

Department of Health
Washington State Board of Pharmacy
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Pharmacy Self-Inspection Procedures

The purpose of this document is to provide instructions necessary to complete a pharmacy “Self-Inspection” using a *Pharmacy Inspection Report* form. The intent of pharmacy self-inspections is to help pharmacists comply with state and federal laws and regulations.

The *Pharmacy Inspection Report* form is used to assess the pharmacy’s law and regulation compliance in four categories. They include: General Requirements, Patient Health and Safety Requirements, Professional Requirements, and Facilities. Law references identifiable with specific aspects of the inspection process are listed in each of the four sections.

Instructions

1. Identify the pharmacy in the upper left corner of the *Pharmacy Inspection Report* form. A blank prescription label works well. Add the inspection date, telephone number, date of last inspection and class. Check “self” under inspection purpose.
2. Responsible Manager: List the name of the pharmacist owner or the designated pharmacist. If the responsible manager is a designated pharmacist, make sure the letter of designation is available per WAC 246-863-060 and WAC 246-869-070.
3. License Number: Record the pharmacist license number of the responsible manager.
4. Ownership: “C” means corporation, “P” partnership, and “S” sole proprietor.
5. Type of Pharmacy: “C” means community, “H” hospital, “P” parenteral, “L” long-term care, “N” nuclear, and “O” other.

Section A: General Requirements (10 Points)

A total of 10 points may be earned for compliance with all provisions in the “General Requirements section.” A maximum of 3 points may be subtracted for non-compliance in each of the four sub-categories.

1. WAC 246-869-190(6) requires the inspection certificate to be in conspicuous view of the general public. The *Pharmacy Inspection Report* form does not have to be visible.
2. RCW 18.64.140 requires that the current license of all pharmacists be conspicuously displayed to the public. Photocopies may be used when pharmacists are employed at multiple sites and it is acceptable to conceal the home address.
3. RCW 18.64.043(2) requires the location license, and corporation license if applicable, to be exhibited visible to the Pharmacy Board Investigator.
4. WAC 246-887-020 and 21 CFR 1301.35(c) requires the DEA certificate of registration to be maintained at the registered location in a readily retrievable manner.
5. List the names of all pharmacists and their license numbers. Identify preceptors with the letter “X.” List the names of pharmacy interns and pharmacy technicians along with their certificate numbers. Identify interns by writing “INT” and technicians with the word “TECH.” Additional pages may be used if needed.

Section B: Patient Health and Safety Requirements (30 Points)

A total of 30 points may be earned for compliance with all provisions in the “Patient Health and Safety” section. A maximum of 5 points may be subtracted for noncompliance in each of the sub-categories one through five. A special point deduction list is used for sub-category six.

1. WAC 246-875 requires a patient medication record system and specifies minimum requirements and procedures for its utilization. The system must maintain patient allergies, idiosyncrasies, and chronic conditions that may relate to drug utilization.
2. WAC 246-869-220 requires a pharmacist to explain to the recipient of a new prescription the directions for use and any additional information to assure proper utilization of the medication or device prescribed. This

is generally done orally, however, written information may be provided as allowed in the regulation. It is important to note that an offer to counsel is not acceptable. The rule requires counseling unless refused by the patient. Also, it is not acceptable for support staff to determine if counseling for new a prescription is desired from patients.

3. RCW 69.41 and WAC 246-899 require the substitution of therapeutically equivalent generic drugs when authorized by the prescriber. Prescribers are required to use a prescription blank with two signature lines. Dual signature lines are not required for oral prescriptions; the pharmacist is only required to note whether substitution is permitted or not on the face of the prescription. At least 60% of the savings in wholesale price must be passed on to the purchaser. The manufacturer or distributor of the drug product actually dispensed, or its NDC or short name code, or trade name must be noted on the permanent record and on the patient medication record if this document is used for providing and recording refills. This requirement also applies to refill prescriptions when a different manufacturer's product is used. When an automated medication system is used, an audit trail must be available if a change in distributor or manufacturer occurs, otherwise the information must be kept on the hard copy of the prescription. RCW 69.41.160 requires that a sign with specific language be posted concerning generic substitution.
4. WAC 246-869-230 states that all legend drugs intended for oral use shall be dispensed in a child resistant container (CRC) as required by federal law or regulation, unless authorization to use a non-CRC is obtained from the prescriber, patient or patient's representative. Authorization for the use of a non-CRC shall be verified. The patient (or agent) may sign a statement on the back of the prescription, on a patient medication record, or any other permanent record. The record must be readily retrievable.
5. WAC 246-869-200 requires the Poison Control Center telephone number be readily available and at least one one-ounce bottle of Ipecac syrup to be in stock at all times.
6. WAC 246-869-150(2) requires the removal of all merchandise from stock that has exceeded its expiration date. Note the special point deduction system for specific numbers of outdated items listed on the *Pharmacy Inspection Report* form. The term "item" is defined as the aggregate of a product, not individual bottles, i.e., products of the same name, strength, package size and expiration date constitute one item.

Section C: Professional Requirements (40 Points)

A total of 40 points may be earned for compliance with all provisions in the "Professional Requirements" section. A maximum of 5 points may be subtracted for non-compliance in each of the twelve sub-categories.

1. WAC 246-887-020, 21 CFR 1305.06, 21 CFR 1305.07, and 21 CFR 1305.09 require that order forms (DEA form 222) must be filled out completely, including date received and quantity received. A proper power-of-attorney form must be available if someone other than the original DEA registration applicant signs the order forms.
2. WAC 246-887-020(3) and 21 CFR 1304.11 require a biennial inventory of controlled substances, and retention of separate records of receipt and distribution. Schedule II items must be separate from Schedule III-V on the inventory. Name, address, DEA number of registrant, date taken, if taken at open or close of business, and the signature of person taking inventory must be recorded on the inventory. Inventories must be maintained for two years. Use form DEA 106 to notify DEA and the Pharmacy Board of a loss by theft or destruction.
3. WAC 246-887-030 requires the use of a register book for OTC Schedule V controlled substance sales. Duplicate pages must be returned to the Pharmacy Board office when a page is completed or on the last day of the month sales are recorded, whichever is earlier. Photo identification of all purchasers is required. Note restrictions on quantities and frequency of sales.
4. WAC 246-869-070 requires Pharmacy Board notification of the responsible manager.
5. WAC 246-869-180 requires all pharmacies to have one up-to-date copy of Washington State statutes, rules and regulations governing the practice of pharmacy. The lawbook does not have to be maintained in a binder.
6. WAC 246-869-180 requires all pharmacies to have up-to-date references that will enable the pharmacist to furnish patients and practitioners with drug information.
7. WAC 246-901 sets forth requirements for the use of pharmacy ancillary personnel. WAC 246-901-100 requires pharmacies to make application to the board if they choose to utilize ancillary personnel. Be sure to evaluate the duties of pharmacy ancillary personnel. Is there a Pharmacy Board approved utilization plan that reflects current practice at the site? If not, an updated plan should be submitted for board approval. Note: WAC 246-869-190(7) requires an automatic unsatisfactory grade for non-compliance that results in a five-point deduction.

8. WAC 246-863-095 describes pharmacist professional responsibilities that may not be delegated.
9. WAC 246-869-150(4) requires all stock and materials to be properly labeled per federal and state statutes, rules and regulations. Each pre-pack or repack must be labeled with the drug name, strength, quantity, expiration date and lot number.
10. RCW 18.64.246, RCW 69.41.050, WAC 246-869-210, WAC 246-875-020(1)(h), 21 CFR 1306.14 and 21 CFR 1306.24 require that prescription labels include:
 - Pharmacy name and address
 - Prescription number
 - Prescriber name
 - Complete directions for use (the term “as directed” is prohibited)
 - Drug name and strength unless exempted by the prescriber on the prescription
 - Date filled
 - Pharmacist initials
 - Expiration date of the drug as determined by the pharmacist, but in no case later than the manufacturer’s expiration date
 - The statement — “Warning: State or Federal Law prohibits transfer of this drug to any person other than the person for whom it was prescribed.” (Exact wording is required.)
11. WAC 246-869-100, WAC 246-887-020 and 21 CFR 1304.04 identify prescription record requirements. All Schedule II prescriptions must be maintained in a separate prescription file.

It is important to note that pursuant to DEA rule, pharmacies with automatic data processing systems, or other electronic record keeping systems for prescriptions which permit identification by prescription number and retrieval of original documents by prescriber’s name, patient’s name, drug dispensed, and date filled, are permitted to file Schedule III, IV, and V controlled substance prescriptions without marking them with a red letter “C.” The Pharmacy Board adheres to this standard and state rule will be revised accordingly.

At the time of dispensing, a serial number, date of dispensing and initials of the dispensing pharmacist must be placed on the face of the prescription. The patient’s address must be readily available except in the case of controlled substances where 21 CFR 1306.05 requires the patient’s address, prescriber’s address and prescriber’s DEA registration number be on the face of the prescription. When prescriptions are refilled, the date of refilling, pharmacist’s initials, and any changes made must be recorded on the back of the prescription, in a separate record book, or in the patient medication record. No prescription may be filled more than one year following issue. “PRN” prescriptions thus expire one year from date of issue. If the medication is to be continued a new authorization must be obtained from the prescriber. Prescriber authorization must be obtained before filling prescription copies.

Questions: Does the pharmacy accept non-emergency Schedule II controlled substance prescriptions by telephone in violation of 21 CFR 1306.11(a)? Do prescribers provide signed prescriptions within 7 days when Schedule II emergency oral prescriptions are filled?

12. RCW 18.64.160 and 165 address regulation compliance. This section is typically used for pharmacies that are required to have policies and procedures. Are all the policies available in writing? Is there documentation of annual review? Do the policies and procedures reflect current practices at the site?

Section D: Facilities (20 Points)

A total of 20 points may be earned for compliance with all provisions in the “Facilities” section. A maximum of 2 points may be subtracted for non-compliance in each of the ten sub-categories.

1. WAC 246-869-020 requires adequate security for drug supplies and records if differential hours are maintained. In the absence of a pharmacist, the prescription department must be closed and the prescription department telephone unanswerable in other parts of the store.
2. WAC 246-869-160(7) requires the prescription department to be situated so the general public does not have access to the area where legend drugs, controlled substances, poisons or other restricted items are stored, compounded or dispensed.
3. WAC 246-869-170(5) requires that all professional personnel and staff keep themselves and their apparel neat and clean while working in the pharmacy.

4. WAC 246-869-160(3) requires a minimum counter space of three linear feet by eighteen inches in depth for each pharmacist working at the same time. This area must be clear of all extraneous items.
5. WAC 246-869-160(5) requires a sink with hot and cold running water to be in the prescription compounding area.
6. WAC 246-869-160(6) requires refrigeration facilities, maintained between 36° and 46° Fahrenheit with a thermometer to verify the temperature, to be in the prescription compounding area. The refrigerator must also be clean and defrosted, and food and drug items must be separated.
7. WAC 246-869-170(2) requires adequate trash receptacles be available in both prescription compounding and retail areas.
8. WAC 246-869-170(3) states that if a restroom is provided there must be a sink with hot and cold running water, soap and towels. Also, the toilet must be kept clean and sanitary.
9. WAC 246-869-150(3), WAC 246-869-160(4) and WAC 246-869-170(1) require all stock and displays to be free of contamination, the prescription counter to be uncluttered and clean at all times, and walls, ceilings, floors and windows to be clean and in sound repair and order.
10. WAC 246-869 sections 170 and 180 require necessary equipment to fulfill pharmacy functions. All equipment must be clean and in good repair. Note: Although the Pharmacy Board has removed specific requirements for stirring rods, spatulas, etc., each pharmacy is still required to have necessary equipment. Be sure the equipment compares favorably with the prescriptions filled.

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