2025
COMMUNITY HEALTH CLINIC
(CHC) DRUG OUTLET
SELF-INSPECTION FORM

ATTENTION: MEDICAL DIRECTOR or DESIGNATED CLINIC REPRESENTATIVE

Failure to complete an annual review of the outlet on the form provided by the Board of Pharmacy may result in disciplinary action (OAR 855-043-0710(2)(a)). This form must be completed by July 1, 2025.

OAR 855-043-0700

(1) The purpose of 855-043-0700 to 855-043-0750 is to provide minimum requirements of operation for a Community Health Clinic (CHC) to utilize a Registered Nurse to dispense medications. A legend or non-prescription drug may be dispensed to a client for the purpose of birth control, caries prevention, the treatment of amenorrhea, the treatment of a communicable disease, hormone deficiencies, urinary tract infections or sexually transmitted diseases by a practitioner who has been given dispensing privileges by their licensing Board, or a Registered Nurse, who is an employee of a clinic or local public health authority (LPHA), and is recognized by the Oregon Public Health Division for the purposes of providing public health services.

(2) Dispensing must be pursuant to the order or prescription of a person authorized by their Board to prescribe a drug or established by the Medical Director or clinic practitioner with prescriptive and dispensing authority.

OAR 855-043-0710

(2) A CHC Drug Outlet must designate a representative employee who will act as the contact person for the Oregon Board of Pharmacy. The designated representative must be onsite the majority of the CHC's normal operating hours.

(a) The Medical Director or designated representative must conduct and document an annual review of the outlet on a form provided by the Board. The completed report must be filed at the outlet, retained on file for three years, and be available for inspection by the Board.

Requirements: Oregon law states that the Medical Director and Designated Representative are responsible for ensuring the drug outlet is compliant with all applicable state and federal laws and rules. The completed report must be filed in the outlet, retained on file for three years and be available to the Board for inspection.

Scope: The primary objective of completing the self-inspection is to identify and correct areas of non-compliance with any state and federal laws and rules. This process is not exhaustive, however, and laws and rules often change between annual updates to this form. Subsequently, it is your responsibility to ensure compliance with any changes, or applicable laws and rules, not referenced herein.

Internal Use: Following completion of the self-inspection form, ensure it is signed and dated, reviewed with all staff, and filed in a conspicuous manner (DO NOT SEND to the agency office). It is advisable to store the documents in a binder, using tabs to partition and organize where possible. Otherwise, please CLEARLY indicate on the form where auxiliary documents are located.

Agency Use: During an inspection, Compliance Officers use the self-inspection form as a general guide to assess drug outlet compliance. The CHC should be prepared and able to retrieve this form and locate any auxiliary documents referenced within at the time of inspection.

Email all compliance-related questions to: pharmacy.compliance@bop.oregon.gov

2025
COMMUNITY HEALTH CLINIC (CHC) DRUG OUTLET
SELF-INSPECTION FORM

Date Self-Inspection Completed: _____ / _____ / _____

Outlet Name: _____ Registration #: _____

Address: _____

City: _____ State: _____ Zip Code: _____

Telephone: (_____) _____-_____ Fax: (_____) _____-_____

Medical Director Name: _____ License #: _____

Medical Director Work Email: _____ Phone: (_____) _____-_____

Designated Representative Name (if different than Medical Director): _____

Designated Representative Work Email: _____ Phone: (_____) _____-_____

DEA Registration #: _____ EXP: _____ / _____ / _____

CHC Registration # (if applicable): _____ EXP: _____ / _____ / _____

Hours of operation: _____

INSTRUCTIONS:
Verify compliance of each section by marking the corresponding box. Should any non-compliance be identified, rectify the deficiencies and record the correction date.

General Requirements

Yes	No			Rule Reference
☐	☐	1.	Does the outlet employ a Medical Director who is an Oregon-licensed practitioner, with prescriptive and dispensing authority?	OAR 855-043-0710(1) OAR 855-043-0715
☐	☐	2.	Does the Medical Director establish and enforce policies and procedures, drug dispensing formularies and protocols for the dispensing of drugs by authorized persons in the CHC?	OAR 855-043-0710(2)(b)
☐	☐	3.	Does the outlet employ a designated representative who works onsite the majority of the CHC's normal operating hours and who is the contact person for the Oregon Board of Pharmacy? **Note:** This may be the Medical Director.	OAR 855-043-0710(2)
☐	☐	4.	Does the outlet have written policies and procedures for all of the following topics related to drug management? (mark box once confirmed) ☐ Security ☐ Acquisition ☐ Storage ☐ Dispensing ☐ Delivery ☐ Disposal ☐ Record keeping ☐ RN Training (related to drug dispensing) Where are these policies and procedures located? _____ _____ _____	OAR 855-043-0715(1) and (2)
☐	☐	5.	Does the CHC have established procedures to train an employee Registered Nurse (RN) to ensure continued competence in the dispensing of drugs? Where are the training documents located? _____ _____	OAR 855-043-0715
☐	☐	6.	Does the outlet have access to the most current issue of at least one pharmaceutical reference with current, properly filed supplements and updates appropriate to and based on the standards of practice for the setting? Where are the references located? _____ _____ _____	OAR 855-043-0740(9)

Drug Security and Dispensing

Yes	No			Rule Reference
☐	☐	7.	Does the outlet ensure that a RN only dispenses medications that fit within the scope of the CHC's authority? **Note:** • A legend or non-prescription drug may be dispensed to a client for the purpose of birth control, caries prevention, the treatment of amenorrhea, the treatment of a communicable disease, hormone deficiencies, urinary tract infections or sexually transmitted diseases by a RN, who is an employee of a clinic or local public health authority (LPHA), and is recognized by the Oregon Public Health Division for the purposes of providing public health services. • Dispensing must be pursuant to the order or prescription of a person authorized by their Board to prescribe a drug	OAR 855-043-0700(1)(2) ORS 689.605(6)
☐	☐	8.	Does a RN only provide over-the-counter drugs pursuant to established CHC protocols?	OAR 855-043-0740
☐	☐	9.	Does the outlet **only** acquire drugs from suppliers registered with the Oregon Board of Pharmacy? Names of suppliers and their OBOP registration numbers: _____ _____ _____ _____ _____ Where are the invoices located? _____ _____ _____ **Note:** Verify a supplier's Board of Pharmacy registration at https://orbop.mylicense.com/verification/	OAR 855-043-0725
☐	☐	10.	Are all drugs (including samples) stored in accordance with the manufacturer's labeling and stored in appropriate conditions of temperature, light, humidity, sanitation, ventilation, and space?	OAR 855-043-0730
☐	☐	11.	Does the outlet store all drugs in a locked cabinet or designated storage area that is sufficiently secure to deny access to unauthorized persons? How does the outlet maintain security? _____ _____ _____ **Note**: Per OAR 855-043-0720, the drug storage cabinet or area must remain locked and secure when not in use, and only a physician, clinical nurse specialist, nurse practitioner, or RN shall have access to the key.	OAR 855-043-0720(1) and (2)

Yes	No			Rule Reference
☐	☐	12.	Are all recalled, outdated/expired, damaged, deteriorated, suspect, illegitimate, misbranded, or adulterated drugs properly quarantined and physically separated from other drugs until destroyed or returned to the supplier? Where does the outlet keep drugs quarantined, awaiting destruction or disposal? _____ _____ _____	OAR 855-043-0745
☐	☐	13.	Are all prescriptions labeled with each of the following required elements? • Unique identifier ("prescription number") • Name of patient • Name of prescriber • Name, address, and phone number of CHC • Date of dispensing • Drug name and strength – when a generic name is used, the label must also contain the identifier of the manufacturer or distributor • Quantity dispensed • Directions for use • Initials of the practitioner with dispensing privileges, or the RN • Cautionary statements, if any, as required by law • Manufacturer's expiration date, or an earlier date if preferable, after which the drug should not be used (*e.g., the expiration date on NuvaRing® should not exceed 4 months from the date dispensed).* **Note:** For additional information on assigning expiration dates, see OAR 855-041-1130(10)-(12)	OAR 855-043-0735(1)(a-k)
☐	☐	14.	Are dual language prescription labels available in each of the 14 required languages, and provided upon request by the patient or patient's agent? **Note:** The prescription must bear a label in **both** English and the language requested.	ORS 689.564 OAR 855-043-0736
☐	☐	15.	Are all drugs prepackaged for later own use dispensed in a container that meets USP standards and is labeled to identify the following information, at minimum? • Drug name (brand, or generic name plus manufacturer or distributor) • Strength • Lot number • Manufacturer's expiration date, or an earlier date if preferable	OAR 855-043-0735
☐	☐	16.	Are drugs dispensed in compliance with the current provisions of the Poison Prevention Packaging Act in CFR Title 16, Chapter II, Subchapter E, Parts 1700 – 1702 (01/01/2023)?	OAR 855-043-0740(6)
☐	☐	17.	Does the practitioner or RN provide the patient with appropriate drug information for medications at the time of dispensing?	OAR 855-043-0740(5) OAR 855-043-0740(12)

Yes	No			Rule Reference
			Note: Each authorized dispenser of a prescription drug product for which a Medication Guide is required must provide the Medication Guide directly to each patient or patient's agent when the product is dispensed, unless an exemption applies. FDA Medication Guide Database	
☐	☐	18.	Are all of the following requirements met for each prescription that is delivered or mailed to a patient? • Drug is maintained in proper storage conditions • Offer for direct counseling is provided in writing, along with instructions on how to contact the practitioner, and information about the drug, including but not limited to: o Drug name, class, and indications o Proper storage and use o Common side effects o Precautions and contraindications o Significant drug interactions	OAR 855-043-0740(10)
		19.	How does the CHC ensure that all prescriptions, prescription refills, and drug orders are correctly dispensed in accordance with the prescribing practitioner's authorization and any other requirement of State or federal law?	OAR 855-043-0740(11)
☐	☐	20.	Is staff aware that a CHC may not accept the return of drugs from a previously dispensed prescription and must maintain a list of sites in Oregon where drugs may be disposed? https://medtakebackoregon.org	OAR 855-043-0740(8)

Records

Yes	No			Rule Reference
☐	☐	21.	Is a unique dispensing record maintained separately from the patient chart and kept for a minimum of 3 years? Where are the records kept? _____ _____ _____	OAR 855-043-0750(1)
☐	☐	22.	Does the dispensing record contain all of the following required elements? • Name of patient • Unique identifier ("prescription number") • Drug name (brand, or generic name plus manufacturer or distributor), dose, dosage form, and quantity dispensed • Directions for use • Date of dispensing • Initials of person dispensing the prescription	OAR 855-043-0750(1)(a-f)

Yes	No			Rule Reference
☐	☐	23.	Are all records for the receipt and disposal of drugs kept for a minimum of three years? Where are the records kept? _____ _____ _____	OAR 855-043-0750(2)

I hereby certify that to the best of my knowledge, this outlet is compliant with all applicable laws and rules, and that the answers marked on this form are true and correct.

Date: _____ **/** _____ **/** _____

Printed Name and Tile (Medical Director or Designative Representative): _____

Signature: _____