

Community Health Clinic Drug Outlet

855-043-0700

Purpose and Scope

- (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.
- (3) Family Planning or County Health Clinic registrations that expire March 31, 2017 will be converted to the CHC category upon renewal in 2017. However, rules take effect on July 1, 2016.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.305

855-043-0705

Registration

- (1) A Community Health Clinic Drug Outlet must register with the Board on a form prescribed by the Board, and must renew its registration annually on a renewal form prescribed by the Board.
- (2) An initial application and renewal application must be accompanied by the fee established in Division 110 of this Chapter.
- (3) A certificate of registration will be issued upon Board approval of the application.
- (4) The CHC Drug Outlet registration expires March 31, annually. If the annual renewal fee is not paid by February 28 of the current year, the applicant for renewal must submit the delinquent fee established in Division 110 of this Chapter with the renewal application.
- (5) The registration is not transferable and the registration fee cannot be prorated.
- (6) The registrant must notify the Board, within 15 days, of any substantial change to the information provided on the registration application. A substantial change shall include but not be limited to: a change of ownership; change of business address; change of normal business

hours; any disciplinary action taken or pending by any state or federal authority against the registrant, or any of its principals, owners, directors, officers, or Medical Director.

(7) A new registration form is required for a change of ownership or location and must be submitted to the Board with the fees as specified in Division 110 of this Chapter within 15 days of the change.

(8) A CHC Drug Outlet may be inspected by the Board.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.305

855-043-0710

Personnel

(1) A Community Health Clinic Drug Outlet must employ a Medical Director who is an Oregon practitioner with prescriptive and dispensing authority. The Medical Director shall establish and enforce policies and procedures, drug dispensing formulary, and protocols for the dispensing of drugs by authorized persons in the CHC.

(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 in the outlet, retained on file for three years and be available to the Board for inspection.

(b) The Medical Director shall develop policies and procedures for the outlet in collaboration with the designated representative.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.305

Policies and Procedures

855-043-0715

Policies and Procedures

The Community Health Clinic must:

(1) Maintain written policies and procedures for drug management, including security, acquisition, storage, dispensing and drug delivery, disposal, and record keeping.

(2) Establish procedures to train a Registered Nurse employed by the CHC to ensure continued competence in the dispensing of drugs.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.305

855-043-0720

Security

(1) All drugs must be kept in a locked drug cabinet or designated drug storage area that is sufficiently secure to deny access to unauthorized persons. The drug cabinet or designated drug storage area must remain locked and secured when not in use.

(2) Only a Physician, Clinical Nurse Specialist, Nurse Practitioner, or Registered Nurse shall have a key to the drug cabinet or drug room. In their absence, the drug cabinet or drug room must remain locked.

(3) Upon written request, the Board may waive any of the requirements of this rule if a waiver will further public health or safety or the health and safety of a patient. A waiver granted under this section shall only be effective when it is issued by the Board in writing.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.305

855-043-0725

Drug Acquisition

The CHC must verify that all drugs are acquired from a registrant of the Board.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.305

855-043-0730

Storage of Drugs

All drugs, including drug samples, must be stored according to the manufacturer's published guidelines and be stored in appropriate conditions of temperature, light, humidity, sanitation, ventilation, and space.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.305

855-043-0735

Labeling

(1) A prescription must be labeled with the following information:

(a) Unique identifier (i.e. prescription number);

(b) Name of patient;

- (c) Name of prescriber;
- (d) Name, address, and phone number of the clinic;
- (e) Date of dispensing;
- (f) Name of drug, strength, and quantity dispensed; when a generic name is used, the label must also contain the identifier of the manufacturer or distributor;
- (g) Quantity dispensed;
- (h) Directions for use;
- (i) Initials of the practitioner who has been given dispensing privileges by their licensing Board or the Registered Nurse;
- (j) Cautionary statements, if any, as required by law; and
- (k) Manufacturer's expiration date, or an earlier date if preferable, after which the patient should not use the drug.

(2) Notwithstanding any other requirements in this rule, when a drug is dispensed in the practice of an Expedited Partner Therapy treatment protocol, the name of the patient may be omitted from the label, the patient's name may be omitted from the records and a drug may be dispensed to the patient to be given to the patient's partner even if the partner has not been examined by a licensed health care provider acting within their scope of practice.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.305, 689.505

855-043-0740

Dispensing and Drug Delivery

- (1) A drug may only be dispensed by a practitioner who has been given dispensing privileges by their licensing Board or by a Registered Nurse.
- (2) A Registered Nurse may only provide over-the-counter drugs pursuant to established CHC protocols.
- (3) A Registered Nurse may only dispense a drug listed in, or for a condition listed in, the formulary.
- (4) Nonjudgmental dispensing functions may be delegated to staff assistants when the accuracy and completeness of the prescription is verified by a practitioner who has been given dispensing privileges by their licensing Board, or by a Registered Nurse, prior to being delivered or transferred to the patient.

(5) The CHC will provide appropriate drug information for medications dispensed to a patient, which can be provided by the Registered Nurse or practitioner at the time of dispensing.

(6) All drugs must be dispensed in a new container that complies with the current provisions of the Federal Consumer Packaging Act (Public Law 91-601, 91st Congress, S. 2162) and rules or regulations and with the current United States Pharmacopoeia/National Formulary monographs for preservation, packaging, storage and labeling.

(7) Drugs must be repackaged by the practitioner, Registered Nurse, a pharmacy; or a manufacturer registered with the Board.

(8) 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.

(9) A CHC must 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.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.305

855-043-0745

Disposal of Drugs

Drugs that are outdated, damaged, deteriorated, misbranded, adulterated, or identified as suspect or illegitimate must be documented, quarantined and physically separated from other drugs until they are destroyed or returned to the supplier.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.305

855-043-0750

Record Keeping

(1) A dispensing record must be maintained separately from the patient chart and kept for a minimum of three years. The record must show, at a minimum, the following:

(a) Name of patient;

(b) Unique identifier (i.e. prescription number);

(c) Dose, dosage form, quantity dispensed and either the brand name of drug, or generic name and name of manufacturer or distributor;

(d) Directions for use;

(e) Date of dispensing; and

(f) Initials of person dispensing the prescription.

(2) All records of receipt and disposal of drugs must be kept for a minimum of three years.

(3) All records required by these rules or by other State and federal law must be readily retrievable and available for inspection by the Board.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.305