



2024
COMMUNITY HEALTH CLINIC (CHC) DRUG OUTLET
SELF-INSPECTION FORM

ATTENTION: MEDICAL DIRECTOR or DESIGNATED CLINIC REPRESENTATIVE

This form is to be completed by July 1, 2024.

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 Community Health Clinic Drug Outlet registration replaces a Family Planning or County Health Drug Outlet registration. 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 on-site for 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 in the outlet, retained on file for three years and be available to the Board for inspection.

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. As these inspections are not coordinated with the CHC, all staff should be able to retrieve the form and locate any auxiliary documents referenced within.

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

**2024
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 Rep. Work Email: _____ Phone: (_____) _____ - _____

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

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

Hours of operation: _____

INSTRUCTIONS

You are required to confirm whether the outlet is compliant. Mark the appropriate box to the left of each item, resolve all deficiencies and write the date of correction, if applicable.

General Requirements

Yes	No		Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	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
<input type="checkbox"/>	<input type="checkbox"/>	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)
<input type="checkbox"/>	<input type="checkbox"/>	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)

Yes	No			Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	4	<p>Does the outlet have <u>written</u> policies and procedures for all of the following topics related to drug management? (mark box once confirmed)</p> <ul style="list-style-type: none"> <input type="checkbox"/> Security <input type="checkbox"/> Acquisition <input type="checkbox"/> Storage <input type="checkbox"/> Dispensing <input type="checkbox"/> Delivery <input type="checkbox"/> Disposal <input type="checkbox"/> Record keeping <input type="checkbox"/> RN Training (related to drug dispensing) <p>Where are these policies and procedures located?</p>	OAR 855-043-0715(1) and (2)
<input type="checkbox"/>	<input type="checkbox"/>	5	Are all policies and procedures developed in collaboration between the Medical Director and the Designated Representative?	OAR 855-043-0710(2)(b)
		6	Where are the outlet's pharmaceutical references kept?	OAR 855-043-0740(9)

Drug Security and Dispensing

Yes	No			Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	7	<p>Does the outlet utilize a Registered Nurse (RN) to dispense medications?</p> <p>Note: Pursuant to the order of a person authorized to prescribe a drug or device, an RN employed by a registered CHC may dispense a drug or device to a client for purposes of caries prevention, birth control or prevention, or treatment of a communicable disease.</p>	OAR 855-043-0700(1) ORS 689.605(6)
<input type="checkbox"/>	<input type="checkbox"/>	8	<p>How does the outlet ensure a RN's continued competence in the dispensing of drugs?</p> <p>Where are the training documents located?</p>	OAR 855-043-0715(2)

Yes	No		Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	9 Does the RN only provide prescription and non-prescription drugs pursuant to established CHC protocols? Note: A RN may only provide prescription medications and OTC medications pursuant to protocols established and enforced by the Medical Director.	OAR 855-043-0740
<input type="checkbox"/>	<input type="checkbox"/>	10 Does the outlet only acquire drugs from suppliers registered with the Oregon Board of Pharmacy? Names of suppliers and their OBOP registration numbers: <ul style="list-style-type: none"> ▪ ▪ ▪ ▪ ▪ Where are the invoices located? Note: Verify a supplier's Board of Pharmacy registration at https://orbop.mylicense.com/verification/	OAR 855-043-0725
<input type="checkbox"/>	<input type="checkbox"/>	11 Is dispensing completed only by an Oregon-licensed individual that has the authority to dispense? Please provide the name and license number for each person dispensing at this drug outlet:	OAR 855-043-0700
<input type="checkbox"/>	<input type="checkbox"/>	12 Are all drugs (including samples) stored in accordance with the manufacturer's labeling?	OAR 855-043-0730
<input type="checkbox"/>	<input type="checkbox"/>	13 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		
<input type="checkbox"/>	<input type="checkbox"/>	14	<p>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?</p> <p>Where does the outlet keep drugs quarantined, awaiting destruction or disposal?</p>	OAR 855-043-0745
<input type="checkbox"/>	<input type="checkbox"/>	15	<p>Are all prescriptions labeled with each of the following required elements?</p> <ul style="list-style-type: none"> • 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 (<i>e.g., the expiration date on NuvaRing® should not exceed 4 months from the date dispensed</i>). <p>Note: For additional information on assigning expiration dates, see OAR 855-041-1130(10)-(12).</p>	OAR 855-043-0735(1)(a-k)
<input type="checkbox"/>	<input type="checkbox"/>	16	<p>Are dual language prescription labels available in each of the 14 required languages, and provided upon request by the patient or patient’s agent?</p> <p>Note: The prescription must bear a label in both English and the language requested.</p>	ORS 689.564 OAR 855-043-0736
<input type="checkbox"/>	<input type="checkbox"/>	17	<p>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?</p> <ul style="list-style-type: none"> • 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
<input type="checkbox"/>	<input type="checkbox"/>	18	<p>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)?</p>	OAR 855-043-0740(6)
<input type="checkbox"/>	<input type="checkbox"/>	19	<p>Does the practitioner or RN provide the patient with appropriate drug information for medications at the time of dispensing?</p>	OAR 855-043-0740(5)

Yes	No			Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	20	<p>Are all of the following requirements met for each prescription that is delivered or mailed to a patient?</p> <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> ○ Drug name, class, and indications ○ Proper storage and use ○ Common side effects ○ Precautions and contraindications ○ Significant drug interactions 	855-043-0740(10)
<input type="checkbox"/>	<input type="checkbox"/>	21	<p>Is staff aware that a CHC may not accept the return of drugs from a previously dispensed prescription, may not re-dispense a prescription that was already released to a patient, and must maintain a list of sites in Oregon where drugs may be disposed?</p>	OAR 855-043-0740(8)

Records

Yes	No			Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	22	<p>Is a unique dispensing record maintained separately from the patient chart and kept for a minimum of 3 years?</p> <p>Where are the records kept?</p>	OAR 855-043-0750(1)
<input type="checkbox"/>	<input type="checkbox"/>	23	<p>Does the dispensing record contain all of the following required elements?</p> <ul style="list-style-type: none"> • 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)
<input type="checkbox"/>	<input type="checkbox"/>	24	<p>Are all records for the receipt and disposal of drugs kept for a minimum of three years?</p> <p>Where are the records kept?</p>	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: ____ / ____ / _____

Name and Title (Medical Director or Designative Representative):

Signature: