



Read this Page Carefully

Pharmacy Quality Assurance Commission 2024 Health Care Entity (HCE) Self-Inspection Worksheet

Attention: Responsible Pharmacy Manager (or Equivalent Manager)

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

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

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

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

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

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



Health Care Entity (HCE) Self-Inspection Worksheet

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

Date self-inspection worksheet was complete: _____

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: _____

HCE: _____ Fax: _____ DEA #: _____

Telephone: _____ Address: _____ HCE 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.

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

Document and Record Review

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

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

2024 Health Care Entity (HCE) Self-Inspection Worksheet

| | Rule Reference |
|--|--|
| <p>Completed CII order forms (DEA Form 222) and/or finalized CSOS documentation for the last 2 years</p> <p>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>Schedule II Invoices for the last 2 years</p> <p>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(4) "Credential holders and pharmaceutical firms shall maintain records for Schedule II drugs separately from all other records."</p> |
| <p>Schedule III-V Invoices for the last 2 years</p> <p>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 loss by theft or destruction forms (DEA Form 106) for the last 2 years</p> <p>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</p> <p>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>Change of Responsible Pharmacy Manager forms for the last 2 years</p> <p>Location:</p> | <p>WAC 246-945-480(1) "The outgoing and incoming responsible pharmacy manager must report in writing to the commission a change in a responsible pharmacy manager designation within ten business days of the change." WAC 246-945-020 (1) "Unless an alternative standard for a specified record type, form, or format is expressly stated a pharmaceutical firm must maintain and retain records required as evidence of compliance with statutes and rules enforced by the commission in a readily retrievable form and location for at least two years from the date the record was created or received, whichever date is later. (2) A pharmaceutical firm must allow the commission, or its designee, access to the pharmaceutical firm's records upon request for the purposes of monitoring compliance with statutes and rules enforced by the commission."</p> |
| <p>Prescription Records for the last 2 years</p> <p>Location:</p> | <p>WAC 246-945-410(12) "A facility's paper prescriptions must be maintained in accordance with WAC 246-945-020 and as follows: (a) Paper prescriptions for Schedule II drugs must be maintained as a separate file from other prescriptions. (b) Paper prescriptions for Schedule III, IV, and V drugs must be maintained as a separate file or maintained in a separate file with prescriptions for non-controlled legend drugs as allowed under federal law."</p> |

2024 Health Care Entity (HCE) Self-Inspection Worksheet

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

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| Compliant | | | # | | Rule Reference | Notes/Corrective Action |
|--------------------------|--------------------------|--------------------------|-----|---|---|-------------------------|
| Yes | No | N/A | | | | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 7. | Are the drug storage areas appropriately secure from unauthorized access and are staff working within their scope of practice? | WAC 246-945-410(10) "Access to the drug storage area located within the facility should be limited to pharmacists unless one of the following applies: (a) A pharmacy intern, or pharmacy ancillary personnel enter under the immediate supervision of a pharmacist; or (b) A pharmacist authorizes temporary access to an individual performing a legitimate nonpharmacy function under the immediate supervision of the pharmacist; or (c) The facility has a policy and procedure restricting access to a health care professional licensed under the chapters specified in RCW 18.130.040, and the actions of the health care professional are within their scope of practice." | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 8. | Are medication refrigerator temperatures maintained between 2- 8°C (36-46°F)? ** Electronic monitoring is acceptable. ** | WAC 246-945-410(2) "The facility shall be properly equipped to ensure the safe, clean, and sanitary condition necessary for the proper operation, the safe preparation of prescriptions, and to safeguard product integrity." | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 9. | Are medication freezer temperatures maintained between -25°& -10°C (-13° & 14°F) or within acceptable range based on product packaging? ** Electronic monitoring is acceptable. ** | WAC 246-945-410(2) "The facility shall be properly equipped to ensure the safe, clean, and sanitary condition necessary for the proper operation, the safe preparation of prescriptions, and to safeguard product integrity." | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 10. | Is drug stock stored under proper conditions (temperature, humidity, light) as recommend by the drug label? **Including samples under the control of the HCE** | RCW 69.45.040(3) "Drug samples shall be stored and transported in such a manner as to be free of contamination, deterioration, and adulteration. (4) Drug samples shall be stored under conditions of temperature, light, moisture, and ventilation so as to meet the label instructions for each drug." 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"/> | 11. | Is all drug stock in date? | RCW 69.04.100 "Whenever the director shall find in intrastate commerce an article subject to this chapter which is so adulterated or misbranded that it is unfit or unsafe for human | |

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| Compliant | | | # | Rule Reference | Notes/Corrective Action | |
|-----------|----|-----|---|---|---|--|
| Yes | No | N/A | | | | |
| | | | | <p>**Including OTC medications and samples under the control of the HCE**</p> <p>*It's advised to perform an inventory check for expired medications while filling out this self-inspection worksheet.*</p> | <p>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>RCW 69.45.040(5) “Drug samples which have exceeded the expiration date shall be physically separated from other drug samples until disposed of or returned to the manufacturer.”</p> <p>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.”</p> | |

Policies and Procedures

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

| | | | | | | |
|--------------------------|--------------------------|--------------------------|-------|---|--|--|
| | | | 12. | Does the HCE have policies and procedures in place for the following: | <p>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.”</p> | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 12. a | Purchasing | | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 12. b | Ordering | | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 12. c | Storing | | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 12. d | Compounding | | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 12. e | Delivering | | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 12. f | Dispensing | | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 12. g | Administration | | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 13. | Does the HCE have policies and procedures addressing administration of patient owned medications? | <p>WAC 246-945-440 “Facilities shall develop written policies and procedures for the administration of patient owned medications.”</p> | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 14. | Does the HCE accept dispensed drugs or prescription devices for return and reuse appropriately? | <p>WAC 246-945-485(1) “A dispensed drug or prescription device must only be accepted for return and reuse as follows: (a) Noncontrolled legend drugs that have been maintained in the custody and control of the institutional facility, dispensing</p> | |

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| Compliant | | | # | | Rule Reference | Notes/Corrective Action |
|--------------------------|--------------------------|--------------------------|-----|---|---|-------------------------|
| Yes | No | N/A | | | | |
| | | | | | 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"/> | 15. | Does the HCE accept dispensed drugs or prescription devices for return and destruction appropriately? | WAC 246-945-485(2) “A dispensed drug or prescription device may be accepted for return and destruction if: (a) The dispensed drug or prescription device was dispensed in a manner inconsistent with the prescriber's instructions; (b) The return is in compliance with the Washington state safe medication return program laws and rules, chapters 69.48 RCW and 246-480 WAC; or (c) The return and destruction is in compliance with the facility's policies and procedures.” | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 16. | Does the HCE have policies and procedures addressing computer system downtime? | WAC 246-945-417(7) “HCEs or HPACs that maintain an electronic record system must be done in accordance with subsections (2) through (7) of this section.” WAC 246-945-417(4) “The pharmacy shall have policies and procedures in place for system downtime. (a) The procedure shall provide for the maintenance of all patient recordkeeping information as required by this chapter. (b) Upon restoration of operation of the electronic recordkeeping system the information placed in the auxiliary recordkeeping procedure shall be entered in each patient's records within two working days, after which the auxiliary records may be destroyed. (c) This section does not require that a permanent dual recordkeeping system be maintained.” | |
| Recordkeeping | | | | | | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 17. | Are complete patient medical records maintained in either paper or electronic format? | WAC 246-945-418 “If an HPAC or HCE does not maintain an electronic recordkeeping system their manual records must contain all information required in WAC 246-945-417.” | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 18. | If applicable, does the HCE maintain electronic record system including patient allergies, idiosyncrasies or chronic conditions, and prescription, refill, transfer | 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.” | |

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| Compliant | | | # | | Rule Reference | Notes/Corrective Action |
|--------------------------|--------------------------|--------------------------|-----|--|---|-------------------------|
| Yes | No | N/A | | | | |
| | | | | information, and other information necessary to provide safe and appropriate patient care? | WAC 246-945-417(7) HCEs or HPACs that maintain an electronic record system must be done in accordance with subsections (2) through (7) of this section. | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 19. | Does the electronic recordkeeping system include security features to protect confidentiality and integrity of patient records? | WAC 246-945-417(3) "The electronic recordkeeping system must include security features to protect the confidentiality and integrity of patient records including: (a) Safeguards designed to prevent and detect unauthorized access, modification, or manipulation of prescription information and patient medication records; and (b) Functionality that documents any alteration of prescription information after a prescription is dispensed, including the identification of the individual responsible for the alteration." | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 20. | If applicable, does the manual patient medical record system have the capability to store patient medication records e.g. allergies, idiosyncrasies or chronic conditions, and prescription, refill, transfer, and other information as required in WAC 246-945-417? | <p>WAC 246-945-417(7) "HCEs or HPACs that maintain an electronic record system must be done in accordance with subsections (2) through (7) of this section."</p> <p>WAC 246-945-417 (1) A pharmacy shall use an electronic recordkeeping system to establish and store patient medication records, including patient allergies, idiosyncrasies or chronic conditions, and prescription, refill, transfer information, and other information necessary to provide safe and appropriate patient care. (a) Systems must prevent auto-population of user identification information. (b) Pharmacies that provide off-site pharmacy services without a pharmacist for product fulfillment or prescription processing must track the identity of each individual involved in each step of the off-site pharmacy services.</p> <p>(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.</p> <p>(3) The electronic recordkeeping system must include security features to protect the confidentiality and integrity of patient records including: (a) Safeguards designed to prevent and detect unauthorized access, modification, or manipulation of prescription information and patient medication records; and (b) Functionality that documents any alteration of prescription</p> | |

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| Compliant | | | # | Rule Reference | Notes/Corrective Action |
|--------------------------|--------------------------|--------------------------|-----|--|-------------------------|
| Yes | No | N/A | | | |
| | | | | <p>information after a prescription is dispensed, including the identification of the individual responsible for the alteration. (4) The pharmacy shall have policies and procedures in place for system downtime. (a) The procedure shall provide for the maintenance of all patient recordkeeping information as required by this chapter. (b) Upon restoration of operation of the electronic recordkeeping system the information placed in the auxiliary recordkeeping procedure shall be entered in each patient's records within two working days, after which the auxiliary records may be destroyed. (c) This section does not require that a permanent dual recordkeeping system be maintained.</p> <p>(5) The pharmacy shall maintain records in accordance with WAC 246-945-020.</p> <p>(6) Electronic prescriptions for prescription drugs must be maintained by the pharmacy in a system that meets the requirements of 21 CFR. Sec. 1311.”</p> <p>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.”</p> | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 21. | <p>RCW 18.64.470 “Every proprietor or manager of a health care entity shall keep readily available a suitable record of drugs, which shall preserve for a period of not less than two years the record of every drug used at such health care entity. The record shall be maintained either separately from all other records of the health care entity or in such form that the information required is readily retrievable from ordinary business records of the health care entity. All recordkeeping requirements for controlled substances must be complied with.”</p> <p>Are suitable records of drugs readily retrievable or maintained separately from all other records? **Including drug samples under the control of the HCE**</p> | |

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| Compliant | | | # | | Rule Reference | Notes/Corrective Action |
|------------------------------|--------------------------|--------------------------|-----|--|---|-------------------------|
| Yes | No | N/A | | | | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 22. | Are all records readily retrievable for at least two years from the date the record was created or received, whichever is later? | <p>WAC 246-945-020(1) "Unless an alternative standard for a specified record type, form, or format is expressly stated a pharmaceutical firm must maintain and retain records required as evidence of compliance with statutes and rules enforced by the commission in a readily retrievable form and location for at least two years from the date the record was created or received, whichever date is later."</p> <p>WAC 246-945-001(7) "'Readily retrievable' means a record that is kept by automatic data processing systems or other electronic, mechanized, or written recordkeeping systems in such a manner that it can be separated out from all other records in a reasonable time."</p> | |
| Controlled Substances | | | | | | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 23. | Are all controlled substances in the HCE locked and secured to prevent unauthorized access? | <p>WAC 246-945-040(1) "The commission adopts 21 CFR. as its own."</p> <p>21 CFR. 1301.75(a) "Controlled substances listed in Schedule I shall be stored in a securely locked, substantially constructed cabinet. (b) Controlled substances listed in Schedules II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet."</p> <p>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."</p> | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 24. | Does the HCE maintain records of receipt and distribution of all 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</p> | |

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| Compliant | | | # | | Rule Reference | Notes/Corrective Action |
|--------------------------|--------------------------|--------------------------|-----|--|---|-------------------------|
| Yes | No | N/A | | | | |
| | | | | | 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." | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 25. | Are records of Schedule II drugs maintained separately from all other controlled substance records? | WAC 246-945-040(4) "Credential holders and pharmaceutical firms shall maintain records for Schedule II drugs separately from all other records." | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 26. | Does the HCE have completed DEA 222 forms or their electronic equivalent for each acquisition or distribution of Schedule II drugs? | WAC 246-945-040(6) "A federal order form is required for each distribution of a Schedule I or II controlled substance. Credential holders and pharmaceutical firms must keep and make readily available these forms and other records to the commission or its designee." | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 27. | Are records of Schedule III-V drugs maintained either separately or in a form that is readily retrievable from other records? | WAC 246-945-040(5) "Credential holders and pharmaceutical firms may maintain records for Schedule III, IV, and V drugs either separately or in a form that is readily retrievable from the business records of the registrant." 21 CFR 1304.04(h)(3) "...Inventories and records of Schedules III, IV, and V controlled substances shall be maintained either separately from all other records of the pharmacy or in such form that the information required is readily retrievable from ordinary business records of the pharmacy." | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 28. | Is an inventory of controlled substances being performed every 2 years? **Including controlled substance samples under the control of the HCE** An inventory of controlled substances must be completed within 30 days of a new responsible pharmacy manager or on the effective date of the addition of a substance to a schedule of controlled substances. | WAC 246-945-420(2) "A facility shall conduct an inventory of controlled substances every two years." WAC 246-945-420(3)(a) "Within thirty days of designating a responsible pharmacy manager. The incoming responsible pharmacy manager, or designee, shall conduct a complete controlled substance inventory. (b) On the effective date of an addition of a substance to a schedule of controlled substances. Each facility that possesses the substance shall take an inventory of the substance on hand, and thereafter, include the substance in each inventory." 21 CFR. 1304.11(a) "Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location." | |

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| Compliant | | | # | | Rule Reference | Notes/Corrective Action |
|--------------------------|--------------------------|--------------------------|-----|---|---|-------------------------|
| Yes | No | N/A | | | | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 29. | Does the HCE have power of attorney forms for ordering schedule II-controlled substances? | 21 CFR. 1305.05(a) "A registrant may authorize one or more individuals, whether or not located at his or her registered location, to issue orders for Schedule I and II controlled substances on the registrant's behalf by executing a power of attorney for each such individual, if the power of attorney is retained in the files, with executed Forms 222 where applicable, for the same period as any order bearing the signature of the attorney. The power of attorney must be available for inspection together with other order records." | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 30. | Has the HCE reported significant losses or disappearances of controlled substances to PQAC and the DEA in the previous 24 months? | 21 CFR 1301.76(b) "The registrant shall notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft." WAC 246-945-040(3)(c) "In the event of a significant loss or theft, two copies of DEA 106 (report of theft or loss of controlled substances) must be transmitted to the federal authorities and a copy must be sent to the commission; ..." | |

Dispensing – HCEs that do not dispense for use outside the HCE and answer “No” to question 31 may skip question numbers 32-42

| | | | | | | |
|--------------------------|--------------------------|--------------------------|-----|--|--|--|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 31. | Does the HCE dispense prescription medications to patients for at home use? | RCW 18.64.450(4) "A health care entity may only administer, dispense, or deliver legend drugs and controlled substances to patients who receive care within the health care entity and in compliance with rules of the commission..." | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 32. | If HCEs dispense medications without a pharmacist's involvement, are they restricting medications dispensed to a seventy-two (72) hour supply? | RCW 18.64.450(4) "...Nothing in this subsection shall prohibit a practitioner, in carrying out his or her licensed responsibilities within a health care entity, from dispensing or delivering to a patient of the health care entity drugs for that patient's personal use in an amount not to exceed seventy-two hours of usage." | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 33. | Does the HCE have valid prescription records for all drugs dispensed to patients? | WAC 246-945-410(7) "Prescription drugs must only be dispensed pursuant to a valid prescription as required by WAC 246-945-011." | |

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| Compliant | | | # | | Rule Reference | Notes/Corrective Action |
|--------------------------|--------------------------|--------------------------|-------|---|--|-------------------------|
| Yes | No | N/A | | | | |
| | | | | | <p>WAC 246-945-011(1) "Prior to dispensing and delivering a prescription, a pharmacist shall verify its validity." (2) A prescription shall be considered invalid if: (a) At the time of presentation, the prescription shows evidence of alteration, erasure, or addition by any person other than the person who wrote it; (b) The prescription does not contain the required information as provided in WAC 246-945-010; (c) The prescription is expired; or (d) The prescription is for a controlled substance and does not comply with the requirements in RCW 69.50.308. (3) A prescription is considered expired when: (a) The prescription is for a controlled substance listed in Schedule II through V and the date of dispensing is more than six months after the prescription's date of issue. (b) The prescription is for a noncontrolled legend drug or OTC's and the date of dispensing is more than twelve months after the prescription's date of issue."</p> | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 34. | Are all non-controlled legend drugs prescribed orally promptly transcribed to a written or electronic prescription? | <p>WAC 246-945-010(8) "A noncontrolled legend drug can only be dispensed pursuant to a valid prescription in accordance with WAC 246-945-011, or an oral prescription. An oral prescription for a noncontrolled legend drug must be promptly reduced to a written or electronic prescription that complies with WAC 246-945-011."</p> | |
| | | | 35. | Do all prescriptions for non-controlled legend drugs include all required elements? | <p>WAC 246-945-010(3) "A prescription for a noncontrolled legend drug must include, but is not limited to, the following: (a) Prescriber's name; (b) Name of patient, authorized entity, or animal name and species; (c) Date of issuance; (d) Drug name, strength, and quantity; (e) Directions for use; (f) Number of refills (if any); (g) Instruction on whether or not a therapeutically equivalent generic drug or interchangeable biological product may be substituted, unless substitution is permitted under a prior-consent authorization; (h) Prescriber's manual or electronic signature, or prescriber's authorized agent signature if allowed by law; and (i) If the prescription is written, it must be written on tamper-resistant prescription pad or paper approved by the commission pursuant to RCW 18.64.500"</p> | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 35. a | Prescriber's Name | | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 35. b | Name of Patient/ Authorized Entity/Animal Name and Species | | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 35. c | Date of Issuance | | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 35. d | Drug Name, Strength, and Quantity | | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 35. e | Directions for Use | | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 35. f | Number of Refills | | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 35. g | Substitution Directions | | |

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| Compliant | | | # | | | Rule Reference | Notes/Corrective Action |
|--------------------------|--------------------------|--------------------------|-----|---|---|---|-------------------------|
| Yes | No | N/A | | | | | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 35. | h | Prescribers Signature | | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 35. | i | If written, on Tamper-Resistant Paper | | |
| | | | 36. | | Do all prescriptions for controlled substances include additional required elements? | WAC 246-945-010(4) "A prescription for a controlled substance must include all the information listed in subsection (1) of this section and the following: (a) Patient's address; (b) Dosage form; (c) Prescriber's address; (d) Prescriber's DEA registration number; and (e) Any other requirements listed in 21 CFR., Chapter II." | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 36. | a | Patient's Address | | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 36. | b | Dosage Form | | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 36. | c | Prescriber's Address | | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 36. | d | Prescriber's DEA Number | | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 37. | | Are all prescriptions properly labeled and stored, in accordance with federal and state statutes, rules, and regulations? **Includes drug samples under the control of the HCE** | RCW 18.64.246(1) "To every box, bottle, jar, tube or other container of a prescription which is dispensed there shall be fixed a label bearing the name and address of the dispensing pharmacy, the prescription number, the name of the prescriber, the prescriber's directions, the name and strength of the medication, the name of the patient, the date, and the expiration date." RCW 69.41.050(1) "To every box, bottle, jar, tube or other container of a legend drug, which is dispensed by a practitioner authorized to prescribe legend drugs, there shall be affixed a label bearing the name of the prescriber, complete directions for use, the name of the drug either by the brand or generic name and strength per unit dose, name of patient and date: PROVIDED, That the practitioner may omit the name and dosage of the drug if he or she determines that his or her patient should not have this information and that, if the drug dispensed is a trial sample in its original package and which is labeled in accordance with federal law or regulation, there need be set forth additionally only the name of the issuing practitioner and the name of the patient." WAC 246-945-016(1) and (3) " (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 | |

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| Compliant | | | # | Rule Reference | Notes/Corrective Action | |
|--------------------------|--------------------------|--------------------------|-----|---|--|--|
| Yes | No | N/A | | | | |
| | | | | prescribed.", except when dispensing to an animal, when a warning sufficient to convey "for veterinary use only" may be used; (d) The name and species of the patient, if a veterinary prescription; and (e) The name of the facility or entity authorized by law to possess a legend drug, if patient is the facility or entity... (3) For the purposes of determining an expiration date as required in RCW 18.64.246, the dispenser shall take the following factors into account: (a) The nature of the drug; (b) The container in which it was packaged by the manufacturer and the expiration date; (c) The characteristics of the patient's container, if the drug is repackaged for dispensing; (d) The expected conditions to which the drug may be exposed; (e) The expected length of time of the course of therapy; and (f) Any other relevant factors." | | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 38. | <p>Are all legend drugs dispensed in child-resistant containers, as required by federal law or regulation? (This includes special packaging used such as customized patient medication packages; blister packs, med-minders, etc.)</p> <p>** Please see the FAQ on commission website. **</p> <p>** Best practice: It is recommended that these authorizations are updated annually. **</p> | <p>WAC 246-945-032 (1) "All legend drugs shall be dispensed in a child-resistant container as required by federal law or regulation, including 16 CFR., Part 1700, unless:</p> <p>(a) Authorization is received from the prescriber to dispense in a container that is not child-resistant.</p> <p>(b) Authorization is obtained from the patient or a representative of the patient to dispense in a container that is not child-resistant."</p> | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 39. | <p>Is supplemental information provided to the patient with each dispensed prescription?</p> | <p>WAC 246-945-410(9) "Each drug dispensed and delivered to a patient must bear a complete and accurate label as required by WAC 246-945-015 through 246-945-018. The information contained on the label shall be supplemented by oral or written information as required by WAC 246-945-325."</p> <p>WAC 246-945-325</p> <p>(1) The pharmacist shall offer to counsel: (a) Upon the initial fill of a prescription for a new or change of therapy. (b) When the pharmacist using their professional judgment determines counseling is necessary to promote safe and effective use and to facilitate an appropriate therapeutic outcome for that patient.</p> | |

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|--------------------------------------|--------------------------|--------------------------|-----|--|--|-------------------------|
| Yes | No | N/A | | | | |
| | | | | | (2) This does not apply to medications that are administered by a licensed health professional acting within their scope of practice. | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 40. | Are electronic prescriptions maintained appropriately? | WAC 246-945-417(6) "Electronic prescriptions for prescription drugs must be maintained by the pharmacy in a system that meets the requirements of 21 CFR. Sec. 1311." (7) HCEs or HPACs that maintain an electronic record system must be done in accordance with subsections (2) through (7) of this section. | |
| Pharmacist Professional Requirements | | | | | | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 41. | <p><u>Unless an exception applies,</u> does the HCE conduct a drug utilization review (DUR) of each prescription before dispensing and delivery?</p> <p>OR</p> <p>If a pharmacist is involved in the dispensing process, is drug utilization review completed?</p> | <p>WAC 246-945-001(29) "Drug utilization review" includes, but is not limited to, the following activities: (a) Evaluation of prescriptions and patient records for known allergies, rational therapy-contraindications, appropriate dose, and route of administration and appropriate directions for use; (b) Evaluation of prescriptions and patient records for duplication of therapy; (c) Evaluation of prescriptions and patient records for interactions between drug-drug, drug-disease, and adverse drug reactions; and (d) Evaluation of prescriptions and patient records for proper utilization, including over- or under-utilization, and optimum therapeutic outcomes." WAC 246-945-410(8) "A drug utilization review of each prescription before dispensing and delivery shall occur except in emergent medical situations, or if: (a) The drug is a subsequent dose from a previously reviewed prescription; (b) The prescriber is in the immediate vicinity and controls the drug dispensing process; (c) The medication delivery system is being used to provide access to medications on override and only a quantity sufficient to meet the immediate need of the patient is removed; or (d) Twenty-four hour pharmacy services are not available, and a pharmacist will review all prescriptions added to a patient's profile within six hours of the facility opening."</p> | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 42. | If a pharmacist is involved in the dispensing process, do pharmacists perform patient counseling? | WAC 246-945-325(1) "The pharmacist shall offer to counsel: (a) Upon the initial fill of a prescription for a new or change of therapy. (b) When the pharmacist using their professional judgment determines counseling is necessary to promote safe and effective use and to facilitate an appropriate therapeutic outcome for that patient." | |