $5,260.

G — Wholesalers and distributors are regulated by another state agency. (FL – Florida Department of Business & Professional Regulation, per Chapter 499, Florida Statutes. TX – Department of State Health Services.)

H — Licensed by Department of Health Services.

I — In-state wholesale distributors vary depending on GAV. GAV less than $200,000 – fee is $1,080. GAV $200,000 to less than $20 million – fee is $1,755. GAV $20 million and over – fee is $2,295. Separate fee from Texas Department of Public Safety for controlled substances. Out-of-state – GAV less than $20 million – fee is $1,300. GAV greater than $20 million – fee is $1,950.

J — Precursor.

K — $465 fee for original license and renewal.

L — The fee is $200 annually for in-state drug wholesalers and $100 annually for out-of-state wholesale distributors. There is an additional annual fee of $130 for controlled substances, where applicable.

M — However, per Board's informal interpretation, if the out-of-state wholesaler has a vendor-managed inventory system within the state, a wholesale distributor license is required.

N — Supported but not required by current regulations.

O — Not addressed in Pharmacy Act or Board regulations.

P — IL 225 ILCS 120/25 (c)(4).

Q — $410 – even years; $239 – odd years.

R — Board has the authority to require.

S — Board of Drug and Device Distributors.

T — Bureau of Drugs, Devices, and Cosmetics.

U — Department of Consumer Protection.

V — For facility manager.

W — Division of Occupational and Professional Licensing.

X — Depending on business structure, officers, owners, and members are required to submit fingerprints for criminal background clearance (CA and FBI).

Y — In-state facilities only and approved subject to satisfactory inspection by the Department of Health, Food and Drug Branch.

Z — Registered, not licensed. (ID – a wholesaler that engages in wholesale distribution of DME supplies, prescription medical devices, or products that contain pseudoephedrine in or into Idaho must be registered by the Board.)

AA — Department of Financial and Professional Regulation.

BB — Department of Health and Human Services, Division of Public Health, Licensure Unit.

CC — Department of Health and Senior Services.

DD — Controlled substance registration required for distributing controlled substances $365.

EE — Regulations pending.

FF — Under consideration.

GG — Yes if located in-state; no if located out-of-state.

HH — Licensed by Health Regulation and Licensing Administration, Pharmaceutical Control Division.

II — To obtain a license, must either pass an inspection conducted by authorized representative of the board or accredited by a board-approved accreditation program. VAWD (now known as Drug Distributor Accreditation) is approved by the board.

JJ — Includes $6 CURES fee.

KK — Plus one-time application fee of $50.

LL — Regulations pending to revise single wholesale license to separate licenses for wholesalers, third-party logistics providers, manufacturers, and repackagers per the Drug Supply Chain Security Act.

MM — VAWD (now known as Drug Distributor Accreditation) is required for out-of-state third-party logistics providers and virtual wholesalers if the entity is not licensed as

16. Wholesale Prescription Drug Distributor Licensure Requirements (cont.)

Legend cont.

a third-party logistics provider or virtual wholesaler in that state.

NN — Submit security deposit of $100,000.

OO — Distributors in Louisiana are regulated by another board, not the Board of Pharmacy.

PP — Licensed by the Department of State Health Services.

QQ — One location $200; two or more locations $500.

RR — Currently being reviewed.

SS — For in-state third-party logistics providers only.

TT — Does not include fingerprinting fee that is required if not licensed health professional or if health professional licensed prior to 2008.

UU — VAWD (now known as Drug Distributor Accreditation) or location in a state with laws substantially equivalent to Maryland, required for out-of-state wholesale distributors.

VV — Maine Revised Statute Title 32 §13758(2).

WW — Fees change annually. Contact the Board.

XX — License required. At this time, the Board is revising the law because of the federal changes related to third-party logistics providers.

YY — VAWD (now known as Drug Distributor Accreditation) is required.

ZZ — However, the entity must attest to being in good standing and submit a National Practitioner Data Bank self-query with the application. Renewal applications request attestation of disciplinary action and submission of related documentation with positive responses. See MT Reg 24.174.1202.

AAA — Criminal background questions regarding drug or controlled substance violations, moral turpitude, and professional license discipline are asked of each applicant for its partners, owners, and board of directors. If an answer is yes, an explanation must accompany the application.

BBB — Application fees are reevaluated in June of even-numbered years.

CCC — However, per OAR 855-065-0006(3), the Board may require them. The Board does not require at this time though.

DDD — Department of Health

EEE — Expires September 30.

FFF — Voluntary.

GGG — However, application includes criminal history questions and requires supporting documentation to be submitted.

HHH — ORC 4729.53(A)(1).

III — For designated representative. (MD – and supervising designated representative. NE – and designated representative supervisor and any owner with greater than 10% ownership.)

JJJ — VAWD (now known as Drug Distributor Accreditation) required for initial licensure/ renewal of nonresident wholesale distributor and required for renewal of in-state wholesale distributor.

KKK — 3PL providers are registered by the Board because they meet the definition of a drug outlet. There is no separate 3PL law, however.

LLL — Per RSA 318:51-a – Expire biennially on June 30 of even-numbered years.

MMM — Application and renewal require facility to conduct background check and fingerprinting of each facility manager and designated representative and put protections in place to ensure that no owner, designated representative, facility manager, or employee has been convicted of any felony related to prescription-only drugs or devices, any felony violation of 21 U.S.C. 331, or any felony violation of 18 U.S.C. 1365 related to product tampering.

NNN — Third-party logistics providers are considered warehouses of prescription drugs and, therefore, required to be licensed as wholesalers under North Carolina law.

OOO — VAWD (now known as Drug Distributor Accreditation) is supported but not required. All out-of-state wholesalers must provide a copy of an inspection by the resident state regulatory authority or third-party inspection program recognized by the Commission – NABP Drug Distributor Accreditation.

NABP*LAW* Online Search Terms

Wholesale Prescription Drug Distributor Licensure Requirements

(type as indicated below)

- third-party logistics provider
- wholesale accreditation VAWD (now known as Drug Distributor Accreditation)
- wholesale criminal history
- wholesale distributor fees
- wholesale license requirements
- wholesale "out-of-state" (or nonresident)
- wholesale renewal

17. Device Wholesale Distributor Licensure Requirements

State	Does State License Device Manufacturers? If Yes, Which Agency?	Does State License Dispensers of Prescription Medical Devices That Are Not Pharmacies? If Yes, Which Agency?
Alabama	Yes Board of Pharmacy QQ	Yes Board of Pharmacy
Alaska	No	No
Arizona	Yes Board of Pharmacy	Yes Board of Pharmacy
Arkansas	Yes Board of Pharmacy GG	Yes Board of Pharmacy GG
California	Yes N	Yes N
Colorado	No	Yes Secretary of State
Connecticut	—	—
Delaware	Yes I	No
District of Columbia	Yes Dept of Health	Yes Dept of Health – Medical Device Program
Florida	Yes OO	Yes OO
Georgia	Yes Board of Pharmacy KK	Yes Board of Pharmacy
Guam	No	No
Hawaii	No	P
Idaho	No E	Yes Board of Pharmacy
Illinois	No	No
Indiana	No	Yes Board of Pharmacy Y
Iowa	Yes Board of Pharmacy GG	Yes Board of Pharmacy VV
Kansas	No	Yes Board of Pharmacy
Kentucky	No	No
Louisiana	Yes LA Dept of Health Z	No
Maine	No	No
Maryland	No	Yes Board of Pharmacy
Massachusetts	Yes MA Drug Control Program III	No
Michigan	Yes TT	No
Minnesota	No	No
Mississippi	No	Yes Board of Pharmacy XX
Missouri	Yes Board of Pharmacy	No
Montana	Yes SS	Yes
Nebraska	—	—
Nevada	None have applied,	Yes Board of Pharmacy
New Hampshire	Yes Board of Pharmacy I	Yes Board of Pharmacy
New Jersey	—	Yes PP
New Mexico	Yes PP	No
New York	No	No
North Carolina	KK	Yes Board of Pharmacy
North Dakota	No	Yes Board of Pharmacy
Ohio	Yes Board of Pharmacy	Yes FF
Oklahoma	Yes J	No K
Oregon	No	Yes Board of Pharmacy LL
Pennsylvania	Yes Board of Pharmacy	Yes MM
Puerto Rico	Yes MM	—
Rhode Island	—	No
South Carolina	No	Yes Board of Pharmacy
South Dakota	Yes Board of Pharmacy	No
Tennessee	No	Yes Board of Pharmacy
Texas	Yes Board of Pharmacy	No
Utah	Yes O	Yes VV
Vermont	Yes VV	No Board of Pharmacy K
Virginia	—	Yes Board of Pharmacy V
Washington	No	No
West Virginia	No	No
Wisconsin	No	No
Wyoming	No	No

Colored text denotes change from 2020 edition.
— Indicates information is not available.

Commission SBAR Communication

Agenda Item/Title: **Commission Delegation Form(s) Renewal**

Date SBAR Communication Prepared: 5/12/2021

Reviewer: **Joanne Miller**

Link to Action Plan:

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

Situation: (Briefly describe the current situation. Give a clear, succinct overview of pertinent issues) Delegation forms are reviewed and renewed biennially or when there is a change in program or commission leadership, or by request.

Background: (Briefly state the pertinent history):

- **Delegation of Signature Authority –**Delegation of Signature Authority (Credentialing, Disciplinary Functions, Compliance, and Rules) this *does not delegate the commission's decision authority is simply allows the designated person to sign on behalf of the Commission*.

- **Delegation of Decision Making** – acting within the authorization of the Commission and under the authority of RCW 18.130.050(8) **option general or case specific.** *The Commission can delegate general authority or case specific. The form further limits the delegation by the areas selected by the Commission.*

- **Delegate Appointment of a Brief Adjudicative Proceeding (BAP) Officer –**

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

Copies of former delegation forms are provided for reference.

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

Follow-up Action: Notify of Pharmacy Commission's decision.

Washington State Department of Health

Form 1-1-19A: Delegation of Signature Authority (Credentialing, Disciplinary Functions, and Rules) (For Board/Commission Authority Professions)

On June 4, 2021, the Pharmacy Quality Assurance Commission delegated signature authority for each of the documents indicated as follows:

☑ Credentialing

	Document	DOH Staff Title(s)
☑	Approval of Routine Credentialing Applications	OCS Credentialing Lead Worker
		OCS Credentialing Supervisor
		OCS Credentialing Manager
☑	Notice of Decision – Denial of Credential	OCS Credentialing Manager
		OILS Case Management Administrator
		OILS Case Manager
☑	Notice of Determination	OCS Credentialing Manager
		OILS Case Management Administrator
		OILS Case Manager
☑	Notice of Required Mental, Physical, or Psychological Evaluation	OCHS Manager/OHP Executive Director
		OILS Case Manager
		OILS Case Management Administrator

☑ Disciplinary

	Document	DOH Staff Title(s)
☑	Citation and Notice (for failure to produce records, documents or other items)	OILS Case Manager
		OILS Case Management Administrator
		OILS Health Care Investigator
☑	Declaration for Failure to Answer or Appear	OILS Case Manager
		OILS Case Management Administrator
		OCHS Manager/OHP Executive Director
☑	Notice of Correction	OCHS Manager/OHP Executive Director
		OILS Case Manager
		OILS Case Management Administrator
☑	Notice of Intent	OCHS Manager/OHP Executive Director
		OILS Case Manager
		OILS Case Management Administrator
☑	Notice of Decision	OCHS Manager/OHP Executive Director
		OILS Case Management Administrator
		OILS Case Manager
☑	Notice of Determination	OCHS Manager/OHP Executive Director

☑	Statement of Allegations	OCHS Manager/OHP Executive Director
		OILS Case Manager
		OILS Case Management Administrator
☑	Statement of Charges	OCHS Manager/OHP Executive Director
		OILS Case Manager
		OILS Case Management Administrator
☑	Subpoenas	OILS Director
		OILS Deputy Director
		OCHS Manager/OHP Executive Dir
		OILS Chief Investigator
		OILS Director
		OILS Deputy Director
		OILS Supervising Staff Attorney
☑	Statement of Allegations	OILS Case Manager
		OILS Case Management Administrator
☑	Notice of Opportunity for Prompt Hearing, Regularly Scheduled Hearing or Settlement	OCHS Manager/OHP Executive Director
		OILS Case Manager
		OILS Case Management Administrator
☑	Notice of Opportunity for Settlement and Hearing	OCHS Manager/OHP Executive Director
		OILS Case Manager
		OILS Case Management Administrator
☑	Withdrawal of: Statement of Charges, Statement of Allegations or Notice of Correction	OCHS Manager/OHP Executive Director
		OILS Case Manager
		OILS Case Management Administrator
☑	Notice of Required Mental, Physical, or Psychological Evaluation	OCHS Manager/OHP Executive Director
		OILS Case Manager
		OILS Case Management Administrator

☑ **Rules**

	Document	**DOH Staff Title(s)**
☑	CR-101	OHP Executive Director
☑	CR-102	OHP Executive Director

☑ **Compliance**

	Document	**DOH Staff Title(s)**
☑	Release from Stipulation to Informal Disposition (STID)	OCHS Manager/OHP Executive Director
		OILS Compliance Manager

This delegation shall remain in effect until revoked, terminated, or modified during the effective period. This delegation shall be reviewed and updated biennially.

Dated this 4th day of June, 20201.

Tim Lynch, Pharm.D, MSM, FABC, FASHP, Chairperson

(Signature of the Chair)

Lauren Lyles-Stolz, Pharm.D, Executive Director

(Executive Director's Signature)

- For the purposes of this document, signature authority means authorization to sign associated documents after the Commission makes a decision.

Washington State Department of Health

Form 1-1-19C: Delegation of Decision- Making

I, Tim Lynch, PharmD, MSM, FABC, FASHP, Chair of the Washington State Pharmacy Quality Assurance Commission

(the board or commission), acting upon authorization of the board or commission and under the authority of RCW 18.130.050(10), delegates each of the functions indicated below:

☑ **Legal Services: (Boards and Commission only)**
Brief Adjudicative Proceedings (Initial Orders) - Delegated to Sara Kirschenman, Supervising Staff Attorney, and Marc Defreyn, Office Director, as described in the Designation of Presiding Officer for Brief Adjudicative Proceeding delegation dated June 19, 2020.

☐ **Legal Services: (Secretary Professions)**
Brief Adjudicative Proceedings (Initial Orders) – Office of Investigative and Legal Services Office Director and Deputy Director

☑ **Review Officer:**
Brief Adjudicative Proceedings (Review of Initial Orders) – Delegated to Mike Ellsworth, Review Officer in the Office of the Secretary.

Adjudicative Services (Delegated to presiding officer serving in the Adjudicative Service Unit) – RCW 18.130.050(10)

☐ To serve as the decision-maker in response to an ex parte motion for summary suspension of a license in which the respondent is alleged to have violated RCW 18.130.400.

☐ To serve as the decision-maker in response to an ex parte motion for summary suspension of a license in which the respondent is alleged to have violated RCW 18.130.370.

☐ To serve as the decision-maker in response to a motion for an investigative mental health or physical health examination under RCW 18.130.170(2)(b).

☑ To serve as the final decision-maker in adjudicative proceedings in which a respondent is in default for failure to submit a request for adjudicative proceeding. This delegation does not include cases pertaining to standards of practice or where clinical expertise is necessary.

☐ To serve as the final decision-maker in adjudicative proceedings in which the respondent is alleged to have violated RCW 18.130.180(5).

☑ To serve as the final decision-maker in adjudicative proceedings where the board or commission has brought a motion for noncompliance.

☐ To serve as the final decision-maker in adjudicative proceedings in which the respondent is charged with violation of RCW 18.130.180(9).

☐ To serve as the final decision-maker in adjudicative proceedings in which the respondent is alleged to have violated RCW 18.130.180(17).

☐ Notwithstanding RCW 18.130.062 to serve as the final decision-maker in adjudicative proceedings in which the respondent is alleged to have violated RCW 18.130.180(24).

☐ To serve as the final decision-maker in adjudicative proceedings in which the respondent is alleged to have violated RCW 18.130.180(23).

☐ To serve as the final decision-maker in adjudicative proceedings in which the respondent is alleged to have violated RCW 18.130.180(6).

☐ To serve as the final decision-maker in adjudicative proceedings in which the respondent is alleged to have violated RCW 18.130.170.

☐ To approve or deny proposed settlements in all cases other than those that pertain to standards of practice or where clinical expertise is necessary, that are filed nine (9) calendar days before the scheduled hearing.

☐ To serve as the final decision-maker in proceedings related to reinstatement of a license previously suspended, revoked, or restricted by the board or commission.

☐ To serve as the final decision-maker in proceedings related to modification of any disciplinary order previously issued by the board or commission.

This delegation remains in effect until revoked, terminated or modified. To the extent that this delegation conflicts with prior delegations to presiding officers at the Adjudicative Service Unit, this delegation prevails.

DATED this 4 day of December, December, 2020.

(Signature) _____

(Name) Tim Lynch, PharmD, MSM, FABC, FASHP
Chairperson

(Board/Commission) Pharmacy Quality Assurance Commission

FROM THE WASHINGTON STATE

PHARMACY QUALITY ASSURANCE COMMISSION

DESIGNATION OF PRESIDING OFFICER FOR BRIEF ADJUDICATIVE PROCEEDING

We, a quorum of the Pharmacy Quality Assurance Commission, do hereby delegate to Marc Defreyn, Office Director, Office of Investigative and Legal Services and Sara Kirschenman, Supervising Staff Attorney, Office of Investigative and Legal Services, under Chap. 34.05 RCW, RCW 18.64.005(4) and WAC 246-11-430(1) to serve as a presiding officer to perform the duties necessary to conduct Brief Adjudicative Proceedings on behalf of the Pharmacy Quality Assurance Commission.

This delegation shall remain in effect as long as Mr. Defreyn and Ms. Kirschenman serve in their current capacities or until earlier revoked or withdrawn by the undersigned or my designee.

Dated this _____ day of _____, 2021.

_____

NAME, TITLE (E.g., Chair, Vice Chair, Member, etc.)
Washington State Pharmacy Quality Assurance Commission

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: March 05, 2021
TIME: 9:44 AM

WSR 21-07-016

RULE-MAKING ORDER
EMERGENCY RULE ONLY

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

Agency: Department of Health- Pharmacy Quality Assurance Commission

Effective date of rule:

Emergency Rules

☒ Immediately upon filing.

☐ Later (specify)

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

☐ Yes ☒ No If Yes, explain:

Purpose: WAC 246-945-010 Prescription labeling, records, and advertising - Minimum requirements. The Pharmacy Quality Assurance Commission (commission) is adopting emergency rules to reduce burdens on practitioners prescribing Schedule II substances during the coronavirus disease (COVID-19) outbreak. This emergency rule was originally filed on April 21, 2020 under WSR 20-09-133. It was re-filed most recently on November 5, 2020 under WSR 20-23-012. This emergency rule will continue the existing emergency rule amending WAC 246-945-010 to increase the duration of time a practitioner has to deliver a signed prescription of a Schedule II substance to the pharmacy from seven days to fifteen days when a prescription is dispensed in an emergency. It also defines what a "signed prescription" means and allows for a practitioner to accomplish this requirement through paper, electronic transmission, facsimile, photograph, or scanned copy. These alternative methodologies support patients, practitioners, and pharmacists' efforts to practice social distancing and to help mitigate communal spread.

Citation of rules affected by this order:

New: N/A
Repealed: N/A
Amended: WAC 246-945-010
Suspended: N/A

Statutory authority for adoption: RCW 18.64.005; chapter 69.50 RCW

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 amendment of this existing rule is necessary for the preservation of public health, safety, and general welfare. Stakeholders and leaders from the pain community have highlighted this is an immediate need for Washingtonians. This emergency rule has been in effect since April 21, 2020. This emergency rule allows more time and more avenues for complying with the requirements during the ongoing COVID-19 pandemic, reducing burdens on practitioners and pharmacists, and sustaining patient access during this difficult time. The emergency rules follow guidance from the US drug enforcement agency and will help address this problem and reduce barriers for providers and patient populations in need of Schedule II prescriptions throughout this public health emergency. Observing the time requirements of notice and opportunity to comment upon adoption of a permanent rule would be contrary to public interest.

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

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

The number of sections adopted in order to comply with:

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

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

	New	0	Amended	0	Repealed	0

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

	New	0	Amended	1	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	0	Amended	1	Repealed	0

Date Adopted: 03/05/2021	**Signature:** 
Name: Tim Lynch, PharmD, MS, FABC, FASHP	
Title: Pharmacy Quality Assurance Commission Chair	

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

WAC 246-945-010 Prescription and chart order—Minimum requirements. (1) For the purposes of this section, prescription does not include chart orders as defined in RCW 18.64.011(3).

(2) For the purposes of WAC 246-945-010 through 246-945-013, prescription includes written and electronic prescriptions.

(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;

(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 C.F.R., Chapter II.

(5) A chart order must meet the requirements of RCW 18.64.550 and any other applicable requirements listed in 21 C.F.R., Chapter II.

(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~~)) fifteen days after authorizing an emergency oral prescription or if delivered by mail it must be postmarked within the ((~~seven~~)) fifteen day period, and further the pharmacist must note on the prescription that it was filled on an emergency basis.

(c) For the purposes of this subsection, a "signed prescription" shall be either:

(i) A paper prescription;

(ii) An electronic prescription;

(iii) A copy of the paper prescription sent via facsimile to the pharmacy; or

(iv) A photograph or scanned copy of the paper prescription sent to the pharmacy.

(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.

(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.

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: March 05, 2021
TIME: 9:37 AM

WSR 21-07-015

Agency: Department of Health- Pharmacy Quality Assurance Commission

Effective date of rule:

Emergency Rules

☒ Immediately upon filing.
☐ Later (specify)

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

☐ Yes ☒ No If Yes, explain:

Purpose: WAC 246-945-056 Schedule V. The Pharmacy Quality Assurance Commission (commission) is adopting emergency rules to remove Epidiolex from the list of Schedule V controlled substances in Washington state. This emergency rule was originally filed on May 20, 2020 under WSR 20-11-078. It was re-filed most recently on November 6, 2020 under WSR 20-23-013. Epidiolex is an FDA-approved cannabidiol with less than 0.3% tetrahydrocannabinal (THC). De-scheduling the drug from Schedule V will maintain the emergency rule. It also aligns Washington state rule with the federal decision to exclude all hemp products with less than 0.3% THC from the definition of marijuana.

Citation of rules affected by this order:

New: N/A
Repealed: N/A
Amended: WAC 246-945-056
Suspended: N/A

Statutory authority for adoption: RCW 18.64.005; RCW 69.50.201

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 amendment of this existing rule is necessary for the preservation of public health, safety, and general welfare. Epidiolex is an FDA-approved cannabidiol with less than 0.3% THC used to help treat some seizure disorders. The 2018 Agricultural Improvement Act amended the Controlled Substances Act and declassified hemp products with less than 0.3% THC from Schedule I; however, Epidiolex was placed on Schedule V until April 6, 2020 when the United States drug enforcement agency announced that it would be de-scheduled as a federally controlled substance. This emergency rule will maintain the emergency rule already in effect and update Washington rule to align with the federal decision. Emergency rules are necessary to reduce burdens on practitioners prescribing Epidiolex and allow patients easier access to the care they need. This rule may also help reduce pressure on the health system during the ongoing COVID-19 pandemic. Observing the time requirements of notice and opportunity to comment upon adoption of a permanent rule would be contrary to the public interest. The commission has initiated permanent rulemaking to de-schedule Epidiolex.

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

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

The number of sections adopted in order to comply with:

Federal statute:	New	0	Amended	0	Repealed	0
Federal rules or standards:	New	0	Amended	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	0	Amended	1	Repealed	0

Date Adopted: 03/05/2021	**Signature:** 
Name: Tim Lynch, PharmD, MS, FABC, FASHP	
Title: Pharmacy Quality Assurance Commission Chair	

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

WAC 246-945-056 Schedule V. The commission finds that the following substances have low potential for abuse relative to substances in Schedule IV under RCW 69.50.210 and WAC 246-945-055 and have currently accepted medical use in treatment in the United States and that the substances have limited physical dependence or psychological dependence liability relative to the substance in Schedule IV. In addition to the substances listed in RCW 69.50.212, the commission places each of the following drugs and substances by whatever official name, common or usual name, chemical name, or brand name in Schedule V.

Depressants. Unless specifically exempted or excluded or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts:

(1) Brivaracetam ((2S)-2-[(4R)-2-oxo-4-propylpyrrolidin-1-yl] butanamide); also referred to as BRV; UCB-34714; Briviact;

(2) Ezogabine [N-[2-amino-4-(4-fluorobenzylamino)-phenyl]-carbamic acid ethyl ester].

((~~(3) Approved cannabidiol drugs. A drug product in finished dosage formulation that has been approved by the U.S. Food and Drug Administration that contains cannabidiol (2-[1R-3-methyl-6R-(1-methylethenyl)-2-cyclohexen-1-yl]-5-pentyl-1,3-benzenediol) derived from cannabis and no more than 0.1 percent (w/w) residual tetrahydrocannabinols, also known as Epidiolex.~~))