

**DRAFT RULES**

**Central Fill Drug Outlets**

**855-041-3005**

**Purpose and Scope**

**The purpose of OAR 855-041-3005 through 855-041-3045 is to provide minimum requirements of operation for centralized prescription drug filling by a pharmacy. Any facility established for the purpose of filling drug orders on behalf of an Oregon pharmacy shall be licensed as a retail or institutional drug outlet. An applicant must submit to the Board for approval their policies and procedures, which includes how utilizing central fill will improve patient safety and redirect a pharmacist at a primary pharmacy from a distributive task to a cognitive task.**

**Stat. Auth.: ORS 689.205**

**Stats. Implemented: ORS 689.155**

**855-041-3010**

**Definitions**

**The following words and terms, when used OAR 855-041-3005 through 855-041-3045 shall have the following meanings, unless the context clearly indicates otherwise. Any term not defined in this section shall have the definition set out in OAR Chapter 855, Division 006.**

**(1) “Central Fill Pharmacy” means an Oregon licensed pharmacy that provides centralized prescription filling for both initial or prescription refills on behalf of a primary pharmacy.**

**(2) “Primary Pharmacy” means a pharmacy located and licensed in Oregon that receives a patient’s or a prescribing practitioner’s request to fill a prescription, dispenses the prescription directly to the patient or patient’s agent, or the pharmacy delivers the drug to the patient’s agent for administration. The primary pharmacy maintains ownership of the prescription.**

**Stat. Auth.: ORS 689.205**

**Stats. Implemented: ORS 689.155**

855-041-3015

General Requirements

An Oregon licensed pharmacy may outsource prescription drug filling to a central fill pharmacy provided that both pharmacies:

- (1) Have the same owner; or
- (2) Have a written shared pharmacy services contract or agreement that specifies:
  - (a) The services to be provided by each pharmacy;
  - (b) The responsibilities of each pharmacy; and
  - (c) The accountabilities of each pharmacy.
- (3) Maintain a separate Oregon pharmacy license for each location involved in providing prescription drugs and services to Oregon patients;
- (4) Share a common electronic file or have appropriate technology or interface to allow access to information required to fill a prescription drug order;
- (5) Establish, maintain and enforce a policy and procedures manual as required by OAR 855-041-3015;
- (6) Ensure that each prescription has been properly processed and filled and that counseling has been provided to the patient;
- (7) Designate a pharmacist-in-charge. To qualify for this designation, the person must hold a license to practice pharmacy in the state of Oregon and in the pharmacy's resident state if the pharmacy is out-of-state. The pharmacist-in-charge must be in good standing with both licensing boards;
- (8) Conduct an annual review of the written policies and procedures and document such review;
- (9) Comply with all applicable federal and state laws and rules;
- (10) Direct all patient communication to the primary pharmacy.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.155

855-041-3020

## Policies and Procedures

(1) In addition to the requirements of OAR 855-041-1040, the central fill pharmacy and the primary pharmacy is each accountable for establishing, maintaining, and enforcing its written policies and procedures manual that includes, but need not be limited to the following:

(a) The responsibilities of each pharmacy;

(b) The confidentiality and integrity of patient information;

(c) Compliance with all applicable federal and state laws and rules;

(d) Cancellation of a filled prescription after the prescription is filled by the primary pharmacy;

(e) Records sufficient to identify by name, initials or unique identification code, the identify and specific activities of each pharmacist or technician who performed any centralized filling function, and the pharmacy where each activity was performed;

(f) The mechanism for tracking the prescription drug order during each step in the filling and dispensing process;

(g) Pharmacist completion of a Drug Utilization Review (DUR) on each prescription;

(h) A continuous quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems;

(i) Documentation of any errors or irregularities identified by the quality improvement program;

(2) This manual shall be maintained at both the central fill and primary pharmacy and must be made available to the Board upon request.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.155

855-041-3025

Labeling

**(1) The label affixed to the prescription container filled by a central fill pharmacy on behalf of the primary pharmacy shall:**

**(a) Include all information required by OAR 855-041-1130 and OAR 855-041-1140;**

**(b) Comply with all labeling requirements identifying only the primary pharmacy.**

**(2) If the Central Pharmacy dispenses the completed prescription to the patient, the label must also comply with retail labeling requirements in OAR 855-041-1130 through 855-041-1140.**

**Stat. Auth.: ORS 689.205**

**Stats. Implemented: ORS 689.155**

**855-041-3030**

### **Record Keeping**

**(1) The record keeping requirements in OAR 855-041-3005 through 855-041-3045 are in addition to the requirements of other record keeping rules of the Board.**

**(2) Each record keeping system must include quality improvement program documentation.**

**(3) Unless otherwise specified, all records and documentation required by OAR 855-041-3005 through 855-041-3045 must be retained for three years and made available to the Board for inspection upon request. Records must be stored onsite for at least one year and after one year, may be stored in a secured off-site location if retrievable within three business days. Records and documentation may be kept in hard copy, electronic copy, or a combination of the two.**

**(4) Each pharmacy must be able to produce an audit trail which identifies each prescription process in their pharmacy.**

**(5)The primary pharmacy shall maintain the original prescription for a period of three years from the date the prescription was filled.**

**(6)The primary pharmacy must maintain records that:**

**(a) Identify by prescription or drug order, the name or unique identification code of the pharmacist who performed the drug utilization review. Identify by prescription drug order the pharmacist or technician that transmitted the prescription drug order to the central fill pharmacy. These records may be maintained separately by each pharmacy and pharmacist or technician or in a common electronic file as long**

**as the data processing system is capable of producing a printout that lists each function performed by each pharmacy and pharmacist or technician and identifies the pharmacist or technician who performed each function;**

**(b) Document the date the filled prescription was received from the central fill pharmacy and the name of the person accepting delivery.**

**(7) The central fill pharmacy must maintain records that:**

**(a) List the name, address, telephone numbers, and all license and registration numbers of the pharmacies involved in centralized prescription filling; and**

**(A) Document verification of each license and registration; and**

**(B) Document the name of the individual responsible for verification of licensure and registration status.**

**(b) Track the prescription drug order during each step in the filling process and identify the name, initials, or unique identification code and specific activity of each pharmacist or pharmacy technician who performed any portion of the process including transmission, filling, dispensing and delivery of information.**

**(A) The date the prescription was received by the central fill pharmacy;**

**(B) The name and address where the filled prescription was shipped;**

**(C) The method of delivery (e.g., private, common, or contract carrier).**

**Stat. Auth.: ORS 689.205**

**Stats. Implemented: ORS 689.155**

**855-041-3035**

**Delivery of Medications**

**(1) A central fill pharmacy may deliver or mail medications to the primary pharmacy or patient in compliance with OAR 855-041-1050.**

**(2) A central fill pharmacy must comply with all federal and state requirements when using private, common or contract carriers to transport filled prescriptions for delivery. When central fill pharmacies contract with private, common or contract carriers to transport filled prescriptions the central fill pharmacy is responsible for reporting in-transit losses upon detection by use of a DEA Form 106.**

**(3) A central fill pharmacy must maintain and use adequate storage or shipment containers and shipping processes to ensure drug stability and potency. Such shipping processes shall include the use of packaging material and devices to ensure that the drug is maintained at the temperature range required to maintain the integrity of the medication throughout the delivery process.**

**(4) Filled prescriptions must be shipped in containers that are sealed in a manner that shows evidence of opening or tampering.**

**Stat. Auth.: ORS 689.205**

**Stats. Implemented: ORS 689.155**

**855-041-3040**

### **Filled Prescriptions**

**(1) Any filled prescription that has not been picked up, may be put into the primary pharmacy's inventory. Each pharmacy is responsible for documenting any such transfer of a drug.**

**(2) A prescription for a controlled substance may be filled by a central fill pharmacy when permitted by law, consistent with federal requirements set forth at 21 C.F.R. § 1300 et seq;**

**(3) The pharmacy that fills the prescription and the pharmacy to which the filled prescription is provided for dispensing to the patient shall each be responsible for ensuring the prescription has been properly filled.**

**(4) Primary pharmacy will notify the patient of the possible use of a central fill pharmacy.**

**Stat. Auth.: ORS 689.205**

**Stats. Implemented: ORS 689.155**

**855-041-3045**

### **Prohibited Practices**

**(1) A primary pharmacy may not use the services of a central fill pharmacy that is not registered with the Board.**

**(2) A central fill pharmacy may not fill a prescription on behalf of a primary pharmacy that is not registered with the Board if the laws and rules of Oregon require the primary pharmacy to be registered with the Board.**

**Stat. Auth.: ORS 689.205**

**Stats. Implemented: ORS 689.155**