

Pharmacy Inspection Committee

Stakeholder Meeting

November 7, 2016

Documents

1. Preliminary Pharmacy Inspection Draft Rule
2. Retail Rx Inspection Form – with detail
3. Retail Rx Inspection Form – Rule Statements
4. Retail Rx Inspection Form – with detail and rule statements

WAC 246-869-040

New pharmacy registration.

The ~~state board of pharmacy~~ commission shall issue no new pharmacy registrations, unless:
after December 1, 1976 unless:

- (1) ~~A pharmacy that dispenses or prepares medications will operate~~ The pharmacy will operate a bona fide prescription department, with such equipment, facilities, supplies and pharmaceuticals as are specified by ~~state board~~ commission regulations and appropriate with the scope of the services provided;
- (2) The pharmacy ~~passes~~ completes an inspection ~~with a minimum of an "A" grade without deficiencies noted; and~~
- (3) The pharmacy in a new or remodeled building can produce evidence of being built or remodeled in accordance with all building, health and fire codes required for the particular area.

WAC 246-869-190

Pharmacy inspections.

- (1) ~~(1)~~ All pharmacies shall be subject to periodic inspections to determine compliance with the laws regulating the practice of pharmacy. (Make sure this addresses the subject of what aspects are inspected, and notification of inspection.)
- (2) ~~Each inspected pharmacy shall receive a classification rating which will depend upon the extent of that pharmacy's compliance with the inspection standards.~~
- (3) ~~There shall be three rating classifications:~~
 - (a) ~~"Class A" for inspection scores of 90 to 100;~~
 - (b) ~~"Conditional" for inspection scores of 80 to 89; and,~~
 - (c) ~~"Unsatisfactory" for inspection scores below 80.~~
- (4) ~~Any pharmacy receiving a conditional rating shall have sixty days to raise its inspection score rating to 90 or better. If upon reinspection after sixty days, the pharmacy fails to receive a rating of 90 or better, then the pharmacy will be subject to disciplinary action.~~
- (5) ~~Any pharmacy receiving an unsatisfactory rating shall have fourteen days to raise its inspection score rating to 90 or better. If upon reinspection after fourteen days, the pharmacy fails to receive a rating of 90 or better, then the pharmacy will be subject to disciplinary action.~~

Comment [h1]: What is the level of expectation for inspection? What makes a pharmacy a pharmacy to make it inspected? Where medications are dispensed?

~~(6) The certificate of inspection must be posted in conspicuous view of the general public and shall not be removed or defaced.~~

~~(7) Noncompliance with the provisions of chapter 18.64A18.64A RCW (Pharmacy assistants) and, chapter 246-901246-901 WAC (Pharmacy assistants) resulting in a deduction of at least five points shall result in an automatic unsatisfactory rating regardless of the total point score.~~

~~(2) The ~~pharmacist in charge~~responsible manager (or designee) shall be responsible for conducting an ~~an annual~~ inspection of the pharmacy using the ~~PIC~~Responsible Manager ~~Annual~~Self-Inspection Form provided by the commission, ~~completed within the month of March by February 1~~ each year. The completed self-inspection forms must be signed and dated by the ~~PIC~~ responsible manager and maintained for ~~three~~two years from the date of completion; when a change in responsible manager occurs, the new responsible manager (or designee) shall complete an inspection on the Responsible Manager Annual Self-Inspection Form. ~~and~~ The self-inspection form must be signed and dated by the new ~~PIC~~responsible manager within ~~45~~ 30 calendar days of becoming responsible manager;~~

~~(3) All deficiencies shall be noted in writing on an inspection report and describe in detail the nature and facts of the violation of the deficiency, including a reference to the applicable statutes or regulations violated. A written notice of deficiency shall be provided to the pharmacy by the pharmacist investigator within 14 calendar days of the close of the inspection. At the conclusion of the inspection, deficiencies that are a significant threat to public health and safety will be shared with the ~~PIC~~responsible manager or designee. A "notice of deficiency" is an inspection report completed by a commission pharmacist investigator identifying one or more deficiencies.~~

~~(4) Deficiencies noted must be promptly remedied.~~

~~(a) Identified deficiencies that are not ~~major, broadly systemic, or of a recurring nature~~ a significant threat to public health or safety require the pharmacy to submit a plan of correction addressing each deficient practice identified to the Commission, within 30 calendar days of receipt of the notice of deficiencies. A "plan of correction" is a proposal devised by the applicant or licensee and approved by the ~~commission's~~ designee, within 30 calendar days, that includes specific corrective actions that must be taken to correct identified deficiencies and~~

a time frame in which to complete them. Implementation of corrective actions is required within the approved time frame, and is subject to verification by the commission's designee.

(b) Identified deficiencies that are ~~broadly systemic, recurring,~~ or of a significant threat to public health and safety require:

(i) The pharmacy to submit a plan of correction addressing each deficient practice identified on the inspection report to the commission's designee, within 14 calendar days of receipt of notice of deficiencies and approved by the commission's designee, within 14 calendar days;

(ii) If a submitted plan is deemed insufficient by the commission's designee. The commission's designee will ~~to~~ offer a directed plan of correction. A "directed plan of correction" is a plan of correction based on a notice of deficiencies, and includes specific corrective actions that must be taken and a time frame in which to complete them. The final content of a directed plan of correction will be reached during meetings between the commission, or its designee, and the licensee, following an initial statement of general requirements by the commission. Timelines will be reduced to the minimum necessary, even prior to formalization of the directed plan of correction, to redress problems.

(2)(5) The Commission must notify the pharmacy when a submitted plan of correction adequately addresses the inspection report findings, and may require the facility to submit a progress report(s) attesting to the correction of deficiencies.

(3)(6) Reinspection. If required, one follow-up inspection may be performed by the commission at no cost.

(8)(7) Pharmacies ~~receiving an unsatisfactory rating which~~ with deficiencies that represent a clear and present danger to the public health, safety and welfare will be subject to summary suspension of the pharmacy license.



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READ THIS PAGE CAREFULLY

(YEAR)

RETAIL PHARMACY
RESPONSIBLE MANAGER
PHARMACY SELF-INSPECTION REPORT

ATTENTION: RESPONSIBLE MANAGER

Washington law holds the responsible 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 report within the month of March or within 30 days of becoming responsible manager (as required by WAC 246-869-190) may result in disciplinary action.

Following your self-inspection and completion of the report, please review it with your staff pharmacists, ancillary staff and interns, correct any deficiencies noted, sign and date the report, and file it so it will be readily available to Commission investigators. DO NOT SEND to the Commission office. You are responsible for ensuring your completed report is available at the time of inspection.

The primary objective of this report, 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 report also serves as a necessary document used by Commission inspectors during an inspection to evaluate a pharmacy's level of compliance.

When a Commission investigator discovers an area of non-compliance, they will issue a **Notice of Deficiency**. The responsible manager must provide a written response addressing all areas of non-compliance. Identifying and correcting an area of non-compliance prior to a Commission inspection may eliminate the receipt of a Notice of Deficiency for that item. Do not *assume* that you are in compliance with any statement; take the time to personally verify that compliance exists. A situation of non-compliance that "is the way it has been" is the current responsible manager's responsibility to immediately correct to avoid the possibility of a Notice and/or disciplinary action. If you have any questions, please contact your investigator.

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

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.

(YEAR) RESPONSIBLE MANAGER
RETAIL PHARMACY SELF-INSPECTION REPORT
WA Pharmacy Quality Assurance Commission
TEL: (360) 236-4946 FAX: (360) 236-2260
EMAIL: WSPQAC@doh.wa.gov

All responsible managers of RETAIL pharmacies MUST complete and sign this self-inspection report within the month of March or within 30 days of becoming responsible manager and have it available for inspection (as required by WAC 246-869-190). **DO NOT SEND TO THE COMMISSION OFFICE.**

Form completed after 3/31/XXXX. **Change in responsible manager** **Other, please explain**

Date responsible manager Inspection was performed: ____/____/____

Signature of responsible manager: _____

Print Name & Lic. #: _____

Responsible Manager E-mail: _____

Pharmacy: _____ Telephone: _____ Fax: _____

Address: _____ DEA #: _____ Exp: ____ / ____ / ____

Pharmacy License #: _____

Inspector Signature: _____
Date: ____/____/____
Deficiency Notice: ____
Comments: _____

PHARMACY PERSONNEL—KEEP CURRENT THROUGHOUT THE YEAR AS NEEDED

Have each licensee review this inspection form, corresponding documents and procedures, and be prepared to assist in locating information during an inspection and sign below certifying their review. Attach additional pages if needed.

Please check the box next to the technicians name to indicate you have verified that you have documentation of each individual's technician training available for Commission inspection.

	NAME	FULL WASHINGTON LICENSE NUMBER	WASHINGTON LICENSE EXPIRATION DATE	LICENSEE'S SIGNATURE
	Ex.: Charles Roast	RPH-	6/30/2017	

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 rule references require the documentation printed below, by listing the location of these documents **you are also confirming your compliance with the referenced rule.**

	Rule Reference
Responsible manager Inspection Reports for Last 2 Years:	WAC 246-869-190
Current Biennial Controlled Substance Inventory:	WAC 246-887-020(3) 21 CFR 1304.04(h)(1)
Schedule II Invoices for the last 2 years:	WAC 246-887-020(3)(a)
Schedule III-V Invoices for the last 2 years:	WAC 246-887-020(3)(a)
Completed CII Order Forms (DEA Form 222) for the last 2 years:	WAC 246-887-020, 21 CFR 1305.13(e) 21 CFR 1305.22(g)
Completed loss by theft or destruction forms (DEA Form 106):	WAC 246-887-020(3)(c) 21 CFR 1301.76(b)
Power of Attorney for staff authorized to order controlled substances:	WAC 246-887-020 21 CFR 1305.05(a)
Ancillary Utilization Plan:	RCW 18.64A.060
Technician training documents, if applicable:	WAC 246-901-050
Collaborative Drug Therapy Agreement(s) (CDTA), if applicable:	WAC 246-863-100 RCW 18.64.011
Immunization CDTA, if applicable:	WAC 246-863-100 RCW 18.64.011
Prescription Records:	WAC 246-869-100

SELF-INSPECTION DIRECTIONS

Carefully confirm whether or not you are compliant and mark the appropriate box to the left of each item. If you find items that need correcting, rectify the deficiency and write the date of correction and then mark the 'yes' box. Do not mark 'yes' unless the answer is 'yes'. Note: the correct answer to some questions is 'no'.

General Requirements

Yes	No	N/A			Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>		1.	Are you a retail pharmacy? If not, please use the form appropriate for your practice setting. Note: Neither the self-inspection nor a Commission inspection evaluates your complete compliance with all laws and rules of the practice of pharmacy.	
<input type="checkbox"/>	<input type="checkbox"/>		2.	Is your current pharmacy license(s) posted?	RCW 18.64.043(3)
<input type="checkbox"/>	<input type="checkbox"/>		3.	Are your current pharmacist license(s) posted?	RCW 18.64.140
<input type="checkbox"/>	<input type="checkbox"/>		4.	Is your current inspection certificate posted?	WAC 246-869-190(6)
<input type="checkbox"/>	<input type="checkbox"/>		5.	Do you have DEA registration number, did you list it on page 2?	WAC 246-887-020(2)

Ancillary Personnel

Yes	No	N/A			Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	6.	Are your ancillary personnel certification(s) and registration(s) up to date?	WAC 246-901-060 WAC 246-901-080
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	7.	Do you have a pharmacy technician training program approved by the commission? <i>Please attach relevant documentation.</i>	WAC 246-901-030(1)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8.	Does your ancillary utilization plan limit pharmacy assistants tasks to those not reserved to a pharmacist or pharmacist technician?	WAC 246-901-070
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	9.	Does your ancillary utilization plan describe the functions a pharmacy technician can perform?	WAC 246-901-020(1) WAC 246-901-100(2)(a)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	10.	Are you within the required pharmacist to technician ratio (1:3)?	WAC 246-901-130(1)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	11.	Are all ancillary personnel wearing proper identification?	WAC 246-901-090

Patient Health and Safety Requirements

Yes	No	N/A			Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>		12.	Do you have a patient medical record system? Is it automated or manual? _____	WAC 246-875-001
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		If it is automated/digital do you have an auxiliary recordkeeping system in place for new or refill prescription tracking if your system is down?	WAC 246-875-050
<input type="checkbox"/>	<input type="checkbox"/>		13.	Do you patient records include all required information? - Patient full name and address - Serial number assigned to each new prescription - Date of all instances of dispensing a drug - The identification of the dispenser who filled the prescription	WAC 246-875-020 WAC 246-875-030 WAC 246-869-230

<input type="checkbox"/>	<input type="checkbox"/>		<ul style="list-style-type: none"> - Name, strength, dosage form, and quantity of drug dispensed - Prescriber's name address, and DEA number where required. <p>(Continued on next page) <u>Automated record systems must also include:</u></p> <ul style="list-style-type: none"> - Any refill instructions by the prescriber - Complete directions for use of the drug, which prohibits use of "as directed". - Authorization for other than child-resistant containers, if applicable. <p><i>Please select 10 patient profiles to confirm compliance, and document below.</i></p>	
<input type="checkbox"/>	<input type="checkbox"/>	14.	<p>Manual and Automated Systems must also include: <i>"Any patient allergies, idiosyncrasies, or chronic condition which may relate to drug utilization. If there are no patient allergy data the pharmacist should indicate none or "NKA" (no known allergy) on the patient medication record."</i></p> <p>Does your record system comply with this requirement?</p>	<p>WAC 246-875-020(1)(i) WAC 246-875-030(1)(g)</p>

Question 13 and 14 - Patient Medical Records - Compliance

	<u>Patient Name</u>	<u>Allergy</u>	<u>Conditions</u>
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			

Yes	No	N/A			Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	15.	Do your pharmacists perform drug utilization reviews for each new prescription? This includes review of patient record to determine the possibility of a clinically significant drug interaction, reaction, or therapeutic duplication.	WAC 246-875-040 WAC 246-863-095

				Please select 5 different patient profiles to confirm compliance and document on the next page.	
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**Question 15 – Drug Utilization Reviews – Include
(1) Drug-Drug; (2) Duplicate Prescription; (3) Drug-Allergy; & (4) DUR Chronic Conditions (x2)**

	<u>Patient Name</u>	<u>Allergy (Hard Copy v. Profile)</u>	<u>Conditions profile v. system</u>
1.			
2.			
3.			
4.			
5.			

Yes	No	N/A		Rule Reference	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	16.	Do your pharmacists perform patient counseling: - New prescriptions - Refill prescriptions	WAC 246-869-220 WAC 246-863-095
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		Do you have a system in place for ancillary staff to know when counseling should take place?	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	17.	Are all legend drugs dispensed in child-resistant containers? <i>(This includes special packaging used such as customized patient medication packages; blister packs, med-minders, etc.)</i> If not, do you have valid patient signed authorizations? _____ Where are these located? _____	WAC 246-869-230 WAC 246-869-255
				<i>Please select 5 different patients in the will call section packaged in non-child resistant containers and confirm you have valid authorization records, and document below:</i>	

Question 17 – Non-Child Resistant Container Authorizations

	<u>Patient Name</u>	<u>Authorization</u>	<u>Date</u>
1.			
2.			
3.			
4.			
5.			

<input type="checkbox"/>	<input type="checkbox"/>		18.	Do you have a sign posted in view of patients informing them of generic substitution requirements?	RCW 69.41.160 WAC 246-860-150
<input type="checkbox"/>	<input type="checkbox"/>		19.	Is the telephone number to the nearest poison	WAC 246-869-200

				control center readily available?	
<input type="checkbox"/>	<input type="checkbox"/>		20.	Is any of your stock expired? Do you have a process in place to check and properly dispose of expired medications? <i>(It's advised to perform an inventory check for expired medications while filling out this self-inspection report.)</i>	WAC 246-869-150
<input type="checkbox"/>	<input type="checkbox"/>		21.	Do you participate in a drug take back program? <i>Please review WAC 246-869-130 for the allowances of return and exchange of drugs, and the commission's guidance document located on their webpage.</i>	WAC 246-869-130
<input type="checkbox"/>	<input type="checkbox"/>		22.	Do you possess, distribute, or dispense legend drug samples?	WAC 246-877-020 prohibits this action.

Professional Requirements

Yes	No	N/A			Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>		23.	Do you have a copy of the pharmacy law book, either a hard copy or on your internet?	WAC 246-869-180(2)
<input type="checkbox"/>	<input type="checkbox"/>		24.	Do you have an up-to-date reference source available? What is it? _____ Do you fill animal medications? What is your reference resource? _____	WAC 246-869-180(3)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	25.	Are all drugs properly labeled and stored including prepackaged medications, in accordance with federal and state statutes, rules and regulations?	WAC 246-869-150
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	26.	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) USP 795
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	27.	Do you place suitable beyond use date or discard by date on patient prescriptions? - Quantity dispensed - Warnings regarding transfer of drugs <i>Check will call areas for prescriptions in original packaging to confirm that prescription label expiration date does not exceed actual manufacturer expiration date.</i>	WAC 246-869-210
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	28.	Do your original prescription records contain: - Time of dispensing	WAC 246-869-100

				<ul style="list-style-type: none"> - Serial number - Date of Dispensing - Initials of the responsible pharmacist on the face of the prescription - Patient's address is readily available to the pharmacist 	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	29.	<p>Do you have refill prescription authorizations?</p> <p>Do your refill prescription records contain:</p> <ul style="list-style-type: none"> - Time of dispensing - Date of refilling - Quantity of the drug (if other than original) - Name of authorizing person (if other than original) <p>Initials of the responsible pharmacist is on the back of prescription or in a separate record book or patient medication record</p>	WAC 246-869-100
Yes	No	N/A			Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	30.	<p>TRANSFERRING PRESCRIPTION: When transferring original prescription information for a non-controlled legend drug for the purpose of refill dispensing, do you:</p> <ul style="list-style-type: none"> - Communicate directly with the pharmacist receiving the transfer. - Record in the patient medication record system that a copy has been issued. - Record in the patient medication record system the name and address of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescription information. 	WAC 246-869-090(1)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	31.	<p>RECEIVING A TRANSFERRED PRESCRIPTION: When a pharmacist receives a transferred prescription, do they:</p> <ul style="list-style-type: none"> - Write "TRANSFER" on the face of the transferred prescription - Provide all information required to be on the prescription: <ul style="list-style-type: none"> o Patient Name and Address o Prescriber's name and address o Date of issuance of original prescription o Number of refills remaining and date of last refill o Pharmacy's name, address, and original prescription number of the transferring pharmacy o Name of the transferor pharmacy 	WAC 246-869-090(2) Controlled Substance Transfers must comply with: 21 CFR 1305.25
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	32.	Do all of your prescriptions contain an instruction on whether or not a therapeutically	RCW 69.41.120

				equivalent generic drug or interchangeable biological produce may be substituted in its place? <i>This is not necessary if substitution is permitted by a prior-consent authorization.</i>	
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Facilities

Yes	No	N/A			
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	33.	Are your hours permanently displayed next to the pharmacy or adjacent to the entrance?	WAC 246-869-020(8)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	34.	If applicable, do you have a mail slot or drop box for prescription drop offs outside of pharmacy hours?	WAC 246-869-020(3)

Yes	No	N/A			Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		If you located in a larger mercantile building are your hours posted at the pharmacy and permanently outside?	WAC 246-869-020(8)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	35.	Do you have a mail slot or drop box for prescription drop offs outside of pharmacy hours?	WAC 246-869-020(3)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		Separate phone line for the pharmacy?	WAC 246-869-020(6)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	36.	Is the pharmacy area where drugs are secured and stored restricted from access from the public?	WAC 246-869-160(7)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		Are deliveries stored within the secured pharmacy area?	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	37.	Does your pharmacy meeting the following facility requirements: <ul style="list-style-type: none"> - Have proper lighting - Well ventilated, with a constant flow of are throughout the work area - Minimum of 3 linear feet by 18 inch deep counter working space, with space for each person filing prescriptions - Prescription counter is not cluttered 	WAC 246-869-160
<input type="checkbox"/>	<input type="checkbox"/>		38.	Do you have a properly operational sink, both hot and cold running water?	WAC 246-869-160(5)
<input type="checkbox"/>	<input type="checkbox"/>			Are your refrigerators temperatures maintained between 2-8°C (36-46°F)?	WAC 246-869-160
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	39.	Is your freezer between -25°& 10°C (-13° & 14°F)	RCW 18.64.270(2) USP Chapter 32 10.30.10
<input type="checkbox"/>	<input type="checkbox"/>		40.	Are there adequate trash receptacles?	WAC 246-869-170(2)
<input type="checkbox"/>	<input type="checkbox"/>		41.	Is there a restroom located in the pharmacy? If yes, does it have an operational sink, with hot and cold running water, it is clean and sanitary?	WAC 246-869-170(2)
<input type="checkbox"/>	<input type="checkbox"/>		42.	Are the walls, ceilings, floors and windows shall be clean, free from cracked and peeling paint or plaster, and in general good repair and order.	WAC 246-869-170(1)

<input type="checkbox"/>	<input type="checkbox"/>		43.	Does your facility have all the necessary equipment and supplies necessary for the practice of pharmacy? All equipment must be in good repair.	WAC 246-869-180
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Non-Sterile Compounding (Need to create questions)

Yes	No	N/A			

Other Areas of Non-Compliance

The Commission and its investigators reserve the right to note areas of non-compliance not specifically identified above on this self-inspection form. If an investigator identifies an issue of non-compliance they will note it in the section below and it will be included in a Notice of Deficiency.

DRAFT

Pharmacy Quality Assurance Commission Retail Pharmacy Self-Assessment Compliance Checklist

Introduction:

- This checklist includes references to the federal, state, and commission statutes and regulations as they are applied to **ONLY** retail pharmacy practice. If your pharmacy engages in other forms of pharmacy practice, this may not be applicable to your practice setting.
- Neither the self-inspection nor a Commission inspection evaluates your complete compliance with all statutes and regulations relative to the practice of pharmacy.
- This checklist is designed to be a tool to guide and aid you in evaluating your compliance with federal, state, and commission statutes and regulations. This checklist is not all inclusive, please refer to laws and rules that apply to your various practices.
- At times, the language in this checklist is not all inclusive of applications of statutes and regulations during an inspection. If there is a need to clarify the requirements, please refer to specific CFR, RCW, or WAC for additional language.
- The Department of Health Office of Investigation and Inspection can help you interpret these requirements, and help you understand how to comply with these requirements.

Checklist Contents:

Section Name	Requirement numbers	Page numbers
General Requirements		
Professional Requirements		
Pharmacy Facilities		
Misc.:		
795 Compounding		
Customized patient medication packages		

DRAFT

Retail Pharmacy Self-Assessment Compliance Checklist

Required annually by February 28

Date Self-Assessment Completed:		Pharmacy Name:	
Self-Assessment Conducted by:		Facility License Number:	
Pharmacist license number:		Signature:	

Item Number	For each requirement mark "X" the appropriate box:	Compliant	Non-Compliant	Non-Applicable (N/A)	Plan of Correction
General Requirements					
1.	Pharmacy Inspection Certificate Posted : WAC 246-869-190(6) The certificate of inspection must be posted in conspicuous view of the general public and shall not be removed or defaced.				
2.	Personnel Licenses Posted: RCW 18.64.140 Every licensed pharmacist who desires to practice pharmacy shall secure from the department a license, the fee for which shall be determined by the secretary under RCW <u>43.70.250</u> and <u>43.70.280</u> . The current license shall be conspicuously displayed to the public in the pharmacy to which it applies.				
3.	Pharmacy Licenses Posted RCW 18.64.043(3) It shall be the duty of the owner to immediately notify the department of any change of location or ownership and to keep the license of location or the renewal thereof properly exhibited in said pharmacy.				
4.	DEA Registration: DEA No: _____ Expiration Date: _____ WAC 246-887-020 (2) A separate registration is required for each place of business (as defined in section 1301.23) where controlled substances are manufactured, distributed or dispensed.				
Patient Health and Safety Requirements					

Item Number	For each requirement mark "X" the appropriate box: <ul style="list-style-type: none"> • Compliant = your facility is 100% compliant with the requirement • Non-Compliant = your facility is not currently 100% compliant with the requirement • Non-Applicable (N/A) = your facility does not need to meet requirement 	Compliant	Non-Compliant	Non-Applicable (N/A)	Plan of Correction
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5.	<p>Patient Medical Records/ Computer Software System: WAC 246-875-001 The purpose of this chapter shall be to insure that a patient medical record system is maintained by all pharmacies and other sites where the dispensing of drugs takes place. in order to insure the health and welfare of the patients served. This system will consist of certain patient and prescription information, and shall provide the pharmacist within the pharmacy means to retrieve all new prescription and refill prescription information relevant to patients of the pharmacy. It shall be designed to provide adequate safeguards against the improper manipulation or alteration of records, and to provide an audit trail. It may be either a manual system or an automated data processing system for the storage and retrieval of prescription and patient information. If an automated data processing system is utilized, an auxiliary recordkeeping procedure shall be available for documentation of new and refill prescriptions in case the automated system is inoperative for any reason. Establishment of a patient medication record system is intended to insure that the information it contains will be reviewed by the pharmacist in a manner consistent with sound professional practice when each prescription is filled. WAC 246-875-020 Minimum required information in an automated patient medication record system. An automated patient medication record system is an electronic system that must have the capability of capturing any data removed on a hard copy of microfiche copy. The hard copy of the original prescription and all documents in the audit trail shall be considered a part of this system.</p> <p>(1) All automated patient medication record systems must maintain the following information with regard to ambulatory patients:</p> <ul style="list-style-type: none"> (a) Patient's full name and address. (b) A serial number assigned to each new prescription. (c) The date of all instances of dispensing a drug. (d) The identification of the dispenser who filled the prescription. (e) The name, strength, dosage form and quantity of the drug dispensed. (f) Any refill instructions by the prescriber. (g) The prescriber's name, address, and DEA number where required. (h) The complete directions for use of the drug. The term "as directed" is prohibited pursuant to RCW 18.64.246 and 69.41.050. (i) Any patient allergies, idiosyncrasies, or chronic condition which may relate to drug utilization. If there is no patient allergy data the pharmacist should indicate none or "NKA" (no known allergy) on the patient medication record. (j) Authorization for other than child-resistant containers pursuant to WAC 246-869-230, if 				
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6.	<p>If you have a manual patient medication system, then WAC 246-875-030 applies.</p> <p>A manual patient medication record system consists of the hard copy of the original prescription and a card or filing procedure that contains all data on new and refill prescriptions for a patient. This data must be organized in such a fashion that information relating to all prescription drugs used by a patient will be reviewed each time a prescription is filled.</p> <p>(1) All manual patient medication record systems must maintain the following information with regard to ambulatory patients:</p> <ul style="list-style-type: none"> (a) Patient's full name and address. (b) A serial number assigned to each new prescription. (c) The date of all instances of dispensing a drug. (d) The identification of the dispenser who filled the prescription. (e) The name, strength, dosage form and quantity of the drug dispensed. (f) The prescriber's name, address and DEA number where appropriate. (g) Any patient allergies, idiosyncrasies or chronic conditions which may relate to drug utilization. If there is no patient allergy data the pharmacist should indicate none or "NKA" (no known allergy) on the patient medication record. 				
7.	<p>Auxiliary recordkeeping system in place for backup as required: WAC 246-875 050 If an automated data processing system is used to maintain a patient's medication record, an auxiliary recordkeeping procedure must be available for use when the automated data system is temporarily inoperative due to scheduled or unscheduled system interruption.</p>				
	<p>The following applies to items 8-9 WAC 246-875 -020 (i) Any patient allergies, idiosyncrasies, or chronic condition which may relate to drug utilization. If there is no patient allergy data the pharmacist should indicate none or "NKA" (no known allergy) on the patient medication record.</p>				
8.	<p>Patient Medical Records: Allergies</p>				
9.	<p>Patient Medical Records: Significant Chronic Conditions</p>				
	<p>The following applies to items 10-11 WAC 246-875-040 Upon receipt of a prescription or drug order, a dispenser must examine visually or</p>				

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	via an automated data processing system, the patient's medication record to determine the possibility of a clinically significant drug interaction, reaction or therapeutic duplication, and to determine improper utilization of the drug and to consult with the prescriber if needed.				
10.	Patient Medical Records: DUR Chronic Conditions				
11.	Patient Medical Records: DUR verification for Drug-Drug; Duplicate Tx; Drug- Allergy; Drug- Disease				
12.	Patient counseling required WAC 246-869-220 The purpose of this counseling requirement is to educate the public in the use of drugs and devices dispensed upon a prescription. (1) The pharmacist shall directly counsel the patient or patient's agent on the use of drugs or devices. (2) For prescriptions delivered outside of the pharmacy, the pharmacist shall offer in writing, to provide direct counseling and information about the drug, including information on how to contact the pharmacist. (3) For each patient, the pharmacist shall determine the amount of counseling that is reasonable and necessary under the circumstance to promote safe and effective administration of the medication and to facilitate an appropriate therapeutic outcome for that patient from the prescription. (4) This rule applies to all prescriptions except where a medication is to be administered by a licensed health professional authorized to administer medications.				
13.	Child Resistant Caps (CRC): [Also consider any special packaging used such as Customized patient medication packages; Blister Packs; Med-minders, etc.] WAC 246-869-230 (1) All legend drugs shall be dispensed in a child-resistant container as required by federal law or regulation, including C.F.R. Part 1700 of Title 16, 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. (2) Authorization from the patient to the pharmacist to use a regular container (non-child resistant) shall be verified in one of the following ways: (a) The patient or his agent may sign a statement on the back of the prescription requesting a container that is not child-resistant. (b) The patient or his agent may sign a statement on a patient medication record requesting containers that are not child-resistant. (c) The patient or his agent may sign a statement on any other permanent record requesting containers that are not child-resistant. (3) No pharmacist or pharmacy employee may designate himself or herself as the patient's agent.				
14.	Poison Center Phone Number Posted (1-800-222-1222) WAC 246-869-200 (1) The telephone number of the nearest poison control center shall be readily				

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	available.				
15.	<p>WAC 246-869-130 Return or exchange of drugs. Except as provided in this rule, prescriptions, drugs, medicines, sick room supplies and items of personal hygiene shall not be accepted for return or exchange by any pharmacist or pharmacy after such prescriptions, drugs, medicines, sick room supplies or items of personal hygiene have been taken from the premises where sold, distributed or dispensed.</p> <p>(1) Those drugs and sick room supplies legally dispensed by prescription in unit dose forms or in sealed single or multiple dose ampoules or vials in which the pharmacist can readily determine that entry or attempted entry by any means has not been made and which, in the pharmacist's professional judgment, meet the standards of the United States Pharmacopeia for storage conditions including temperature, light sensitivity, chemical and physical stability may be returned.</p> <p>(2) Pharmacies serving hospitals and long-term care facilities may accept for return and reuse, unit dose packages or full or partial multiple dose medication cards based on the following criteria;</p> <p>(a) The pharmacist can readily determine that entry or attempt at entry to the unit dose package or blister card has not been made;</p> <p>(b) In the pharmacist's professional judgment, the unit dose package or full or partial multiple dose medication card meets the standards of the United States Pharmacopeia for storage conditions including temperature, light sensitivity, chemical and physical stability;</p> <p>(c) The drug has been stored in such a manner as to prevent contamination by a means that would affect the efficacy and toxicity of the drug;</p> <p>(d) The drug has not come into physical possession of the person for whom it was prescribed and control of the drug being returned is known to the pharmacist to have been the responsibility of a person trained and knowledgeable in the storage and administration of drugs;</p> <p>(e) The drug labeling or packaging has not been altered or defaced so that the identity of the drug, its potency, lot number, and expiration date is retrievable.</p> <p>(f) If the drug is prepackaged, it shall not be mixed with drugs of different lot numbers and/or expiration dates unless the specific lot numbers are retrievable and the expiration dates accompany the drug. If the drug is extemporaneously packaged, it shall not be mixed with drugs of different expiration dates unless the earliest expiration date appears on the label of the drug.</p> <p>(3) This rule shall not include items such as orthopedic appliances, crutches, canes, wheelchairs and other similar items unless otherwise prohibited.</p> <p>(4) Controlled substances shall not be returned to a pharmacy except for destruction in accordance with rules of the drug enforcement administration or the Washington state board of pharmacy.</p>				
16.	<p>Outdated/Recalled/ Deteriorated Stock WAC 246-869-150 Physical standards for pharmacies</p> <p>(2) Dated items—All merchandise which has exceeded its expiration date must be removed from stock.</p> <p>(3) All stock and materials on shelves or display for sale must be free from contamination,</p>				

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	<p>deterioration and adulteration.</p> <p>(4) All stock and materials must be properly labeled according to federal and state statutes, rules and regulations.</p> <p>(5) Devices that are not fit or approved by the FDA for use by the ultimate consumer shall not be offered for sale and must be removed from stock.</p> <p>(6) All drugs shall be stored in accordance with USP standards and shall be protected from excessive heat or freezing except as those drugs that must be frozen in accordance with the requirements of the label. If drugs are exposed to excessive heat or frozen when not allowed by the requirements of the label, they must be destroyed.</p>				
17.	<p>WAC 246-877-020 Drug sample prohibitions.</p> <p>(1) The possession, distribution or dispensing of legend drug samples by a pharmacy is hereby prohibited.</p>				
Professional Requirements					
18.	<p>DEA Order Forms/CSOS (Controlled Substance Ordering System)</p> <p>WAC246-887-020, 21CFR 1305.13 (e) The purchaser must record on Copy 3 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.</p> <p>CSOS 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.</p> <p>WAC 246-887-020(1) Consistent with the concept of uniformity where possible with the federal regulations for controlled substances (21 C.F.R.), the federal regulations are specifically made applicable to registrants in this state by virtue of RCW 69.50.306.</p>				
19.	<p>Power of Attorney</p> <p>WAC246-887-020, 21CFR 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.</p> <p>WAC 246-887-020(1) Consistent with the concept of uniformity where possible with the federal regulations for controlled substances (21 C.F.R.), the federal regulations are specifically made applicable to registrants in this state by virtue of RCW 69.50.306.</p>				
20.	<p>DEA Inventory Record Biennial Inventory: Date and time completed :</p> <p>WAC 246-887-020(3) Every registrant shall be required to keep inventory records required by section</p>				

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	<p>1304.04 (of the federal rules which have been adopted by reference by Rule 1) and must maintain said inventory records for a period of two years from the date of inventory.</p> <p>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.</p>				
21.	<p>Control Drug Losses : DEA Form 106 21 CFR 1301.76(b) The registrant shall notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft. The registrant shall also complete, and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft. WAC 246-887-020(c) In the event of a loss by theft or destruction, 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;</p>				
22.	<p>WAC 246-863-095 Pharmacist's professional responsibilities. (1) A pharmacist's primary responsibility is to ensure patients receive safe and appropriate medication therapy. (2) A pharmacist shall not delegate the following professional responsibilities: (a) Receipt of a verbal prescription other than refill authorization from a prescriber. (b) Consultation with the patient regarding the prescription, both prior to and after the prescription filling and/or regarding any information contained in a patient medication record system provided that this shall not prohibit pharmacy ancillary personnel from providing to the patient or the patient's health care giver certain information where no professional judgment is required such as dates of refills or prescription price information. (c) Consultation with the prescriber regarding the patient and the patient's prescription. (d) Extemporaneous compounding of the prescription, however, bulk compounding from a formula and IV admixture products prepared in accordance with chapter 246-871 WAC may be performed by a pharmacy technician when supervised by a pharmacist. (e) Interpretation of data in a patient medication record system. (f) Ultimate responsibility for all aspects of the completed prescription and assumption of the responsibility for the filled prescription, such as: Accuracy of drug, strength, labeling, proper container and other requirements. (g) Dispense prescriptions to patient with proper patient information as required by WAC 246-869-220. (i) Professional communications with physicians, dentists, nurses and other health care practitioners. (j) Decision to not dispense lawfully prescribed drugs or devices or to not distribute drugs and</p>				

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	devices approved by the U.S. Food and Drug Administration for restricted distribution by pharmacies.				
23.	<p>WAC 246-863-100 Pharmacist prescriptive authority—Prior board notification of written guideline or protocol required.</p> <p>(1) A pharmacist planning to exercise prescriptive authority in his or her practice (see RCW 18.64.011(11)) by initiating or modifying drug therapy in accordance with written guidelines or protocols previously established and approved for his or her practice by a practitioner authorized to prescribe drugs must have on file at his/her place of practice a properly prepared written guideline or protocol indicating approval has been granted by a practitioner authorized to prescribe. A copy of the written guideline or protocol must also be on file with the board of pharmacy.</p>				
24.	<p>WAC 246-869-090 Prescription transfers.</p> <p>The transfer of original prescription information for a non-controlled substance legend drug for the purpose of refill dispensing is permissible between pharmacies subject to the following requirements:</p> <p>(1) The transfer is communicated directly between two licensed pharmacists and the transferring pharmacist records the following information:</p> <p>(a) Record in the patient medication record system that a copy has been issued.</p> <p>(b) Record in the patient medication record system the name and address of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescription information.</p> <p>(2) The pharmacist receiving the transferred prescription information shall reduce to writing the following:</p> <p>(a) Write the word "TRANSFER" on the face of the transferred prescription.</p> <p>(b) Provide all information required to be on the prescription - patient's name and address; prescriber's name and address, and also include:</p> <p>(i) Date of issuance of original prescription.</p> <p>(ii) Number of valid refills remaining and date of last refill.</p> <p>(iii) The pharmacy's name, address, and original prescription number from which the prescription information was transferred.</p> <p>(iv) Name of transferor pharmacist.</p> <p>(c) Both the original and transferred prescription must be maintained as if they were original prescriptions.</p> <p>(d) A transferred prescription may not be refilled after one year from the date the original was issued.</p> <p>(e) The above subsections apply to the transfer of prescription information for noncontrolled substances. The transfer of controlled substance prescription information must conform to the requirements of 21 C.F.R. 1306.25.</p> <p>(3) When a prescription is transferred, no further refills shall be issued by the transferring pharmacy.</p>				

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	(4) If two or more pharmacies utilize a common electronic data base for prescription recordkeeping, prescriptions may be refilled at any of these pharmacies as long as there is provided an audit trail which documents the location of each filling and provisions are made to assure that the number of authorized refills are not exceeded.				
25.	Responsible Pharmacy Manager (PIC) WAC 246-869-070 Every non-licensed proprietor of one or more pharmacies shall place in charge of each pharmacy a licensed pharmacist who shall be known as the "responsible manager." The non-licensed proprietor shall immediately report to the state board of pharmacy the name of the "responsible manager," who shall ensure that the pharmacy complies with all the laws, rules and regulations pertaining to the practice of pharmacy.				
26.	Pharmacy Law Reference WAC 246-869-180(2) All pharmacies will have in their possession one up-to-date copy of the state of Washington statutes and rules governing the practice of pharmacy, the sale and dispensing of drugs, poisons, controlled substances, and medicines. Electronic or online versions are acceptable.				
27.	Reference Source WAC 246-869-180(3) All pharmacies shall have up-to-date references in order for the pharmacist(s) to furnish patients and practitioners with information concerning drugs.				
28.	Pharmacy Ancillary Staff WAC 246-901-020 (1) Pharmacy technicians may perform certain nondiscretionary and specialized functions consistent with their training in pharmacy practice while under the immediate supervision of a licensed pharmacist.				
29.	Pharmacy Ancillary Staff WAC 246-901-030(1) (a) Formal academic pharmacy technician training program approved by the board. (b) On-the-job pharmacy technician training program approved by the board.				
30.	Pharmacy Ancillary Staff WAC 246-901-070 Pharmacy assistant utilization. Pharmacy assistants may perform, under the general supervision of a licensed pharmacist, all duties except those reserved to the pharmacist and the pharmacy technician. Pharmacy assistants may: (1) Prepackage and label drugs for subsequent use in prescription dispensing operations. (2) Count, pour, and label for individual prescriptions.				
31.	Pharmacy Ancillary Staff WAC 246-901-090 Identification. All pharmacy ancillary personnel working within the pharmacy and having contact with patients or the				

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	general public shall wear badges or tags clearly identifying them as pharmacy assistants or technicians.				
32.	Pharmacy Ancillary Staff 246-901-100(2)(a) Utilization plan for pharmacy technicians. General. The application for approval must describe the manner in which the pharmacy technicians will be utilized and supervised, including job descriptions, task analysis or similar type documents that define the duties performed and the conditions under which they are performed, number of positions in each category, as well as other information as may be required by the board. The board will be notified of all changes to the utilization plan. A copy of the utilization plan must be maintained in the pharmacy.				
33.	Pharmacy Ancillary Staff WAC 246-901-130 (1) A standard ratio of one pharmacist to a maximum of three technicians is established for each licensed pharmacy.				
34.	All Drugs Properly Labeled WAC 246-869-150(4) All stock and materials must be properly labeled according to federal and state statutes, rules and regulations. RCW 18.64.270(2) 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.				
35.	Completed Prescription Labels WAC 246-869-210 To every prescription container, there shall be fixed a label or labels bearing the following information: (1) All information as required by RCW <u>18.64.246</u> , provided that in determining an appropriate period of time for which a prescription drug may be retained by a patient after its dispensing, 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 thereon; (c) The characteristics of the patient's container, if the drug is repackaged for dispensing; (d) The expected conditions to which the article may be exposed; (e) The expected length of time of the course of therapy; and (f) Any other relevant factors. The dispenser shall, on taking into account the foregoing, place on the label of a multiple unit				

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	<p>container a suitable beyond-use date or discard-by date to limit the patient's use of the drug. In no case may this date be later than the original expiration date determined by the manufacturer.</p> <p>(2) The quantity of drug dispensed, for example the volume or number of dosage units.</p> <p>(3) 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."</p> <p>(4) The information contained on the label shall be supplemented by oral or written information as required by WAC <u>246-869-220</u>.</p>				
36.	<p>WAC 246-869-255 Customized patient medication packages.</p> <p>The board approves the use of med-pack containers in the dispensing of prescription drugs within the same pharmacy, provided that:</p> <p>(1) The pharmacy must maintain custody of the original prescription container at the pharmacy;</p> <p>(2) No more than a thirty-one day supply of drugs is packaged;</p> <p>(3) The signature of the patient or the patient's agent is obtained for dispensing in a non-child resistant container;</p> <p>(4) The container's label bear the following information:</p> <p>(a) Pharmacy name and address;</p> <p>(b) Patient's name;</p> <p>(c) Drug name, strength, quantity;</p> <p>(d) Directions;</p> <p>(e) Serial prescription numbers; date</p> <p>(f) Prescriber's name, and pharmacist's initials.</p>				
37.	<p>Prescription Files WAC 246-887-020 and 21 CFR 1304.04 identify prescription record requirements</p> <p>WAC 246-869-100 (1) Records for the original prescription and refill records shall be maintained on the filled prescription or in a separate record book or patient medication record. Such records must be maintained for a period of at least two years and shall be made available for inspection to representatives of the board of pharmacy.</p> <p>(2) The pharmacist shall be required to insure that the following information be recorded:</p> <p>(a) Original prescription— At the time of dispensing, a serial number, date of dispensing, and the initials of the responsible pharmacist shall be placed on the face of the prescription. The patient's address must be readily available to the pharmacist, either from the face of the prescription, a record book, patient medication record, or hospital or clinic record.</p> <p>RCW 69.41.120 Prescriptions to contain instruction as to whether or not a therapeutically equivalent generic drug or interchangeable biological product may be substituted—Out-of-state prescriptions—</p>				

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	<p>Form—Contents—Procedure.</p> <p>(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.</p> <p>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.</p> <p>(2) If an oral prescription is involved, the practitioner or the practitioner's agent shall instruct the pharmacist as to whether or not a therapeutically equivalent generic drug or interchangeable biological product may be substituted in its place. The pharmacist shall note the instructions on the file copy of the prescription.</p> <p>(3) The pharmacist shall note the manufacturer of the drug dispensed on the file copy of a written or oral prescription.</p> <p>(4) The pharmacist shall retain the file copy of a written or oral prescription for the same period of time specified in RCW 18.64.245 for retention of prescription records.</p>				
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Pharmacy Facilities					
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38.	<p>Differential Hours WAC 246-869-020(8) A pharmacy must prominently display in a permanent manner on or adjacent to its entrance the times that it is open for business. If a pharmacy is located within a larger mercantile establishment having hours of operation different from the pharmacy then the pharmacy times of being open for business shall be prominently displayed in a permanent manner at the pharmacy area and on or adjacent to the entrance to the mercantile establishment.</p>				
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39.	<p>Rx Area Secure from Public WAC 246-869-160 (7) The prescription department shall be situated so that the public shall not have free access to the area where legend drugs, controlled substances, poisons, or other restricted items</p>				
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	are stored, compounded or dispensed.				
40.	Appearance of Staff WAC 246-869-170 WAC 246-869-170 (5) All professional personnel and staff, while working in the pharmacy, shall keep themselves and their apparel neat and clean.				
41.	Physical standards for pharmacies—Adequate facilities. WAC 246-869-160(1-4) (1) The prescription department shall be well lighted (adequately to allow any person with normal vision to read a label without strain, 30-50 foot candles). (2) The prescription department shall be well ventilated. There shall be a constant flow of air through the area. (3) There shall be a minimum of three linear feet by a minimum of 18 inches in depth of counter working space for each pharmacist or intern compounding or filling prescriptions at the same time. (4) The prescription counter shall be uncluttered and clean at all times. Only those items necessary to the filling of prescriptions shall be thereon.				
42.	Prescription Area Sink WAC 246-869-160(5) There shall be a sink with hot and cold running water in the prescription compounding <i>area</i> .				
43.	Refrigerator/Freezer WAC 246-869-160(6) There shall be refrigeration facilities with a thermometer in the prescription compounding area for the storage of pharmaceutical items requiring refrigeration. USP standards of refrigeration require that the temperature be maintained between two degrees and eight degrees Centigrade (36 degrees and 46 degrees Fahrenheit). A locked refrigerator in the immediate vicinity of the prescription department will meet the requirements of this paragraph. RCW 18.64.270(2) USP Chapter 32 10.30.10 Freezer indicates a place where the temperature is maintained thermostatically between -25C and -10C (-13F and 14 F)				
44.	Trash Receptacles WAC 246-869-170(2) Adequate trash receptacles shall be available, both in the prescription compounding and in the retail areas.				
45.	Rest Rooms WAC 246-869-170(3) If a restroom is provided, there must be a sink with hot and cold running water, soap and towels, and the toilet must be clean and sanitary.				

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46.	General Cleanliness & Sanitation WAC 246-869-170(1) The walls, ceilings, floors and windows shall be clean, free from cracked and peeling paint or plaster, and in general good repair and order.				
47.	Necessary Equipment WAC 246-869-180(1) All pharmacies shall have in their possession the equipment and supplies necessary to compound, dispense, label, administer and distribute drugs and devices. The equipment shall be in good repair and shall be available in sufficient quantity to meet the needs of the practice of pharmacy conducted therein.				
48.	Physical standards for pharmacies—Sanitary conditions. WAC 246-869-170(4) All equipment must be kept in a clean and orderly manner. That equipment used in the compounding of prescriptions (counting, weighing, measuring, mixing and stirring equipment) must be clean and in good repair.				
Non-Sterile Compounding Requirements GOOD COMPOUNDING PRACTICES WAC 246-878; RCW 18.64.270(2) and USP 795					
49.	WAC 246-878-020 (1) Based on the existence of a pharmacist/patient/prescriber relationship and the presentation of a valid prescription, or in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns, pharmacists may compound, for an individual patient, drug products that are commercially available in the marketplace. (5) The distribution of inordinate amounts of compounded products without a prescriber/patient/pharmacist relationship is considered manufacturing.				
50.	WAC 246-878-030 (1) The pharmacist has the responsibility and authority to inspect and approve or reject all components, drug product containers, closures, in-process materials, and labeling; and the authority to prepare and review all compounding records to assure that no errors have occurred in the compounding process. The pharmacist is also responsible for the proper maintenance, cleanliness, and use of all equipment used in prescription compounding practice. (2) Pharmacists who engage in drug compounding, and level A pharmacy assistants, supervised by pharmacists, who assist in drug compounding, shall be competent and proficient in compounding and shall maintain that proficiency through current awareness and training. Every pharmacist who engages in drug compounding and any level A pharmacy assistant who assists in compounding, must be aware of and familiar with all details of these good compounding practices. (3) Pharmacy personnel engaged in the compounding of drugs shall wear clean clothing appropriate to the operation being performed. Protective apparel, such as coats/jackets, aprons, gowns, hand or arm coverings, or masks shall be worn as necessary to protect personnel from chemical exposure and drug products from contamination.				

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	<p>(4) Only personnel authorized by the responsible pharmacist shall be in the immediate vicinity of the drug compounding operation. Any person shown at any time (either by medical examination or pharmacist determination) to have an apparent illness or open lesions that may adversely affect the safety or quality of a drug product being compounded shall be excluded from direct contact with components, drug product containers, closures, in-process materials, and drug products until the condition is corrected or determined by competent medical personnel not to jeopardize the safety or quality of the products being compounded. All personnel who assist the pharmacist in compounding procedures shall be instructed to report to the pharmacist any health conditions that may have an adverse effect on drug products.</p>				
51.	<p>WAC 246-878-040 Facilities.</p> <p>(1) Pharmacies engaging in compounding shall have an adequate area for the orderly compounding of prescriptions, including the placement of equipment and materials. The drug compounding area for sterile products shall be separate and distinct from the area used for the compounding of nonsterile drug products. The area(s) used for compounding of drugs shall be maintained in a good state of repair.</p> <p>(2) Bulk drugs and other chemicals or materials used in the compounding of drugs must be stored in adequately labeled containers in a clean, dry area or, if required, under proper refrigeration.</p> <p>(3) Adequate lighting and ventilation shall be provided in all drug compounding areas. Potable water shall be supplied under continuous positive pressure in a plumbing system free of defects that could contribute contamination to any compounded drug product. Adequate washing facilities, easily accessible to the compounding area(s) of the pharmacy shall be provided. These facilities shall include, but not be limited to, hot and cold water, soap or detergent, and air driers or single-use towels.</p> <p>(4) The area(s) used for the compounding of drugs shall be maintained in a clean and sanitary condition. It shall be free of infestation by insects, rodents, and other vermin. Trash shall be held and disposed of in a timely and sanitary manner. Sewage and other refuse in and from the pharmacy and immediate drug compounding area(s) shall be disposed of in a safe and sanitary manner.</p>				
52.	<p>WAC 246-878-070 Special precaution products.</p> <p>If drug products with special precautions for contamination, such as penicillin, are involved in a compounding operation, appropriate measures, including either the dedication of equipment for such operations or the meticulous cleaning of contaminated equipment prior to its use for preparation of other drugs, must be utilized in order to prevent cross-contamination.</p>				
53.	<p>WAC 246-878-080 Equipment.</p> <p>(1) Equipment used in the compounding of drug products shall be of appropriate design, appropriate capacity, and suitably located to facilitate operations for its intended use and for its cleaning and maintenance. Equipment used in the compounding of drug products shall be suitable composition so that surfaces that contact components, in-process materials, or drug products shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug</p>				

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	<p>product beyond that desired.</p> <p>(2) Equipment and utensils used for compounding shall be cleaned and sanitized immediately prior to use to prevent contamination that would alter the safety, identity, strength, quality, or purity of the drug product beyond that desired. In the case of equipment, utensils, and containers/closures used in the compounding of sterile drug products, cleaning, sterilization, and maintenance procedures as set forth in WAC 246-871-080.</p> <p>(3) Equipment and utensils used for compounding drugs must be stored in a manner to protect them from contamination. Immediately prior to the initiation of compounding operations, they must be inspected by the pharmacist and determined to be suitable for use.</p> <p>(4) Automatic, mechanical, electronic, or other types of equipment other than commercial scale manufacturing or testing equipment, may be used in the compounding of drug products. If such equipment is used, it shall be routinely inspected, calibrated (if necessary), or checked to ensure proper performance.</p>				
54.	<p>WAC 246-878-090 Control of components and drug product containers and closures.</p> <p>(1) Components, drug product containers, closures, and bagged or boxed components of drug product containers and closures used in the compounding of drugs shall be handled and stored in a manner to prevent contamination and to permit unhindered cleaning of the work area (e.g., floors) and inspection.</p> <p>(2) Drug product containers and closures shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the compounded drug beyond the desired result. Components, drug product containers, and closures for use in the compounding of drug products shall be rotated so that the oldest stock is used first. Container closure systems shall provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the compounded drug product. Drug product containers and closures shall be clean and, where indicated by the intended use of the drug, sterilized and processed to remove pyrogenic properties to assure that they are suitable for their intended use.</p> <p>(3) Drug product containers and closures intended for the compounding of sterile products must be handled, sterilized, processed and stored to remove pyrogenic properties to assure that they are suitable for their intended purpose. Methods of cleaning, sterilizing, and processing to remove pyrogenic properties shall be written and followed for drug product containers and closures used in the preparation of sterile pharmaceuticals. These processes shall be performed by pharmacists, or under the pharmacist's supervision.</p>				
55.	<p>WAC 246-878-100 Drug compounding controls.</p> <p>(1) There shall be written procedures for the compounding of drug products to assure that the finished products have the identity, strength, quality, and purity they purport or are represented to possess. Such procedures shall include a listing of the components (ingredients), their amounts (in weight or volume), the order of component mixing, and a description of the compounding process. All equipment and utensils and the container/closure system, relevant to the sterility and stability of the intended use of the drug, shall be listed. These written procedures shall be followed in the</p>				

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	<p>execution of the drug compounding procedure.</p> <p>(2) Components for drug product compounding shall be accurately weighed, measured, or subdivided as appropriate. These operations should be checked and rechecked by the compounding pharmacist at each stage of the process to ensure that each weight or measure is correct as stated in the written compounding procedures. If a component is transferred from the original container to another (e.g., a powder is taken from the original container, weighed, placed in a container, and stored in another container), the new container shall be identified with the:</p> <p>(a) Component name; and</p> <p>(b) Weight or measure.</p> <p>(3) To assure the reasonable uniformity and integrity of compounded drug products, written procedures shall be established and followed that describe the tests or examinations to be conducted on the product compounded (e.g., degree of weight variation among capsules.) Such control procedures shall be established to monitor the output and to validate the performance of those compounding processes that may be responsible for causing variability in the final drug product. Such control procedures shall include, but are not limited to, the following (where appropriate):</p> <p>(a) Capsule weight variation;</p> <p>(b) Adequacy of mixing to assure uniformity and homogeneity;</p> <p>(c) Clarity, completeness, or pH of solutions.</p> <p>(4) Appropriate written procedures designed to prevent microbiological contamination of compounded drug products purporting to be sterile shall be established and followed. Such procedures shall include validation of any sterilization process.</p>				
56.	<p>WAC 246-878-110 Labeling control of excess products.</p> <p>(1) In the case where a quantity of compounded drug product in excess of that to be initially dispensed in accordance with WAC 246-878-020 is prepared, the excess product shall be labeled or documentation referenced with the complete list of ingredients (components), the preparation date, and the assigned beyond-use date based upon the pharmacist's professional judgment, appropriate testing, or published data. It shall also be stored and accounted for under conditions dictated by its composition and stability characteristics (e.g., in a clean, dry place on shelf or in the refrigerator) to ensure its strength, quality, and purity.</p>				
57.	<p>WAC 246-878-120 Records and reports.</p> <p>(1) Any procedures or other records required to be maintained in compliance with this chapter shall be retained for the same period of time as required in WAC 246-869-100 for the retention of prescription files.</p> <p>(2) All records required to be retained under this chapter, or copies of such records, shall be readily available for authorized inspection during the retention period at the establishment where the activities described in such records occurred. These records or copies thereof shall be subject to photocopying or other means of reproduction as part of any such inspection.</p> <p>(3) Records required under this chapter may be retained either as the original records or as true</p>				

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	copies, such as photocopies, microfilm, microfiche, or other accurate reproductions of the original records.				
58.	Identify any additional specialty services you provide (see OII)				

DRAFT

READ THIS PAGE CAREFULLY

(YEAR)

RETAIL PHARMACY

RESPONSIBLE MANAGER

PHARMACY SELF-INSPECTION REPORT

ATTENTION: RESPONSIBLE MANAGER

Washington law holds the responsible 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 report within the month of March or within 30 days of becoming responsible manager (as required by WAC 246-869-190) may result in disciplinary action.

Following your self-inspection and completion of the report, please review it with your staff pharmacists, ancillary staff and interns, correct any deficiencies noted, sign and date the report, and file it so it will be readily available to Commission investigators. **DO NOT SEND** to the Commission office. You are responsible for ensuring your completed report is available at the time of inspection.

The primary objective of this report, 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 report also serves as a necessary document used by Commission inspectors during an inspection to evaluate a pharmacy's level of compliance.

When a Commission investigator discovers an area of non-compliance, they will issue a **Notice of Deficiency**. The responsible manager must provide a written response addressing all areas of non-compliance. Identifying and correcting an area of non-compliance prior to a Commission inspection may eliminate the receipt of a Notice of Deficiency for that item. Do not *assume* that you are in compliance with any statement; take the time to personally verify that compliance exists. A situation of non-compliance that "is the way it has been" is the current responsible manager's responsibility to immediately correct to avoid the possibility of a Notice and/or disciplinary action. If you have any questions, please contact your investigator.

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

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.



(YEAR) RESPONSIBLE MANAGER
RETAIL PHARMACY SELF-INSPECTION REPORT
WA Pharmacy Quality Assurance Commission
TEL: (360) 236-4946 FAX: (360) 236-2260
EMAIL: WSPQAC@doh.wa.gov

All responsible managers of RETAIL pharmacies MUST complete and sign this self-inspection report within the month of March or within 30 days of becoming responsible manager and have it available for inspection (as required by WAC 246-869-190). **DO NOT SEND TO THE COMMISSION OFFICE.**

Form completed after 3/31/XXXX. **Change in responsible manager** **Other, please explain** _____

Date responsible manager Inspection was performed: ___/___/___

Signature of responsible manager: _____

Print Name & Lic. #: _____

Responsible Manager E-mail: _____

Pharmacy: _____

Telephone: _____

Fax: _____

Address: _____

DEA #: _____

Expiration: ___/___/___

Pharmacy License #: _____

Inspector Signature: _____
Date: ___/___/___
Deficiency Notice: ____
Comments: _____

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 rule references require the documentation printed below, by listing the location of these documents **you are also confirming your compliance with the referenced rule.**

	Rule Reference
Responsible manager Inspection Reports for Last 2 Years:	WAC 246-869-190(2) "The completed self-inspection forms must be signed and dated by the responsible manager and maintained for two years from the date of completion;"
Current Biennial Controlled Substance Inventory:	WAC 246-887-020(3) "Every registrant shall be required to keep inventory records required by section 1304.04 (of the federal rules which have been adopted by reference by Rule 1) and must maintain said inventory records for a period of two years from the date of inventory." 21 CFR 1304.04(h) "(1) Inventories and records of controlled substances listed in Schedules I and II shall be maintained separately from all of the records of the registrant; and (2) Inventories and records of controlled substances listed in Schedules III, IV, and V shall be maintained either separately from all other records of the registrant or in such form that the information required is readily retrievable from the ordinary business records of the registrant."
Schedule II Invoices for the last 2 years:	WAC 246-887-020(3)(a) "Every registrant shall be required to keep inventory records required by section 1304.04 (of the federal rules which have been adopted by reference by Rule 1) and must maintain said inventory records for a period of two years from the date of inventory. Such registrants are further required to keep a record of receipt and distribution of controlled substances. Such record shall include: (a) Invoices, orders, receipts, etc. showing the date, supplier and quantity of drug received, and the name of the drug;" WAC 246-887-020(4) "The records must be maintained separately for Schedule II drugs."
Schedule III-V Invoices for the last 2 years:	WAC 246-887-020(3)(a) "Every registrant shall be required to keep inventory records required by section 1304.04 (of the federal rules which have been adopted by reference by Rule 1) and must maintain said inventory records for a period of two years from the date of inventory. Such registrants are further required to keep a record of receipt and distribution of controlled substances. Such record shall include: (a) Invoices, orders, receipts, etc. showing the date, supplier and quantity of drug received, and the name of the drug;" WAC 246-887-020(4) "The records for Schedule III, IV and V drugs may be maintained either separately or in a form that is readily retrievable"

<p>Completed CII Order Forms (DEA Form 222) for the last 2 years:</p>	<p>from the business records of the registrant.”</p> <p>WAC 246-887-020 “Consistent with the concept of uniformity where possible with the federal regulations for controlled substances (21 C.F.R.), the federal regulations are specifically made applicable to registrants in this state by virtue of RCW <u>69.50.306</u>.”</p> <p>21 CFR 1305.13(e) “The purchaser must record on Copy 3 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.”</p> <p>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.”</p>
<p>Completed loss by theft or destruction forms (DEA Form 106):</p>	<p>WAC 246-887-020(3)(c) “In the event of a loss by theft or destruction, 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;”</p> <p>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.”</p>
<p>Power of Attorney for staff authorized to order controlled substances:</p>	<p>WAC 246-887-020 “Consistent with the concept of uniformity where possible with the federal regulations for controlled substances (21 C.F.R.), the federal regulations are specifically made applicable to registrants in this state by virtue of RCW <u>69.50.306</u>.”</p> <p>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.”</p>
<p>Ancillary Utilization Plan:</p>	<p>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.”</p> <p>WAC 246-901-100(2)(a) “A copy of the utilization plan must be maintained in the pharmacy.”</p>

<p>Technician training documents, if applicable:</p>	<p>WAC 246-901-050 “In order for a program for training pharmacy technicians to be considered for approval by the board, the director of the program, who shall be a pharmacist, shall submit to the board a description of the course of training offered, including subjects taught, method of teaching, and practical experience provided. The director of the program shall also advise the board concerning the skills and knowledge which are obtained in the course, and the method by which the proficiency of the pharmacy technician in those skills and knowledge is tested or ascertained. The board may require such additional information from program sponsors.”</p>
<p>Collaborative Drug Therapy Agreement(s) (CDTA), if applicable:</p>	<p>WAC 246-863-100 “A pharmacist planning to exercise prescriptive authority in his or her practice (see RCW <u>18.64.011(11)</u>) by initiating or modifying drug therapy in accordance with written guidelines or protocols previously established and approved for his or her practice by a practitioner authorized to prescribe drugs must have on file at his/her place of practice a properly prepared written guideline or protocol indicating approval has been granted by a practitioner authorized to prescribe. A copy of the written guideline or protocol must also be on file with the board of pharmacy.”</p>
<p>Immunization CDTA, if applicable:</p>	<p>WAC 246-863-100 “A pharmacist planning to exercise prescriptive authority in his or her practice (see RCW <u>18.64.011(11)</u>) by initiating or modifying drug therapy in accordance with written guidelines or protocols previously established and approved for his or her practice by a practitioner authorized to prescribe drugs must have on file at his/her place of practice a properly prepared written guideline or protocol indicating approval has been granted by a practitioner authorized to prescribe. A copy of the written guideline or protocol must also be on file with the board of pharmacy.”</p>
<p>Prescription Records:</p>	<p>WAC 246-869-100(1) “Records for the original prescription and refill records shall be maintained on the filled prescription or in a separate record book or patient medication record. Such records must be maintained for a period of at least two years and shall be made available for inspection to representatives of the board of pharmacy.”</p>

SELF-INSPECTION DIRECTIONS

Carefully confirm whether or not you are compliant and mark the appropriate box to the left of each item. If you find items that need correcting, rectify the deficiency and write the date of correction and then mark the 'yes' box. Do not mark 'yes' unless the answer is 'yes'. Note: the correct answer to some questions is 'no'.

General Requirements

Yes	No	N/A		Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>		1.	Are you a retail pharmacy? If not, please use the form appropriate for your practice setting. Note: Neither the self-inspection nor a Commission inspection evaluates your complete compliance with all laws and rules of the practice of pharmacy.
<input type="checkbox"/>	<input type="checkbox"/>		2.	Is your 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."
<input type="checkbox"/>	<input type="checkbox"/>		3.	Are your current pharmacist license(s) posted? RCW 18.64.140 "The current license shall be conspicuously displayed to the public in the pharmacy to which it applies."
<input type="checkbox"/>	<input type="checkbox"/>		4.	Is your current inspection certificate posted? WAC 246-869-190(6) "The certificate of inspection must be posted in conspicuous view of the general public and shall not be removed or defaced."
<input type="checkbox"/>	<input type="checkbox"/>		5.	Do you have DEA registration number, did you list it on page 2? WAC 246-887-020(2) "A separate registration is required for each place of business (as defined in section 1301.23) where controlled substances are manufactured, distributed or dispensed."

Ancillary Personnel

Yes	No	N/A		Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	6.	Are your ancillary personnel certification(s) and registration(s) up to date? WAC 246-901-060 "To become certified as a pharmacy technician, an individual must apply to the board for certification." WAC 246-901-080 "Any person desiring registration as a pharmacy assistant shall apply to the board for registration on forms to be supplied by the board."
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	7.	Do you have a pharmacy technician training program approved by the commission? <i>Please attach relevant documentation.</i> WAC 246-901-030(1) "Applicants must obtain education and training from one of the following: (a) Formal academic pharmacy technician training program

					approved by the board. (b) On-the-job pharmacy technician training program approved by the board.”
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8.	Does your ancillary utilization plan limit pharmacy assistants tasks to those not reserved to a pharmacist or pharmacist technician?	WAC 246-901-070 “Pharmacy assistants may perform, under the general supervision of a licensed pharmacist, all duties except those reserved to the pharmacist and the pharmacy technician.”
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	9.	Does your ancillary utilization plan describe the functions a pharmacy technician can perform?	WAC 246-901-020(1) “Pharmacy technicians may perform certain nondiscretionary and specialized functions consistent with their training in pharmacy practice while under the immediate supervision of a licensed pharmacist.” WAC 246-901-100(2)(a) “The application for approval must describe the manner in which the pharmacy technicians will be utilized and supervised, including job descriptions, task analysis or similar type documents that define the duties performed and the conditions under which they are performed, number of positions in each category, as well as other information as may be required by the board.”
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	10.	Are you within the required pharmacist to technician ratio (1:3)?	WAC 246-901-130(1) “A standard ratio of one pharmacist to a maximum of three technicians is established for each licensed pharmacy.”
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	11.	Are all ancillary personnel wearing proper identification?	WAC 246-901-090 “All pharmacy ancillary personnel working within the pharmacy and having contact with patients or the general public shall wear badges or tags clearly identifying them as pharmacy assistants or technicians.”

Patient Health and Safety Requirements

Yes	No	N/A			Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>		12.	Do you have a patient medical record system? Is it automated or manual? _____	WAC 246-875-001 “The purpose of this chapter shall be to insure that a patient medical record system is maintained by all pharmacies and other sites where the dispensing of drugs takes place, in order to insure the health and welfare of the patients served. ... It may be either a manual system or an automated data processing system for the storage and retrieval of prescription and patient information.”
			13.	MANUAL SYSTEMS: Do you patient records include all required information? - Patient full name and address - Serial number assigned to each new prescription - Date of all instances of dispensing a drug	WAC 246-875-030 “A manual patient medication record system consists of the hard copy of the original prescription and a card or filing procedure that contains all data on new and refill prescriptions for a patient. This data must be organized in such a fashion that information relating to all

			<ul style="list-style-type: none"> - The identification of the dispenser who filled the prescription - Name, strength, dosage form, and quantity of drug dispensed - Prescriber's name address, and DEA number where required. 	<p>prescription drugs used by a patient will be reviewed each time a prescription is filled.</p> <p>(1) All manual patient medication record systems must maintain the following information with regard to ambulatory patients:</p> <ul style="list-style-type: none"> (a) Patient's full name and address. (b) A serial number assigned to each new prescription. (c) The date of all instances of dispensing a drug. (d) The identification of the dispenser who filled the prescription. (e) The name, strength, dosage form and quantity of the drug dispensed. (f) The prescriber's name, address and DEA number where appropriate.
		14.	<p>AUTOMATED SYSTEM: Do you patient records include all required information?</p> <ul style="list-style-type: none"> - Patient full name and address - Serial number assigned to each new prescription - Date of all instances of dispensing a drug - The identification of the dispenser who filled the prescription - Name, strength, dosage form, and quantity of drug dispensed - Prescriber's name address, and DEA number where required. - Any refill instructions by the prescriber - Complete directions for use of the drug, which prohibits use of "as directed". - Authorization for other than child-resistant containers, if applicable. 	<p>WAC 246-875-020 "An automated patient medication record system is an electronic system that must have the capability of capturing any data removed on a hard copy of microfiche copy. The hard copy of the original prescription and all documents in the audit trail shall be considered a part of this system.</p> <p>(1) All automated patient medication record systems must maintain the following information with regard to ambulatory patients:</p> <ul style="list-style-type: none"> (a) Patient's full name and address. (b) A serial number assigned to each new prescription. (c) The date of all instances of dispensing a drug. (d) The identification of the dispenser who filled the prescription. (e) The name, strength, dosage form and quantity of the drug dispensed. (f) Any refill instructions by the prescriber. (g) The prescriber's name, address, and DEA number where required. (h) The complete directions for use of the drug. The term "as directed" is prohibited pursuant to RCW 18.64.246 and 69.41.050."
		15.	<p>AUTOMATED SYSTEM: Do you have an auxiliary recordkeeping system in place for new or refill prescription tracking if your system is down?</p>	<p>WAC 246-875-050 "If an automated data processing system is used to maintain a patient's medication record, an auxiliary recordkeeping procedure must be available for use when the automated data system is temporarily inoperative due to scheduled or unscheduled system</p>

				interruption. The auxiliary recordkeeping procedure shall provide for the maintenance of all patient recordkeeping information as required by this chapter.”
<input type="checkbox"/>	<input type="checkbox"/>		16.	Does your record system identify allergies and chronic conditions on all patient records? WAC 246-875-020(1)(i) “Any patient allergies , idiosyncrasies, or chronic condition which may relate to drug utilization. If there is no patient allergy data the pharmacist should indicate none or "NKA" (no known allergy) on the patient medication record.” WAC 246-875-030(1)(g) “Any patient allergies , idiosyncrasies or chronic conditions which may relate to drug utilization. If there is no patient allergy data the pharmacist should indicate none or "NKA" (no known allergy) on the patient medication record.”

Question 12 and 16 – Patient Medical Records – Compliance

Please select 10 patient profiles to confirm compliance, and document below.

	<u>Patient Name</u>	<u>Allergy</u>	<u>Conditions</u>
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			

Yes	No	N/A		Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	17.	Do your pharmacists perform drug utilization reviews for each new prescription? This includes review of WAC 246-875-040 “Upon receipt of a prescription or drug order, a dispenser must examine visually or via an

			patient record to determine the possibility of a clinically significant drug interaction, reaction, or therapeutic duplication.	automated data processing system, the patient's medication record to determine the possibility of a clinically significant drug interaction, reaction or therapeutic duplication, and to determine improper utilization of the drug and to consult with the prescriber if needed." WAC 246-863-095 "(1) A pharmacist's primary responsibility is to ensure patients receive safe and appropriate medication therapy. (2)(e) Interpretation of data in a patient medication record system."
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**Question 17 - Drug Utilization Reviews - Include
(1) Drug-Drug; (2) Duplicate Prescription; (3) Drug-Allergy; & (4) DUR Chronic Conditions (x2)**

Please select 5 different patient profiles to confirm compliance and document below:

	<u>Patient Name</u>	<u>Allergy (Hard Copy v. Profile)</u>	<u>Conditions profile v. system</u>
1.			
2.			
3.			
4.			
5.			

Yes	No	N/A		Rule Reference	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	16.	<p>Do your pharmacists perform patient counseling:</p> <ul style="list-style-type: none"> - New prescriptions - Refill prescriptions <p>Do you have a system in place for ancillary staff to know when counseling should take place?</p>	<p>WAC 246-869-220 "The pharmacist shall directly counsel the patient or patient's agent on the use of drugs or devices." WAC 246-863-095 (2) (b) Consultation with the patient regarding the prescription, both prior to and after the prescription filling and/or regarding any information contained in a patient medication record system provided that this shall not prohibit pharmacy ancillary personnel from providing to the patient or the patient's health care giver certain information where no professional judgment is required such as dates of refills or prescription price information.</p>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	18.	<p>Are all legend drugs dispensed in child-resistant containers? <i>(This includes special packaging used such as customized patient medication packages; blister packs, med-minders, etc.)</i></p>	<p>WAC 246-869-230 "All legend drugs shall be dispensed in a child-resistant container as required by federal law or regulation, including C.F.R. Part 1700 of Title 16, unless: (a) Authorization is received from the prescriber to</p>

			<p>If not, do you have valid patient signed authorizations? _____ Where are these located? _____</p>	<p>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.” WAC 246-869-255 The board approves the use of med-pack containers in the dispensing of prescription drugs within the same pharmacy, provided that: (1) The pharmacy must maintain custody of the original prescription container at the pharmacy; (2) No more than a thirty-one day supply of drugs is packaged; (3) The signature of the patient or the patient's agent is obtained for dispensing in a nonchild resistant container; (4) The container's label bear the following information: (a) Pharmacy name and address; (b) Patient's name; (c) Drug name, strength, quantity; (d) Directions; (e) Serial prescription numbers; date (f) Prescriber's name, and pharmacist's initials.</p>
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Question 18 – Non-Child Resistant Container Authorizations

Please select 5 different patients in the will call section packaged in non-child resistant containers and confirm you have valid authorization records, and document below:

	<u>Patient Name</u>	<u>Authorization</u>	<u>Date</u>
1.			
2.			
3.			
4.			
5.			

<input type="checkbox"/>	<input type="checkbox"/>		19.	<p>Do you have a sign posted in view of patients informing them of generic substitution requirements?</p>	<p>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</p>
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				your doctor. Such substitution, however, may only be made with the consent of your doctor. Please consult your pharmacist or physician for more information.”
<input type="checkbox"/>	<input type="checkbox"/>		20.	Is the telephone number to the nearest poison control center readily available? WAC 246-869-200 “The telephone number of the nearest poison control center shall be readily available.”
<input type="checkbox"/>	<input type="checkbox"/>		21.	Is any of your stock expired? WAC 246-869-150(2) “Dated items—All merchandise which has exceeded its expiration date must be removed from stock.”
<input type="checkbox"/>	<input type="checkbox"/>			Do you have a process in place to check and properly dispose of expired medications? <i>(It’s advised to perform an inventory check for expired medications while filling out this self-inspection report.)</i>
<input type="checkbox"/>	<input type="checkbox"/>		22.	Do you participate in a drug take back program? <i>Please review WAC 246-869-130 for the allowances of return and exchange of drugs, and the commission’s guidance document located on their webpage.</i> WAC 246-869-130 Except as provided in this rule, prescriptions, drugs, medicines, sick room supplies and items of personal hygiene shall not be accepted for return or exchange by any pharmacist or pharmacy after such prescriptions, drugs, medicines, sick room supplies or items of personal hygiene have been taken from the premises where sold, distributed or dispensed. (1) Those drugs and sick room supplies legally dispensed by prescription in unit dose forms or in sealed single or multiple dose ampoules or vials in which the pharmacist can readily determine that entry or attempted entry by any means has not been made and which, in the pharmacist’s professional judgment, meet the standards of the United States Pharmacopeia for storage conditions including temperature, light sensitivity, chemical and physical stability may be returned. (2) Pharmacies serving hospitals and long-term care facilities may accept for return and reuse, unit dose packages or full or partial multiple dose medication cards based on the following criteria; (a) The pharmacist can readily determine that entry or attempt at entry to the unit dose package or blister card has not been made; (b) In the pharmacist’s professional judgment, the unit dose package or full or partial multiple dose medication card meets the standards of the United States Pharmacopeia for storage conditions including temperature, light sensitivity, chemical and physical stability;

					<p>(c) The drug has been stored in such a manner as to prevent contamination by a means that would affect the efficacy and toxicity of the drug;</p> <p>(d) The drug has not come into physical possession of the person for whom it was prescribed and control of the drug being returned is known to the pharmacist to have been the responsibility of a person trained and knowledgeable in the storage and administration of drugs;</p> <p>(e) The drug labeling or packaging has not been altered or defaced so that the identity of the drug, its potency, lot number, and expiration date is retrievable.</p> <p>(f) If the drug is prepackaged, it shall not be mixed with drugs of different lot numbers and/or expiration dates unless the specific lot numbers are retrievable and the expiration dates accompany the drug. If the drug is extemporaneously packaged, it shall not be mixed with drugs of different expiration dates unless the earliest expiration date appears on the label of the drug.</p> <p>(3) This rule shall not include items such as orthopedic appliances, crutches, canes, wheelchairs and other similar items unless otherwise prohibited.</p> <p>(4) Controlled substances shall not be returned to a pharmacy except for destruction in accordance with rules of the drug enforcement administration or the Washington state board of pharmacy.</p>
<input type="checkbox"/>	<input type="checkbox"/>		23.	Do you possess, distribute, or dispense legend drug samples?	WAC 246-877-020 "The possession, distribution or dispensing of legend drug samples by a pharmacy is hereby prohibited. "

Professional Requirements

Yes	No	N/A			Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>		24.	Do you have a copy of the pharmacy law book, either a hard copy or on your internet?	WAC 246-869-180(2) "All pharmacies will have in their possession one up-to-date copy of the state of Washington statutes and rules governing the practice of pharmacy, the sale and dispensing of drugs, poisons, controlled substances, and medicines. Electronic or online versions are acceptable."

<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>		<p>25. Do you have an up-to-date reference source available? What is it? _____</p> <p>Do you fill animal medications? What is your reference resource? _____</p>	<p>WAC 246-869-180(3) All pharmacies shall have up-to-date references in order for the pharmacist(s) to furnish patients and practitioners with information concerning drugs.</p>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<p>26. Are all drugs properly labeled and stored including prepackaged medications, in accordance with federal and state statutes, rules and regulations?</p>	<p>WAC 246-869-150 “(3) All stock and materials on shelves or display for sale must be free from contamination, deterioration and adulteration.</p> <p>(4) All stock and materials must be properly labeled according to federal and state statutes, rules and regulations.</p> <p>(5) Devices that are not fit or approved by the FDA for use by the ultimate consumer shall not be offered for sale and must be removed from stock.</p> <p>(6) All drugs shall be stored in accordance with USP standards and shall be protected from excessive heat or freezing except as those drugs that must be frozen in accordance with the requirements of the label. If drugs are exposed to excessive heat or frozen when not allowed by the requirements of the label, they must be destroyed.”</p>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<p>27. Are components for compounding that do not have an expiration date from the manufacturer or supplier labeled with:</p> <ul style="list-style-type: none"> - The date of receipt - Assigned a conservative expiration date, that does not exceed 3 years after the receipt <p>This date should take into consideration the nature of the component, its degradation mechanism, the packaging/container, and storage conditions.</p>	<p>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.”</p> <p>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.</p>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<p>28. Do you place suitable beyond use date or discard by date on patient prescriptions?</p> <ul style="list-style-type: none"> - Quantity dispensed - Warnings regarding transfer of drugs <p><i>Check will call areas for prescriptions in original packaging to confirm that prescription label expiration</i></p>	<p>WAC 246-869-210 “To every prescription container, there shall be fixed a label or labels bearing the following information:</p> <p>(1) All information as required by RCW 18.64.246, provided that in determining an appropriate period of time for which a prescription drug may be retained by a patient after its dispensing, the dispenser shall take the following</p>

			<p><i>date does not exceed actual manufacturer expiration date.</i></p>	<p>factors into account:</p> <ul style="list-style-type: none"> (a) The nature of the drug; (b) The container in which it was packaged by the manufacturer and the expiration date thereon; (c) The characteristics of the patient's container, if the drug is repackaged for dispensing; (d) The expected conditions to which the article may be exposed; (e) The expected length of time of the course of therapy; <p>and</p> <ul style="list-style-type: none"> (f) Any other relevant factors. <p>The dispenser shall, on taking into account the foregoing, place on the label of a multiple unit container a suitable beyond-use date or discard-by date to limit the patient's use of the drug. In no case may this date be later than the original expiration date determined by the manufacturer.</p> <p>(2) The quantity of drug dispensed, for example the volume or number of dosage units.</p> <p>(3) 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."</p> <p>(4) The information contained on the label shall be supplemented by oral or written information as required by WAC 246-869-220."</p>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<p>29. Do your original prescription records contain:</p> <ul style="list-style-type: none"> - Time of dispensing - Serial number - Date of Dispensing - Initials of the responsible pharmacist on the face of the prescription - Patient's address is readily available to the pharmacist 	<p>WAC 246-869-100 (2) The pharmacist shall be required to insure that the following information be recorded: (a) Original prescription—At the time of dispensing, a serial number, date of dispensing, and the initials of the responsible pharmacist shall be placed on the face of the prescription. The patient's address must be readily available to the pharmacist, either from the face of the prescription, a record book, patient medication record, or hospital or clinic record.</p>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<p>30. Do you have refill prescription authorizations?</p> <p>Do your refill prescription records contain:</p> <ul style="list-style-type: none"> - Time of dispensing - Date of refilling - Quantity of the drug (if other than original) - Name of authorizing person (if other than original) 	<p>WAC 246-869-100(2) (b) Refill prescription authorization—Refills for prescription for legend drugs must be authorized by the prescriber prior to the dispensing of the refill prescription. (c) Refill prescription—At the time of dispensing, the date of refilling, quantity of the drug (if other than original), the name of authorizing person (if other than original), and the initials of the responsible pharmacist shall be recorded on</p>

				Initials of the responsible pharmacist is on the back of prescription or in a separate record book or patient medication record	the back side of the prescription, or in a separate record book or patient medication record.
Yes	No	N/A			Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	31.	<p>TRANSFERRING PRESCRIPTION: When transferring original prescription information for a non-controlled legend drug for the purpose of refill dispensing, do you:</p> <ul style="list-style-type: none"> - Communicate directly with the pharmacist receiving the transfer. - Record in the patient medication record system that a copy has been issued. - Record in the patient medication record system the name and address of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescription information. 	<p>WAC 246-869-090(1) "The transfer is communicated directly between two licensed pharmacists and the transferring pharmacist records the following information:</p> <ul style="list-style-type: none"> (a) Record in the patient medication record system that a copy has been issued. (b) Record in the patient medication record system the name and address of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescription information.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	32.	<p>RECEIVING A TRANSFERRED PRESCRIPTION: When a pharmacist receives a transferred prescription, do they:</p> <ul style="list-style-type: none"> - Write "TRANSFER" on the face of the transferred prescription - Provide all information required to be on the prescription: <ul style="list-style-type: none"> o Patient Name and Address o Prescriber's name and address o Date of issuance of original prescription o Number of refills remaining and date of last refill o Pharmacy's name, address, and original prescription number of the transferring pharmacy o Name of the transferor pharmacy 	<p>WAC 246-869-090(2) "The pharmacist receiving the transferred prescription information shall reduce to writing the following:</p> <ul style="list-style-type: none"> (a) Write the word "TRANSFER" on the face of the transferred prescription. (b) Provide all information required to be on the prescription - patient's name and address; prescriber's name and address, and also include: <ul style="list-style-type: none"> (i) Date of issuance of original prescription. (ii) Number of valid refills remaining and date of last refill. (iii) The pharmacy's name, address, and original prescription number from which the prescription information was transferred. (iv) Name of transferor pharmacist. (c) Both the original and transferred prescription must be maintained as if they were original prescriptions. (d) A transferred prescription may not be refilled after one year from the date the original was issued. (e) The above subsections apply to the transfer of prescription information for noncontrolled substances. The transfer of controlled substance prescription information must conform to the requirements of 21 C.F.R. 1306.25."

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	33.	Do all of your prescriptions contain an instruction on whether or not a therapeutically equivalent generic drug or interchangeable biological produce may be substituted in its place? <i>This is not necessary if substitution is permitted by a prior-consent authorization.</i>	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."
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Facilities

Yes	No	N/A			
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	34.	Are your hours permanently displayed next to the pharmacy or adjacent to the entrance?	WAC 246-869-020(8) "A pharmacy must prominently display in a permanent manner on or adjacent to its entrance the times that it is open for business."
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	35.	If applicable, do you have a mail slot or drop box for prescription drop offs outside of pharmacy hours?	WAC 246-869-020(3) "Written prescription orders and refill request can be delivered to a pharmacy at any time. But if no pharmacist is present then the prescription orders must be deposited, by the patient or his agent delivering the prescription order or refill request to the establishment, into a "mail slot" or "drop box" such that the prescription order is stored in the pharmacy area. The times that the pharmacy is open for business must be so displayed that they are prominently visible to the person depositing the prescription orders."

Yes	No	N/A			Rule Reference
			36.	If you located in a larger mercantile building are your	WAC 246-869-020(8) "If a pharmacy is located within a

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		hours posted at the pharmacy and permanently outside?	larger mercantile establishment having hours of operation different from the pharmacy then the pharmacy times of being open for business shall be prominently displayed in a permanent manner at the pharmacy area and on or adjacent to the entrance to the mercantile establishment.” WAC 246-869-020(6) “Any pharmacy having hours differing from the remainder of an establishment shall have a separate and distinct telephone number from that business establishment. The phone shall not be answerable in the remainder of the establishment unless all conversations, when the pharmacist is absent, are recorded and played back by the pharmacist.”
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Separate phone line for the pharmacy?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	37.	Is the pharmacy area where drugs are secured and stored restricted from access from the public?	WAC 246-869-160(7) “The prescription department shall be situated so that the public shall not have free access to the area where legend drugs, controlled substances, poisons, or other restricted items are stored, compounded or dispensed.”
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		Are deliveries stored within the secured pharmacy area?	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	38.	Does your pharmacy meeting the following facility requirements: <ul style="list-style-type: none"> - Have proper lighting - Well ventilated, with a constant flow of air throughout the work area - Minimum of 3 linear feet by 18 inch deep counter working space, with space for each person filing prescriptions - Prescription counter is not cluttered 	WAC 246-869-160 “(1) The prescription department shall be well lighted (adequately to allow any person with normal vision to read a label without strain, 30-50 foot candles). (2) The prescription department shall be well ventilated. There shall be a constant flow of air through the area. (3) There shall be a minimum of three linear feet by a minimum of 18 inches in depth of counter working space for each pharmacist or intern compounding or filling prescriptions at the same time. (4) The prescription counter shall be uncluttered and clean at all times. Only those items necessary to the filling of prescriptions shall be thereon. (Profile systems are excepted.)”
<input type="checkbox"/>	<input type="checkbox"/>		39.	Do you have a properly operational sink, both hot and cold running water?	WAC 246-869-160(5) “There shall be a sink with hot and cold running water in the prescription compounding area.”
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	40.	Are your refrigerators temperatures maintained between 2-8°C (36-46°F)?	WAC 246-869-160(6) “There shall be refrigeration facilities with a thermometer in the prescription compounding area for the storage of pharmaceutical items requiring refrigeration. USP standards of refrigeration require that the temperature be maintained between two degrees and eight degrees Centigrade (36 degrees and 46 degrees Fahrenheit). A locked refrigerator in the immediate
<input type="checkbox"/>	<input type="checkbox"/>			Is your freezer between -25°& 10°C (-13° & 14°F)	

				vicinity of the prescription department will meet the requirements of this paragraph.” 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 Chapter 32 10.30.10 “Freezer indicates a place where the temperature is maintained thermostatically between -25C and -10C (-13F and 14 F)”
<input type="checkbox"/>	<input type="checkbox"/>		41.	Are there adequate trash receptacles? WAC 246-869-170(2) “Adequate trash receptacles shall be available, both in the prescription compounding and in the retail areas.”
<input type="checkbox"/>	<input type="checkbox"/>		42.	Is there a restroom located in the pharmacy? If yes, does it have an operational sink, with hot and cold running water, it is clean and sanitary? WAC 246-869-170(3) “If a restroom is provided, there must be a sink with hot and cold running water, soap and towels, and the toilet must be clean and sanitary.”
<input type="checkbox"/>	<input type="checkbox"/>		43.	Are the walls, ceilings, floors and windows shall be clean, free from cracked and peeling paint or plaster, and in general good repair and order. WAC 246-869-170(1) “The walls, ceilings, floors and windows shall be clean, free from cracked and peeling paint or plaster, and in general good repair and order.”
<input type="checkbox"/>	<input type="checkbox"/>		44.	Does your facility have all the necessary equipment and supplies necessary for the practice of pharmacy? All equipment must be in good repair. WAC 246-869-180 “(1) All pharmacies shall have in their possession the equipment and supplies necessary to compound, dispense, label, administer and distribute drugs and devices. The equipment shall be in good repair and shall be available in sufficient quantity to meet the needs of the practice of pharmacy conducted therein. (2) All pharmacies will have in their possession one up-to-date copy of the state of Washington statutes and rules governing the practice of pharmacy, the sale and dispensing of drugs, poisons, controlled substances, and medicines. Electronic or online versions are acceptable. (3) All pharmacies shall have up-to-date references in order for the pharmacist(s) to furnish patients and practitioners with information concerning drugs.”

Non-Sterile Compounding (Need to create questions)

Yes	No	N/A	45.	WAC 246-878-020 (1) Based on the existence of a pharmacist/patient/prescriber relationship and the presentation of a valid prescription, or in anticipation of prescription drug orders based on routine, regularly
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				<p>observed prescribing patterns, pharmacists may compound, for an individual patient, drug products that are commercially available in the marketplace.</p> <p>(5)The distribution of inordinate amounts of compounded products without a prescriber/patient/pharmacist relationship is considered manufacturing.</p>
			46.	<p>WAC 246-878-030 (1) The pharmacist has the responsibility and authority to inspect and approve or reject all components, drug product containers, closures, in-process materials, and labeling; and the authority to prepare and review all compounding records to assure that no errors have occurred in the compounding process. The pharmacist is also responsible for the proper maintenance, cleanliness, and use of all equipment used in prescription compounding practice.</p> <p>(2) Pharmacists who engage in drug compounding, and level A pharmacy assistants, supervised by pharmacists, who assist in drug compounding, shall be competent and proficient in compounding and shall maintain that proficiency through current awareness and training. Every pharmacist who engages in drug compounding and any level A pharmacy assistant who assists in compounding, must be aware of and familiar with all details of these good compounding practices.</p> <p>(3) Pharmacy personnel engaged in the compounding of drugs shall wear clean clothing appropriate to the operation being performed. Protective apparel, such as coats/jackets, aprons, gowns, hand or arm coverings, or masks shall be worn as necessary to protect personnel from chemical exposure and drug products from contamination.</p> <p>(4) Only personnel authorized by the responsible pharmacist shall be in the immediate vicinity of the drug compounding operation. Any person shown at any time (either by medical examination or pharmacist determination) to have an apparent illness or open lesions that may adversely affect the safety or quality of a drug product being compounded shall be excluded from direct contact with components, drug product containers, closures, in-process materials, and drug products until the condition is corrected or determined by competent medical</p>

				<p>personnel not to jeopardize the safety or quality of the products being compounded. All personnel who assist the pharmacist in compounding procedures shall be instructed to report to the pharmacist any health conditions that may have an adverse effect on drug products.</p>
			47.	<p>WAC 246-878-040 Facilities.</p> <p>(1) Pharmacies engaging in compounding shall have an adequate area for the orderly compounding of prescriptions, including the placement of equipment and materials. The drug compounding area for sterile products shall be separate and distinct from the area used for the compounding of nonsterile drug products. The area(s) used for compounding of drugs shall be maintained in a good state of repair.</p> <p>(2) Bulk drugs and other chemicals or materials used in the compounding of drugs must be stored in adequately labeled containers in a clean, dry area or, if required, under proper refrigeration.</p> <p>(3) Adequate lighting and ventilation shall be provided in all drug compounding areas. Potable water shall be supplied under continuous positive pressure in a plumbing system free of defects that could contribute contamination to any compounded drug product. Adequate washing facilities, easily accessible to the compounding area(s) of the pharmacy shall be provided. These facilities shall include, but not be limited to, hot and cold water, soap or detergent, and air driers or single-use towels.</p> <p>(4) The area(s) used for the compounding of drugs shall be maintained in a clean and sanitary condition. It shall be free of infestation by insects, rodents, and other vermin. Trash shall be held and disposed of in a timely and sanitary manner. Sewage and other refuse in and from the pharmacy and immediate drug compounding area(s) shall be disposed of in a safe and sanitary manner.</p>
			48.	<p>WAC 246-878-070 Special precaution products.</p> <p>If drug products with special precautions for contamination, such as penicillin, are involved in a compounding operation, appropriate measures, including either the dedication of equipment for such operations or the meticulous cleaning of contaminated equipment prior to its use for preparation of other drugs, must be utilized in</p>

					order to prevent cross-contamination.
			49.		<p>WAC 246-878-080 Equipment.</p> <p>(1) Equipment used in the compounding of drug products shall be of appropriate design, appropriate capacity, and suitably located to facilitate operations for its intended use and for its cleaning and maintenance. Equipment used in the compounding of drug products shall be suitable composition so that surfaces that contact components, in-process materials, or drug products shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug product beyond that desired.</p> <p>(2) Equipment and utensils used for compounding shall be cleaned and sanitized immediately prior to use to prevent contamination that would alter the safety, identity, strength, quality, or purity of the drug product beyond that desired. In the case of equipment, utensils, and containers/closures used in the compounding of sterile drug products, cleaning, sterilization, and maintenance procedures as set forth in WAC 246-871-080.</p> <p>(3) Equipment and utensils used for compounding drugs must be stored in a manner to protect them from contamination. Immediately prior to the initiation of compounding operations, they must be inspected by the pharmacist and determined to be suitable for use.</p> <p>(4) Automatic, mechanical, electronic, or other types of equipment other than commercial scale manufacturing or testing equipment, may be used in the compounding of drug products. If such equipment is used, it shall be routinely inspected, calibrated (if necessary), or checked to ensure proper performance.</p>
			50.		<p>WAC 246-878-090 Control of components and drug product containers and closures.</p> <p>(1) Components, drug product containers, closures, and bagged or boxed components of drug product containers and closures used in the compounding of drugs shall be handled and stored in a manner to prevent contamination and to permit unhindered cleaning of the work area (e.g., floors) and inspection.</p> <p>(2) Drug product containers and closures shall not be reactive, additive, or absorptive so as to alter the safety,</p>

				<p>identity, strength, quality, or purity of the compounded drug beyond the desired result. Components, drug product containers, and closures for use in the compounding of drug products shall be rotated so that the oldest stock is used first. Container closure systems shall provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the compounded drug product. Drug product containers and closures shall be clean and, where indicated by the intended use of the drug, sterilized and processed to remove pyrogenic properties to assure that they are suitable for their intended use.</p> <p>(3) Drug product containers and closures intended for the compounding of sterile products must be handled, sterilized, processed and stored to remove pyrogenic properties to assure that they are suitable for their intended purpose. Methods of cleaning, sterilizing, and processing to remove pyrogenic properties shall be written and followed for drug product containers and closures used in the preparation of sterile pharmaceuticals. These processes shall be performed by pharmacists, or under the pharmacist's supervision.</p>
		51.		<p>WAC 246-878-100 Drug compounding controls.</p> <p>(1) There shall be written procedures for the compounding of drug products to assure that the finished products have the identity, strength, quality, and purity they purport or are represented to possess. Such procedures shall include a listing of the components (ingredients), their amounts (in weight or volume), the order of component mixing, and a description of the compounding process. All equipment and utensils and the container/closure system, relevant to the sterility and stability of the intended use of the drug, shall be listed. These written procedures shall be followed in the execution of the drug compounding procedure.</p> <p>(2) Components for drug product compounding shall be accurately weighed, measured, or subdivided as appropriate. These operations should be checked and rechecked by the compounding pharmacist at each stage of the process to ensure that each weight or measure is correct as stated in the written compounding procedures. If a component is transferred from the original container to</p>

				<p>another (e.g., a powder is taken from the original container, weighed, placed in a container, and stored in another container), the new container shall be identified with the:</p> <ul style="list-style-type: none"> (a) Component name; and (b) Weight or measure. <p>(3) To assure the reasonable uniformity and integrity of compounded drug products, written procedures shall be established and followed that describe the tests or examinations to be conducted on the product compounded (e.g., degree of weight variation among capsules.) Such control procedures shall be established to monitor the output and to validate the performance of those compounding processes that may be responsible for causing variability in the final drug product. Such control procedures shall include, but are not limited to, the following (where appropriate):</p> <ul style="list-style-type: none"> (a) Capsule weight variation; (b) Adequacy of mixing to assure uniformity and homogeneity; (c) Clarity, completeness, or pH of solutions. <p>(4) Appropriate written procedures designed to prevent microbiological contamination of compounded drug products purporting to be sterile shall be established and followed. Such procedures shall include validation of any sterilization process.</p>
			52.	<p>WAC 246-878-110 Labeling control of excess products.</p> <p>(1) In the case where a quantity of compounded drug product in excess of that to be initially dispensed in accordance with WAC 246-878-020 is prepared, the excess product shall be labeled or documentation referenced with the complete list of ingredients (components), the preparation date, and the assigned beyond-use date based upon the pharmacist's professional judgment, appropriate testing, or published data. It shall also be stored and accounted for under conditions dictated by its composition and stability characteristics (e.g., in a clean, dry place on shelf or in the refrigerator) to ensure its strength, quality, and purity.</p>
			53.	<p>WAC 246-878-120 Records and reports.</p> <p>(1) Any procedures or other records required to be maintained in compliance with this chapter shall be</p>

					<p>retained for the same period of time as required in WAC 246-869-100 for the retention of prescription files.</p> <p>(2) All records required to be retained under this chapter, or copies of such records, shall be readily available for authorized inspection during the retention period at the establishment where the activities described in such records occurred. These records or copies thereof shall be subject to photocopying or other means of reproduction as part of any such inspection.</p> <p>(3) Records required under this chapter may be retained either as the original records or as true copies, such as photocopies, microfilm, microfiche, or other accurate reproductions of the original records.</p>
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Other Areas of Non-Compliance

The Commission and its investigators reserve the right to note areas of non-compliance not specifically identified above on this self-inspection form. If an investigator identifies an issue of non-compliance they will note it in the section below and it will be included in a Notice of Deficiency.

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