



Read this Page Carefully

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

Attention: Responsible Pharmacy Manager or Equivalent Manager

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

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

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

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

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

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

Questions highlighted in **blue** are questions that will be focused on during routine pharmacy inspections.

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



2023 Hospital Pharmacy and HPAC Self-Inspection Worksheet

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

Date responsible pharmacy manager inspection was performed: _____

Change in responsible pharmacy manager and effective date of change: _____ Date: _____

Print Name of Responsible Pharmacy Manager & License #: _____

Signature of responsible manager: _____

Responsible Pharmacy Manager E-mail: _____

Pharmacy: _____ Fax: _____ DEA #: _____

Telephone: _____ Address: _____ Pharmacy License #: _____

Endorsements: Use of Ancillary Personnel Dispense Controlled Substances

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

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

Yes	No	
<input type="checkbox"/>	<input type="checkbox"/>	Are you a hospital pharmacy? If yes, you must *only* complete the 2023 Hospital Pharmacy and HPAC Self-Inspection Worksheet, unless you answer yes to any of the following.

If you practice or provide any other pharmaceutical services outside of community pharmacy you must answer the following and perform the appropriate self-inspection addendums.

<input type="checkbox"/>	<input type="checkbox"/>	Does the pharmacy engage in non-sterile compounding of medications? If yes, please complete the 2023 Non-Sterile Compounding Self-Inspection Addendum <u>in addition</u> to the Hospital Pharmacy and HPAC Self-Inspection Worksheet.
--------------------------	--------------------------	--

2023 Hospital Pharmacy and HPAC Self-Inspection Worksheet

<input type="checkbox"/>	<input type="checkbox"/>	<p>Does the pharmacy engage in sterile compounding? If yes, you must also complete the 2023 Sterile Compounding Self-Inspection Addendum <u>in addition</u> to the Hospital Pharmacy and HPAC Self-Inspection Worksheet.</p>
<input type="checkbox"/>	<input type="checkbox"/>	<p>Do you have an endorsement as a Nuclear Pharmacy? If yes, you must also complete the 2023 Nuclear Pharmacy Self-Inspection Addendum.</p>

Document and Record Review

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

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

2023 Hospital Pharmacy and HPAC Self-Inspection Worksheet

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

Compliant			#	Rule Reference	Notes/Corrective Actions
Yes	No	N/A			
General Requirements					
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	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."	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	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."	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	3.	Does the pharmacy have a DEA registration number, is it listed on page 2 of this document? WAC 246-945-040(2) "A separate registration is required for each place of business, as defined in 21 CFR Sec. 1301.12, where controlled substances are manufactured, distributed, or dispensed."	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	4.	Is the responsible pharmacy manager licensed to practice pharmacy in the state of Washington? WAC 246-945-310 Responsible pharmacy manager. The responsible pharmacy manager must be licensed to practice pharmacy in the state of Washington. The responsible pharmacy manager designated by a facility as required under WAC 246-945-410 shall have the authority and responsibility to assure that the area(s) within the facility where drugs are stored, compounded, delivered, or dispensed are operated in compliance with all applicable state and federal statutes and regulations.	
Facility Standards					
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	5.	Is the facility appropriately constructed and equipped to protect equipment, records, drugs/devices and other restricted items from unauthorized access? WAC 246-945-410(1) The facility shall be constructed and equipped with adequate security to protect equipment, records, and supply of drugs, devices, and other restricted sale items from unauthorized access, acquisition, or use.	

2023 Hospital Pharmacy and HPAC Self-Inspection Worksheet

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

2023 Hospital Pharmacy and HPAC Self-Inspection Worksheet

Compliant			#	Rule Reference	Notes/Corrective Actions
Yes	No	N/A			
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	14.	<p>Is the pharmacy adhering to a commission approved 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. The application shall be accompanied by a fee and shall comply with administrative procedures and administrative requirements set pursuant to RCW 43.70.250 and 43.70.280, shall detail the manner and extent to which the pharmacy ancillary personnel would be used and supervised, and shall provide other information in such form as the secretary may require. The commission may approve or reject such applications. In addition, the commission may modify the proposed utilization of pharmacy ancillary personnel and approve the application as modified. Whenever it appears to the commission that pharmacy ancillary personnel are being utilized in a manner inconsistent with the approval granted, the commission may withdraw such approval. In the event a hearing is requested upon the rejection of an application, or upon the withdrawal of approval, a hearing shall be conducted in accordance with chapter 18.64 RCW, as now or hereafter amended, and appeal may be taken in accordance with the administrative procedure act, chapter 34.05 RCW."</p> <p>WAC 246-945-410(11) "In accordance with RCW 18.64A.060 prior to utilizing pharmacy ancillary personnel a facility shall submit to the commission a utilization plan for pharmacy technicians and pharmacy assistants: (a) Utilization plan for pharmacy technicians. The application for approval must describe the manner in which the pharmacy technicians will be utilized and supervised, including job descriptions, task analysis or similar type documents that define the duties performed and the conditions under which they are performed, number of positions in each category, as well as other information as may be required by the commission. The commission will be notified of all changes to the utilization plan. A copy of the utilization plan must be maintained in the pharmacy. The utilization plan must comply with WAC 246-945-315 and 246-945-320. (b) Utilization plan for pharmacy assistants. The application for approval shall list the job title or function of the pharmacy assistant and comply with WAC 246-945-315(3)."</p>	

2023 Hospital Pharmacy and HPAC Self-Inspection Worksheet

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

2023 Hospital Pharmacy and HPAC Self-Inspection Worksheet

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	16.	Does the pharmacy have a copy of the ancillary utilization plan?	WAC 246-945-410(11)(a) "A copy of the utilization plan must be maintained in the pharmacy"	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	17.	Does the pharmacy utilize tech check tech?	WAC 246-945-317(2) A pharmacist may allow for unit-dose medication checking. Following verification of a prescription by the pharmacist, a technician may check unit-dose medication cassettes filled by another pharmacy technician or pharmacy intern in pharmacies serving facilities licensed under chapter 70.41, 71.12, 71A.20, or 74.42 RCW. No more than a forty-eight-hour supply of drugs may be included in the patient medication cassettes and a licensed health professional must check the drug before administering it to the patient.	

Electronic Recordkeeping Requirements

Please perform appropriate audits on pages 19-20

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	18.	Does your record system have the capability to store patient medication records e.g. allergies, idiosyncrasies or chronic conditions, and prescription, refill, transfer, and other information?	WAC 246-945-417(1) "A pharmacy shall use an electronic recordkeeping system to establish and store patient medication records, including patient allergies, idiosyncrasies or chronic conditions, and prescription, refill, transfer information, and other information necessary to provide safe and appropriate patient care."	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	19.	Are all drugs dispensed only upon a valid order?	WAC 246-945-410(7) Prescription drugs must only be dispensed pursuant to a valid prescription as required by WAC 246-945-011. WAC 246-945-011(5) A chart order must meet the requirements of RCW 18.64.550 and any other applicable requirements listed in 21 CFR, Chapter II. RCW 18.64.550(1) A chart order must be considered a prescription if it contains:(a) The full name of the patient; (b) The date of issuance; (c) The name, strength, and dosage form of the drug prescribed;(d) Directions for use; and (e) An authorized signature:	

Policies and Procedures

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	20.	Does the pharmacy have policies and procedures adequate to address pharmacy functions?	WAC 246-945-410(6) The facility shall create and implement policies and procedures related to: (a) Purchasing, ordering, storing, compounding, delivering, dispensing, and administering legend drugs, including controlled substances. (b) Accuracy of inventory records, patient medical records as related to the administration of controlled substances and legend drugs, and any other records required to be kept by state and federal laws. (c) Adequate security of legend drugs, including controlled sub-stances. (d) Controlling access to legend drugs, including controlled sub-stances.	
--------------------------	--------------------------	--------------------------	-----	--	---	--

2023 Hospital Pharmacy and HPAC Self-Inspection Worksheet

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

2023 Hospital Pharmacy and HPAC Self-Inspection Worksheet

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

2023 Hospital Pharmacy and HPAC Self-Inspection Worksheet

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

2023 Hospital Pharmacy and HPAC Self-Inspection Worksheet

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

2023 Hospital Pharmacy and HPAC Self-Inspection Worksheet

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

2023 Hospital Pharmacy and HPAC Self-Inspection Worksheet

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	46.	Does the pharmacy close in the event of a surveillance system failure?	WAC 246-945-430(7) The pharmacy must be closed to the public if any component of the surveillance or visual and audio communication system is malfunctioning, and remain closed until system corrections or repairs are completed or a pharmacist is on-site to oversee pharmacy operations.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	47.	Does the pharmacy maintain a perpetual inventory for legend drugs and controlled substances?	WAC 246-945-420(4) A pharmacy that exclusively stores, dispenses or delivers legend drugs, including controlled substances, without a pharmacist on-site shall maintain a perpetual inventory.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	48.	When 24-hour services are not available does the pharmacist perform retrospective drug utilization review of orders within six hours of being open?	WAC 246-945-510(8)(d) A drug utilization review of each prescription before dispensing and delivery shall occur except in emergent medical situations, or if: Twenty-four hour pharmacy services are not available, and a pharmacist will review all prescriptions added to a patient's profile within six hours of the facility opening.	

Outpatient Dispensing

If the pharmacy provides outpatient dispensing services other than emergency prepackaged medications please complete the General Pharmacy Self-Inspection form in addition to the Hospital Pharmacy Self-Inspection form.

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	49.	Does the pharmacy dispense emergency outpatient prepackaged medications?	RCW 70.41.480(1) "... It is the intent of the legislature to accomplish this objective by allowing practitioners with prescriptive authority to prescribe limited amounts of prepackaged emergency medications to patients being discharged from hospital emergency departments when access to community or outpatient hospital pharmacy services is not otherwise available."	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	50.	Does the pharmacy maintain a list of approved medications to be prepackaged and delivered?	RCW 70.41.480(2)(a) "... The director of pharmacy, in collaboration with appropriate hospital medical staff, develops policies and procedures regarding the following: ... (a) Development of a list, preapproved by the pharmacy director, of the types of emergency medications to be prepackaged and distributed."	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	51.	Does the pharmacy maintain records of prepackaged medications?	WAC 246-945-018 Prepackage medications dispensed pursuant to RCW 70.41.480, medications dispensed in unit dose form, medications dispensed by a pharmacy to a long-term care facility must include a label with the following information: (1) Drug name; (2) Drug strength; (3) Expiration date in accordance with WAC 246-945-016(3);	

2023 Hospital Pharmacy and HPAC Self-Inspection Worksheet

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

2023 Hospital Pharmacy and HPAC Self-Inspection Worksheet

Compliant			#	Rule Reference	Notes/Corrective Actions
Yes	No	N/A			
				RCW 18.64.246 To every box, bottle, jar, tube or other container of a prescription which is dispensed there shall be fixed a label bearing the name and address of the dispensing pharmacy, the prescription number, the name of the prescriber, the prescriber's directions, the name and strength of the medication, the name of the patient, the date, and the expiration date. The security of the cover or cap on every bottle or jar shall meet safety standards adopted by the commission.	

Other Areas of Non-Compliance

The commission and its inspectors reserve the right to note areas of non-compliance not specifically identified above on this self-inspection form. If an inspector identifies an issue of non-compliance they will note it in the section below and it will be included on the inspection report.

Hospital Pharmacy Associated Clinics (HPACs)

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1.	Are there clinics owned, operated, or under common control of the hospital listed as HPACs on the hospital pharmacy license? *If no, you *do not* need to answer the remaining questions.	WAC 246-945-233(1) A parent hospital pharmacy may add or delete a hospital pharmacy associated clinic (HPAC) to a hospital pharmacy license at any time in compliance with WAC 246-945-230(2) (a), (b), and (d).	
--------------------------	--------------------------	--------------------------	----	--	---	--

HPAC Responsible Manager Requirements

Rule Reference for HPAC Questions

WAC 246-945-233 The HPAC must designate a responsible pharmacy manager and notify the commission of changes. ****Policies and procedures regarding HPACs may be incorporated into the overarching hospital pharmacy required policies and procedures.**

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	2.	Are procedures established for the procurement, distribution, and maintenance of a system of accountability for drugs, IV solutions, chemicals, and biologicals related to the practice of pharmacy identified for HPACs?	WAC 246-945-410(6) The facility shall create and implement policies and procedures related to: (a) Purchasing, ordering, storing, compounding, delivering, dispensing, and administering legend drugs, including controlled substances. (b) Accuracy of inventory records, patient medical records as related to the administration of controlled substances and legend drugs, and any other records required to be kept by state and federal laws. (c) Adequate security of legend drugs, including controlled substances. (d) Controlling access to legend drugs, including controlled substances.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	3.	Are drugs located in HPACs properly stored and secured?	WAC 246-945-410(2) The facility shall be properly equipped to ensure the safe, clean, and sanitary condition necessary for the proper operation, the safe preparation of prescriptions, and to safeguard product integrity.	

2023 Hospital Pharmacy and HPAC Self-Inspection Worksheet

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

2023 Hospital Pharmacy and HPAC Self-Inspection Worksheet

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8.	b	Directions for use pharmacist responsible for each dispensing of medication must either be recorded in the pharmacy's record system or on the prescription label. This section shall not apply to the dispensing of medications to in-patients in hospitals. RCW 69.41.050(1) To every box, bottle, jar, tube or other container of a legend drug, which is dispensed by a practitioner authorized to prescribe legend drugs, there shall be affixed a label bearing the name of the prescriber, complete directions for use, the name of the drug either by the brand or generic name and strength per unit dose, name of patient and date: PROVIDED, That the practitioner may omit the name and dosage of the drug if he or she determines that his or her patient should not have this information and that, if the drug dispensed is a trial sample in its original package and which is labeled in accordance with federal law or regulation, there need be set forth additionally only the name of the issuing practitioner and the name of the patient.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8.	c	Brand or Generic Drug name and strength per dose of patient and date: PROVIDED, That the practitioner may omit the name and dosage of the drug if he or she determines that his or her patient should not have this information and that, if the drug dispensed is a trial sample in its original package and which is labeled in accordance with federal law or regulation, there need be set forth additionally only the name of the issuing practitioner and the name of the patient.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8.	d	Name of patient, and WAC 246-945-016 All licensees of the commission who dispense legend drugs to outpatients shall affix a label to the prescription container that meets the requirements of RCW 69.41.050 and 18.64.246, and shall also include: (a) Drug quantity; (b) The number of refills remaining, if any; (c) The following statement, "Warning: State or federal law prohibits transfer of this drug to any person other than the person for whom it was prescribed.", except when dispensing to an animal, when a warning sufficient to convey "for veterinary use only" may be used; (d) The name and species of the patient, if a veterinary prescription; and (e) The name of the facility or entity authorized by law to possess a legend drug, if patient is the facility or entity.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8.	e	Date	

Records

			9.		For *automated* patient record systems: Do patient records include all required information?	WAC 246-945-417(2) The electronic recordkeeping system must be capable of real-time retrieval of information pertaining to the ordering, verification, and processing of the prescription where possible.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	9.	a	Patient full name and address	(3) The electronic recordkeeping system must include security features to protect the confidentiality and integrity of patient records including: (a) Safeguards designed to prevent and detect unauthorized access, modification, or manipulation of prescription information and patient medication records; and	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	9.	b	Serial number assigned to each new prescription		

2023 Hospital Pharmacy and HPAC Self-Inspection Worksheet

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

2023 Hospital Pharmacy and HPAC Self-Inspection Worksheet

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	11.	a	Patient full name and address	record system consists of the hard copy of the original prescription and a card or filing procedure that contains all data on new and refill prescriptions for a patient. This data must be organized in such a fashion that information relating to all prescription drugs used by a patient will be reviewed each time a prescription is filled.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	11.	b	Serial number assigned to each new prescription	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	11.	c	Date of all instances of dispensing a drug	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	11.	d	The identification of the dispenser who filled the prescription	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	11.	e	Name, strength, dosage form, and quantity of drug dispensed	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	11.	f	Prescriber's name address, and DEA number where required.	

Drug Administration

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	12.	<p>Is access to the drug storage area of the HPAC limited only to those WA credentialed personnel acting within their scope of practice? *Nursing students acting within their scope of practice can administer medications.*</p>	<p>WAC 246-945-455(1)(c) Access must be limited to health care professionals licensed under the chapters specified in RCW 18.130.040 acting within their scope, and nursing students as provided in WAC 246-945-450.</p> <p>WAC 246-945-317 Tech check tech. (1) "Verification" as used in this section means the pharmacist has reviewed a patient prescription initiated by an authorized prescriber, has examined the patient's drug profile, and has approved the prescription after taking into account pertinent drug and disease information to ensure the correctness of the prescription for a specific patient. The verification process must generate an audit trail that identifies the pharmacist. The pharmacist who performs the verification of a prescription is responsible for all reports generated by the approval of that prescription. The unit-dose medication fill and check reports are an example.</p> <p>(2) A pharmacist may allow for unit-dose medication checking. Following verification of a prescription by the pharmacist, a technician may check unit-dose medication cassettes filled by another pharmacy technician or pharmacy intern in pharmacies serving facilities licensed under chapter 70.41, 71.12, 71A.20, or 74.42 RCW. No more than a forty-eight hour supply of drugs may be included in the patient medication cassettes and a licensed health professional must check the drug before administering it to the patient.</p>	
--------------------------	--------------------------	--------------------------	-----	---	--	--

2023 Hospital Pharmacy and HPAC Self-Inspection Worksheet

Compliant			#		Rule Reference	Notes/Corrective Actions
Yes	No	N/A				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	13.	Are all drugs in an HPAC dispensed only upon a valid order or a practitioner?	<p>WAC 246-945-410(7) Prescription drugs must only be dispensed pursuant to a valid prescription as required by WAC 246-945-011.</p> <p>WAC 246-945-011(5) A chart order must meet the requirements of RCW 18.64.550 and any other applicable requirements listed in 21 CFR, Chapter II.</p> <p>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.</p>	