

Oregon Board of Pharmacy Community Health Center Outlet

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Agenda

- Introduction
- What exactly is a Community Health Clinic Drug Outlet?
- Board of Pharmacy Rules
- Self Inspection Form
- What to Expect from a Board of Pharmacy Inspection
- Questions

Introduction

- Oregon Board of Pharmacy (OBOP) Mission:
 - To promote, preserve and protect the public health, safety and welfare, by establishing high standards in the practice of pharmacy and in the distribution of drugs in Oregon.
- Some ways we achieve our objective:
 - Licensure & Regulation
 - Education
 - Communication & Outreach
 - Annual Inspections of Drug Outlets

Community Health Clinic (CHC) Drug Outlet

- Combines the County Health & Family Planning licenses into one
- Still is only required when the facility utilizes RNs to dispense medications
- What changes have been made?
 - Personnel:
 - CHC license does not require a Consultant Pharmacist
 - CHC must have a Medical Director
 - CHC must designate a representative employee, who works onsite the majority of the CHC's normal operating hours, and is the contact person for the OBOP.
 - Drug/Health Condition Formulary:
 - Combined - more comprehensive
 - OTCs are added

Board of Pharmacy Rules

- Primary intentions of the CHC rules:
 - Authority for RNs to dispense, under legally authorized circumstances
 - Describe registration requirements with the OBOP
 - Outline compliance expectations for drug management and dispensing processes
 - Provide labeling, record-keeping, and other documentation requirements

Board of Pharmacy Rules (con't)

- OBOP Division 043 Practitioner Dispensing – CHC Drug Outlets
 - Registration
 - Personnel
 - Policies & Procedures
 - Security
 - Drug Acquisition
 - Drug Storage
 - Labeling
 - Dispensing & Drug Delivery
 - Drug Disposal
 - Record Keeping

CHC Self Inspection Form

- To be completed annually by the clinic's Medical Director or designated representative.
 - Standardized form on OBOP website.
 - Will be mailed with outlet renewal paperwork in Q1 2017.
 - Designed to help staff understand compliance expectations related to drug dispensing and confirm compliance with rules.
- Used by the OBOP inspector during the inspection.
- Complete it and keep it filed near the clinic dispensing area.

CHC Self Inspection Form

YES **NO**

OAR 855-043-0720

8. Does the CHC store all drugs intended for dispensing in a locked cabinet or designated storage area that is sufficiently secure to deny access to unauthorized persons? Note: 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 registered nurse shall have access to the key.

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

BOP Inspection

- Inspector will review form and confirm CHC's compliance with drug management and dispensing requirements.
- Focus of inspection is drug dispensing, particularly:
 - Acquisition
 - Storage
 - Labeling
 - Record Keeping
- Inspector will provide the clinic representative or Medical Director with a summary of findings.

Overall “Take-Aways”

- Licensure transition – early 2017
- Expanded Formulary!
- Personnel changes
- Self Inspection Form
- Inspections



Resources

- Oregon Board of Pharmacy home page:
 - <http://www.oregon.gov/pharmacy/Pages/index.aspx>
- Link to Division 043 Rules:
 - http://arcweb.sos.state.or.us/pages/rules/oars_800/oar_855/855_043.html
- Self Inspection Form:
 - <http://www.oregon.gov/pharmacy/Pages/InspectionForms.aspx>
- Contact the Board office:
 - Phone: 971-673-0001
 - Email: pharmacy.board@state.or.us



Questions?

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