



Read this Page Carefully
Pharmacy Quality Assurance Commission
~~2024-2025~~ Wholesaler Self-Inspection Worksheet

Attention: Responsible Pharmacy Manager or Equivalent Manager

Wholesalers are responsible for ensuring compliance with all applicable state and federal laws. Failure to complete this annual worksheet 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, 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 wholesaler's level of compliance.

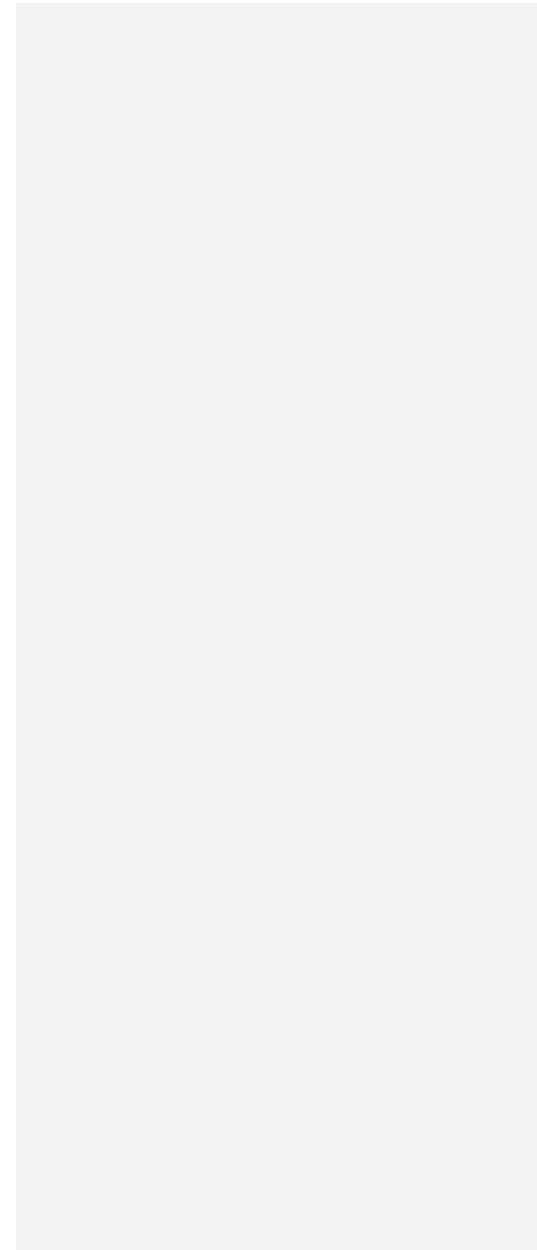
When a commission inspector discovers an area of non-compliance, they will issue an Inspection Report with Noted Deficiencies. The wholesaler must provide a written response (plan of correction) addressing all areas of non-compliance. Identifying and correcting an area of non-compliance prior to a commission 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 designated person 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.

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.

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Wholesaler Self-Inspection Worksheet

All Wholesaler responsible managers (or equivalent managers) ***must*** complete and sign this self-inspection worksheet annually within the month of March and within 30 days of becoming the responsible manager. The form must be available for inspection as required by WAC 246-945-005.

Do not send to the commission office.

Date Wholesaler Self-Inspection was completed on: Click or tap to enter a date. (mm/dd/yy)

Change in Responsible Manager and effective date of change: Click or tap here to enter text.

Print Name of Responsible Manager: Click or tap here to enter text.

Signature of Responsible Manager: Click or tap here to enter text.

Responsible Manager E-mail: Click or tap here to enter text.

Wholesaler: Click or tap here to enter text. Fax: Click or tap here to enter text. DEA #: Click or tap here to enter text.

Telephone: Click or tap here to enter text. Address: Click or tap here to enter text. Wholesaler License #: Click or tap here to enter text.

Endorsements: Controlled Substances Export Wholesaler

2024-2025 Wholesaler Self-Inspection Worksheet

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 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
Wholesaler Self-Inspection Worksheet for last 2 years Location: Click or tap here to enter text.	WAC 246-945-005(4)(a) "The responsible pharmacy manager, or equivalent manager, shall sign and date the completed self-inspection worksheet(s), and maintain completed worksheets for two years from the date of completion." WAC 246-945-005(4)(b) "When a change in responsible pharmacy manager, or equivalent manager occurs, the new responsible pharmacy manager, or equivalent manager, shall conduct a self-inspection as required under this section. The new responsible pharmacy manager, or equivalent manager, shall sign and date the self-inspection worksheet(s) within thirty days of becoming responsible pharmacy manager, or equivalent manager, and maintain completed worksheets for two years from the date of completion."
Wholesaler License Location: Click or tap here to enter text.	RCW 18.64.046(1) "The owner of each place of business which sells legend drugs and nonprescription drugs, or nonprescription drugs at wholesale shall pay a license fee to be determined by the secretary, and thereafter, on or before a date to be determined by the secretary as provided in RCW 43.70.250 and 43.70.280, a like fee to be determined by the secretary, for which the owner shall receive a license of location from the department, which shall entitle such owner to either sell legend drugs and nonprescription drugs or nonprescription drugs at wholesale at the location specified..."
DEA Registration Location: Click or tap here to enter text.	WAC 246-945-040(2)(3) "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: Click or tap here to enter text.	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. (3) 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." 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."
Power of Attorney for staff authorized to order controlled substances Location: Click or tap here to enter text.	WAC 246-945-040(1) "The commission adopts <u>and incorporates Title 21 of the Code of Federal Regulations in effect as of March 2, 2023, by reference, 21 CFR as its own.</u> " 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."
Schedule II Invoices for the last 2 years Location: Click or tap here to enter text.	WAC 246-945-040(3)(4)(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;"