Washington State Pharmacy Quality Assurance Commission
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READ THIS PAGE CAREFULLY

2018 RESPONSIBLE MANAGER GENERAL PHARMACY SELF-INSPECTION WORKSHEET

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 annual worksheet and applicable self-inspection worksheet addendums 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 worksheet(s), please review it with your staff pharmacists, ancillary staff and interns, correct any deficiencies noted, sign and date the worksheet(s), and file it so it will be readily available to Commission inspectors. DO NOT SEND to the Commission office. You are responsible for ensuring your completed worksheet(s) is available at the time of inspection.

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

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

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

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

2018 RESPONSIBLE MANAGER
GENERAL PHARMACY SELF-INSPECTION WORKSHEET
WA Pharmacy Quality Assurance Commission
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All responsible managers of pharmacies MUST complete and sign this self-inspection worksheet 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). This worksheet focuses on **community/retail practice**, but includes regulations applicable across all areas of pharmacy. **DO NOT SEND TO THE COMMISSION OFFICE.**

In addition to this worksheet, if you engage in more than one type of pharmacy, identified below, you must complete all addendum worksheets associated with that practice.

Type of Pharmacy: ☐ Hospital ☐ Nuclear ☐ Sterile-Compounding

☐ Long-term Care (Closed door, or supply drugs for residents of long-term care facilities or hospice programs.)

Date responsible manager inspection was performed: _____

Form completed after 3/31/2018. ☐ Change in responsible manager ☐ Other, please explain _____

Signature of responsible manager: _____

Print Name & License #: _____

Responsible Manager Work E-mail *(optional)*: _____

Pharmacy: _____ Telephone: _____ Fax: _____

Address: _____ DEA #: _____ Expiration: _____

Pharmacy License #: _____

Endorsements: ☐ Use of Ancillary Personnel ☐ Differential Hours ☐ Dispense Controlled Substances

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 Self-Inspection Worksheet for last 2 years Location:	**WAC 246-869-190(1)** "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 Location:	**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. **21 CFR 1304.11(c)** "After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date." ***See also WAC 246-887-200(4)*** .
Schedule II Invoices for the last 2 years Location:	**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. 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."

	Rule Reference
Schedule III-V Invoices for the last 2 years Location:	**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. 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 from the business records of the registrant."
Completed CII order forms (DEA Form 222) and/or finalized CSOS documentation for the last 2 years Location:	**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 69.50.306." **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." **21 CFR 1305.22(g)** "When a purchaser receives a shipment, the purchaser must create a record of the quantity of each item received and the date received. The record must be electronically linked to the original order and archived."
Completed loss by theft or destruction forms (DEA Form 106) for the last 2 years Location:	**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;" **21 CFR 1301.76(b)** "The registrant shall notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft. The registrant shall also complete, and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft."
Power of Attorney for staff authorized to order controlled substances Location:	**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 69.50.306." **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."

	Rule Reference
Ancillary Utilization Plan Location:	**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." **WAC 246-901-100(2)(a)** "A copy of the utilization plan must be maintained in the pharmacy."
Technician training documents, if applicable Location:	**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." **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."
Collaborative Drug Therapy Agreement(s) (CDTA), including Immunization CDTAs, if applicable Location:	**WAC 246-863-100** "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."
Prescription Records for the last 2 years Location:	**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."

Yes	No	N/A	#		Rule Reference	Notes/Corrective Actions
				General Requirements		
			1	Is the current pharmacy license posted?	**RCW 18.64.043(3)** "It shall be the duty of the owner to immediately notify the commission of any change of location, ownership, or licensure and to keep the license of location or the renewal thereof properly exhibited in said pharmacy."	
			2	Are the pharmacist license(s) posted and up to date?	**RCW 18.64.140** "The current license shall be conspicuously displayed to the public in the pharmacy to which it applies."	
			3	Does the pharmacy have a DEA registration number, is it listed on page 2 of this document?	**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		
			4	Are ancillary personnel certification(s) and registration(s) up to date? *Please provide documentation of a regular staff roster with credential and expiration date.*	**WAC 246-901-060** "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."	
			5	Are pharmacy assistants adhering to the Commission approved ancillary utilization plan?	**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."	
			6	Are pharmacy technicians adhering to the Commission approved ancillary utilization plan?	**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."	

Yes	No	N/A	#		Rule Reference	Notes/Corrective Actions
			7	Is the pharmacy approved for pharmacy technicians to perform specialized functions?	**WAC 246-901-100(2)(b)** "Specialized function. The utilization plan for pharmacy technicians performing specialized functions. The utilization plan must include: **(i)** The criteria for selection of pharmacy technicians to perform specialized functions; **(ii)** A description of the methods of training and of initial demonstration of proficiency; **(iii)** A copy of the part of the section of the pharmacy's quality assurance plan related to pharmacy technician specialized functions; **(iv)** Other information that may be required by the board."	
			8	Is the pharmacy within the required pharmacist to technician ratio, or as otherwise authorized? **The ratio includes pharmacy assistants currently enrolled in a technicians in training.**	**WAC 246-901-130(1)** "A standard ratio of one pharmacist to a maximum of three technicians is established for each licensed pharmacy." **RCW 18.64A.040(3)** The commission may by rule modify the standard ratios set out in subsection (2) of this section governing the utilization of pharmacy technicians by pharmacies and pharmacists. Should a pharmacy desire to use more pharmacy technicians than the standard ratios, the pharmacy must submit to the commission a pharmacy services plan for approval.	
			9	Are all ancillary personnel wearing proper identification as required?	**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."	
Prescription Record Requirements ***Please perform appropriate audits on pages 20-21***						
				A patient medical record system is required, it may be automated, manual or a combination. *** If a system is part automated and part manual, each part of the system must meet the respective requirements outlined in questions 10-13. ***	**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."	

Yes	No	N/A	#		Rule Reference	Notes/Corrective Actions
			10	For MANUAL patient record system: Do 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 - Name, strength, dose, and quantity of drug dispensed - Prescriber's name address, and DEA number where required.	**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 prescription drugs used by a patient will be reviewed each time a prescription is filled. **(1)** All manual patient medication record systems must maintain the following information with regard to ambulatory patients: **(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."	
			11	For AUTOMATED patient record system: Do 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 - 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.	**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. **(1)** All automated patient medication record systems must maintain the following information with regard to ambulatory patients: **(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."	

Yes	No	N/A	#		Rule Reference	Notes/Corrective Actions
			12	For automated patient record systems, is an auxiliary recordkeeping system in place for new or refill prescription tracking if automated systems are down?	**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. The auxiliary recordkeeping procedure shall provide for the maintenance of all patient recordkeeping information as required by this chapter."	
			13	Does your record system identify allergies and chronic conditions on all patient records?	**WAC 246-875-020(1)(i) and WAC 246-875-030(1)(g)** "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."	
			14	Do you fill prescriptions for residents of a long term care facility or hospice program based on chart orders?	**RCW 18.64.550 "(1)** A chart order must be considered a prescription if it contains…"	
			15	If yes to question 14, do the chart orders include: - Patient's full name - Date order was issued - Name, strength, and dosage form of drug - Directions for use; and - Authorized Signature **Quantity is not required, and authorized signature may be the practitioner's agent.**	**RCW 18.64.550 (1)** A chart order must be considered a prescription if it contains: **(a)** The full name of the patient; **(b)** The date of issuance; **(c)** The name, strength, and dosage form of the drug prescribed; **(d)** Directions for use; and **(e)** An authorized signature: **(i)** For written orders, the order must contain the prescribing practitioner's signature or the signature of the practitioner's authorized agent, including the name of the prescribing practitioner; or **(ii)** For electronic or digital orders, the order must contain the prescribing practitioner's electronic or digital signature, or the electronic or digital signature of the practitioner's authorized agent, including the name of the prescribing practitioner.	

Yes	No	N/A	#		Rule Reference	Notes/Corrective Actions
			16	Do 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** "Upon receipt of a prescription or drug order, a dispenser must examine visually or 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." **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."	
			17	Do pharmacists perform patient counseling: - New prescriptions - Refill prescriptions	**WAC 246-869-220** "The pharmacist shall directly counsel the patient or patient's agent on the use of drugs or devices." ***See PQAC Policy #52 Patient Counseling****	
			18	Is there a system in place for ancillary staff to know when counseling should take place?	**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."	

Yes	No	N/A	#		Rule Reference	Notes/Corrective Actions
			19	Are all legend drugs dispensed in child-resistant containers? *(This includes special packaging used such as customized patient medication packages; blister packs, med-minders, etc.)* If not, does the pharmacy have valid patient signed authorizations? _____ Where are these located? _____ *** Best practice recommendation: It is recommended that these authorizations are updated annually. **	**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 (nonchild-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. **WAC 246-869-255** The board approves the use of medpack 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."	

Yes	No	N/A	#		Rule Reference	Notes/Corrective Actions
			20	Is a sign posted in view of patients informing them of generic substitution requirements?	**RCW 69.41.160** "Every pharmacy shall post a sign in a location at the prescription counter that is readily visible to patrons stating, 'Under Washington law, a less expensive interchangeable biological product or equivalent drug may in some cases be substituted for the drug prescribed by your doctor. Such substitution, however, may only be made with the consent of your doctor. Please consult your pharmacist or physician for more information.'"	
			21	Is the telephone number to the nearest poison control center readily available, either posted or available online?	**WAC 246-869-200** "The telephone number of the nearest poison control center shall be readily available."	
			22	Is all merchandise in date?	**WAC 246-869-150(2)** "Dated items—All merchandise which has exceeded its expiration date must be removed from stock." *Including OTC medications anywhere within the store, not solely behind the counter.*	
			23	Is there a process in place to check and properly dispose of expired medications? **It's advised to perform an inventory check for expired medications while filling out this self-inspection report.**	**WAC 246-869-150(2)** "Dated items—All merchandise which has exceeded its expiration date must be removed from stock." *Including OTC medications anywhere within the store, not solely behind the counter.*	
			24	Does the pharmacy participate in a drug take back program? *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.*	**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.	
			25	Does the pharmacy 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**."	

Yes	No	N/A	#		Rule Reference	Notes/Corrective Actions
Professional Requirements						
			26	Is there access to up-to-date copies of the state of Washington statutes and rules governing the practice of pharmacy? (Electronic or online access is acceptable.)	**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	Does the pharmacy have up-to-date reference sources available, electronic resources are acceptable? Give Examples:_____	**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	Does the pharmacy fill prescriptions for animals? What are your up-to-date reference resources for these prescriptions? _____ ** Best practice recommendation: It is recommended you have species specific reference resources when filling prescriptions for animals. It is also recommended if you perform compounding to have USP reference resources.**	**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."	
			29	Are all drugs properly labeled and stored including prepackaged medications, in accordance with federal and state statutes, rules and regulations?	**WAC 246-869-150 (3)** "All stock and materials on shelves or display for sale must be free from contamination, deterioration and adulteration. **(4)** All stock and materials must be properly labeled according to federal and state statutes, rules and regulations. **(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. **(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."	

Yes	No	N/A	#		Rule Reference	Notes/Corrective Actions
			30	Are components for compounding that do not have an expiration date from the manufacturer or supplier labeled with: - The date of receipt - Assigned a conservative expiration date, that does not exceed 3 years after the receipt This date should take into consideration the nature of the component, its degradation mechanism, the packaging/container, and storage conditions.	**RCW 18.64.270(2)** "Any medicinal products that are compounded for patient administration or distribution to a licensed practitioner for patient use or administration shall, at a minimum, meet the standards of the official United States pharmacopeia as it applies to nonsterile products and sterile administered products." **USP 795 Component Selection, Handling, and Storage** "For components that do not have expiration dates assigned by the manufacturer or supplier, the compounder shall label the container with the date of receipt and assign a conservative expiration date, not to exceed three years after receipt, to the component based on the nature of the component and its degradation mechanism, the container in which it is packaged, and the storage conditions."	
			31	Are suitable beyond use date or discard by date placed on patient prescriptions? - Quantity dispensed - Warnings regarding transfer of drugs *Check will call areas for prescriptions in original packaging to confirm that prescription label expiration date does not exceed actual manufacturer expiration date.*	**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 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 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. *(Citation continues on next page).*	

Yes	No	N/A	#		Rule Reference	Notes/Corrective Actions
			Question 31 Citation Continued		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. (2) The quantity of drug dispensed, for example the volume or number of dosage units. (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. (4) The information contained on the label shall be supplemented by oral or written information as required by WAC 246-869-220."	
			32	Do original prescription records contain: - 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	**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."	
			33	Does the pharmacy have refill prescription authorizations?	**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."	
			34	Do refill prescription records contain: - Date of refilling - Quantity of the drug (if other than original) - Name of authorizing person (if other than original) - Initials of the responsible pharmacist is on the back of prescription or in a separate record book or patient medication record	**WAC 246-869-100(2)(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 the back side of the prescription, or in a separate record book or patient medication record."	

Yes	No	N/A	#		Rule Reference	Notes/Corrective Actions
			35	TRANSFERRING PRESCRIPTION: When transferring original prescription information for a non-controlled legend drug for the purpose of refill dispensing, does a pharmacist: - 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)** "The transfer is communicated directly between two licensed pharmacists and the transferring pharmacist records the following information: **(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."	
			36	RECEIVING A TRANSFERRED PRESCRIPTION: When a pharmacist receives a transferred prescription, do they: - Write "TRANSFER" on the face of the transferred prescription - Provide all information required to be on the prescription: 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)** "The pharmacist receiving the transferred prescription information shall reduce to writing the following: **(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: **(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."	

Yes	No	N/A	#		Rule Reference	Notes/Corrective Actions
			37	Do all of prescriptions contain an instruction on whether or not a therapeutically equivalent generic drug or interchangeable biological product may be substituted in its place? *This is not necessary if substitution is permitted by a prior consent authorization.*	**RCW 69.41.120(1)** "Every drug prescription shall contain an instruction on whether or not a therapeutically equivalent generic drug or interchangeable biological product may be substituted in its place, unless substitution is permitted under a prior consent authorization. If a written prescription is involved, the prescription must be legible and the form shall have two signature lines at opposite ends on the bottom of the form. Under the line at the right side shall be clearly printed the words "DISPENSE AS WRITTEN." Under the line at the left side shall be clearly printed the words "SUBSTITUTION PERMITTED." The practitioner shall communicate the instructions to the pharmacist by signing the appropriate line. No prescription shall be valid without the signature of the practitioner on one of these lines. In the case of a prescription issued by a practitioner in another state that uses a one-line prescription form or variation thereof, the pharmacist may substitute a therapeutically equivalent generic drug or interchangeable biological product unless otherwise instructed by the practitioner through the use of the words "dispense as written," words of similar meaning, or some other indication."	
<u>Facilities</u>						
			38	If the pharmacy is located in a larger mercantile building, are the pharmacy hours permanently displayed at the pharmacy **and** permanently outside at all entrances?	**WAC 246-869-020(8)** "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."	
			39	If the pharmacy is located in a larger mercantile building, is there a separate phone line for the pharmacy?	**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."	

Yes	No	N/A	#		Rule Reference	Notes/Corrective Actions
			40	If applicable, does the pharmacy 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."	
			41	Is the pharmacy area where drugs are secured and stored restricted from access from the public? Are deliveries stored within the secured pharmacy area?	**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."	
			42	Does the pharmacy meet the following facility requirements: - 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 filling 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.)"	
			43	Does the pharmacy have a properly operating sink, with 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."	
			44	Are refrigerators temperatures maintained between 2-8°C (36-46°F)? *** Electronic monitoring is acceptable. **	**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."	

Yes	No	N/A	#		Rule Reference	Notes/Corrective Actions
			45	Are freezers between -25°& -10°C (-13° & 14°F)?	**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 -25°C and -10°C (-13°F and 14°F)"	
			46	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."	
			47	If there is a restroom located in the pharmacy, does it have an operating sink, with hot and cold running water, 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."	
			48	Are the walls, ceilings, floors, and windows 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."	
			49	Does the pharmacy 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."	

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 on the inspection report.

Question 10 through 13 – Patient Medical Records – Compliance *Please audit 10 patient profiles to confirm compliance, and document below.*			
	Rx#	*Allergy*	*Conditions*
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			

Question 16 – Drug Utilization Reviews – Include (1) Drug-Drug; (2) Duplicate Prescription; (3) Drug-Allergy; & (4) DUR Chronic Conditions (x2) *Please audit 5 different patient profiles to confirm compliance and document below:*			
	Rx#	*Allergy (Hard Copy v. Profile)*	*Conditions*
1			
2			
3			
4			
5			

Question 19 – Non-Child Resistant Container Authorizations *Please audit 5 different patients in the will call section packaged in non-child resistant containers and confirm you have valid authorization records, and document below:*			
	Rx#	*Allergy (Hard Copy v. Profile)*	*Conditions*
1			
2			
3			
4			
5			