

DRAFT RULES

Remote Processing Drug Outlets

855-041-3100

Purpose and Scope

The purpose of OAR 855-041-3100 through 855-041-3130 is to provide minimum requirements of operation for remote prescription drug processing by a pharmacy. Any facility established for the purpose of processing drug orders on behalf of an Oregon pharmacy shall be licensed as a retail or institutional drug outlet registration. An applicant must submit to the Board for approval their policies and procedures which includes how utilizing remote processing 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

855-041-3105

Definitions

The following words and terms, when used in OAR 855-041-3100 through OAR 855-041-3130, 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) “Remote Processing Pharmacy” means an Oregon licensed pharmacy operated under the direction of a pharmacist-in-charge that processes information related to the practice of pharmacy and engages in remote prescription processing, including central processing. Remote processing functions may include, but are not limited to, data entry, prospective drug utilization reviews, refill authorizations, interventions, claims submission, claims resolution and adjudication. This does not include the filling process.

(2) “Primary Pharmacy” means an instate Oregon licensed pharmacy that receives a patient’s or a prescribing practitioner’s request to fill a prescription or drug order and delivers the drug or device directly to the patient or patient’s agent, and maintains ownership of the prescription or drug order.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.155

855-041-3110

General Requirements

An Oregon licensed pharmacy may outsource prescription drug processing to a remote processing pharmacy provided 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 services;

(4) Share a common electronic file or have appropriate technology or interface to allow access to information required to process and fill a prescription drug order;

(5) Establish, maintain and enforce a policy and procedures manual as required by OAR 855-041-3115;

(6) Ensure that each prescription has been properly processed, filled and 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) Prospective drug utilization reviews, refill authorizations, interventions, patient counseling, claims submission, claims resolution and adjudication for an Oregon patient must be performed by an Oregon licensed Pharmacist;

(9) Ensure that each technician processing an order for an Oregon patient is a Certified Oregon Pharmacy Technician and must be supervised by a licensed pharmacist;

(10) Comply with all applicable federal and state laws and rules;

(11) Conduct an annual review of the written policies and procedures and document such review.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.155

855-041-3115

Policies and Procedures

(1) In addition to the requirements of OAR 855-041-1040, both the primary and remote processing pharmacy is 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) Records sufficient to identify by name, the initials, or unique identification code, the identity and the specific activities of each pharmacist or technician who performed any processing function, and the location where each activity was performed;

(e) 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; and

(f) Documentation of any errors or irregularities identified by the quality improvement program.

(2) The written policies and procedures manual shall be maintained at all pharmacies involved in remote processing and must be available to the Board upon request.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.155

855-041-3120

Record Keeping

(1) The record keeping requirements OAR 855-041-3100 through 855-041-3130 are in addition to the requirements of other record keeping rules of the Board.

(2) The remote processing pharmacy must maintain all required records unless these records are maintained in the primary pharmacy.

(3) Both record keeping systems must:

(a) List the name, address, telephone number, and all license and registration numbers of each pharmacy involved in remote prescription processing;

(A) Document verification of each license and registration;

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

(b) Identify by name, initials, or unique identification code the identity and the specific activities of each pharmacist or technician who performed any portion of the process;

(c) Include quality improvement program documentation;

(d) Be able to produce an audit trail showing each prescription process.

(4) Unless specified otherwise, all records and documentation required by these rules, 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 may be stored in a secured off-site location if retrievable within three business days. Records and documentation may be written, electronic or a combination of the two;

(5) The primary pharmacy shall maintain records which:

(a) Indicate the date the request for processing was transmitted to the remote processing pharmacy; and

(b) Indicate the date the prescription information was received by the primary pharmacy.

(6) The remote processing pharmacy shall maintain records which:

(a) Track the prescription drug order during each step in the order entry process;

(b) Identify the name, initials, or unique identification code and the specific activity of each pharmacist or pharmacy technician who performed any portion of the process including receipt, transmission or delivery of information.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.155

855-041-3125

Prescription or Drug Order Processing

A prescription for a controlled substance may be processed by a remote processing pharmacy when permitted by law and consistent with Federal regulations.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.155

855-041-3130

Prohibited Practices

A remote processing pharmacy may not process a prescription on behalf of a primary pharmacy that is not registered with the Board, if required by the laws and rules of Oregon to be registered.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.155