

PROPOSED RULES

DIVISION 43

PRACTITIONER DISPENSING

855-043-0002

Definitions

In this division of rules:

(1) "Administer" means the direct application of a drug or device whether by injection, inhalation, ingestion, or any other means, to the body of a patient by:

(a) A practitioner or the practitioner's authorized agent; or

(b) The patient at the direction of the practitioner.

(2) "Dispense" or "Dispensing" means the preparation and delivery of a prescription drug pursuant to a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to or use by a patient or other individual entitled to receive the prescription drug.

(3) "Formulary" means a list of drugs **or classes of drugs**, or a list of disease states, health conditions or preventative measures such as immunization or birth control approved by the Board or by the Department of Human Services (DHS).

(4) "Health Officer" means a physician licensed by the Oregon Medical Board or the Oregon Board of Naturopathic Medicine and employed by or under contract with a county or district health department or DHS.

(5) "Supervising Physician Dispensing Outlet" (SPDO) means any clinic, office, health care center, treatment center, or other establishment located within or out of this state from which a physician assistant dispenses drugs within this State, but that is not otherwise registered with the Board in the category of Retail Drug Outlet.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.155

Hist.: PB 2-1992, f. & cert. ef. 3-26-92; PB 4-1992, f. & cert. ef. 8-25-92; Renumbered from 855-043-0120 by BP 1-2010, f. & cert. ef. 2-8-10

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Supervising Physician Dispensing Outlets

855-043-0405

Purpose and Scope

A supervising physician or supervising physician organization that supervises a physician assistant with dispensing authority must register the dispensing site with the Board as a Supervising Physician Dispensing Outlet (SPDO) and must comply with the rules in OAR Chapter 855, Division 43.

855-043-0410

Registration

(1) A Supervising Physician Dispensing Outlet must register with the Board as a SPDO in the category of Retail Drug Outlet on a form provided by the Board, and must renew its registration annually on a renewal form provided by the Board.

(2) The initial application must state the location of the SPDO and the name of the person applying for registration. When the person applying for registration is not the owner of the dispensing site, the application must disclose the name and address of the owner and the applicant's affiliation with the owner.

(a) If the more than one individual owns the dispensing site, the names and addresses of the partners or persons holding the three largest ownership interests must be disclosed on the application.

(b) If the owner is a corporation, the application must state the name of the corporation as filed with the Corporation Division of the Oregon Secretary of State, including the names of the corporation's officers.

(3) Upon request by the Board, the applicant shall furnish such information as required by the Board regarding the partners, stockholders, or other persons not named in the application.

(4) An initial application must be accompanied by the fee established in Division 110 of this Chapter.

(5) A certificate of registration will be issued upon Board approval of the application.

(6) All registration renewal applications must be accompanied by the annual renewal fee established in Division 110 of this Chapter and must contain the information required in sections (2) and (3) of this rule.

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(7) The SPDO registration expires March 31, annually. If the annual renewal fee referred to in section (5) of this rule 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.

(8) The registration is not transferable and the registration fee cannot be prorated.

855-043-0415

Consulting Pharmacist

(1) A SPDO must retain a pharmacist licensed in Oregon for consultation purposes.

(2) The consulting pharmacist must conduct and document an annual inspection of the outlet on a form provided by the Board. The completed report form must be filed in the outlet, retained on file for three years and be available to the Board for inspection.

(3) The duties of the consulting pharmacist shall be clearly defined in writing within the organization. The consulting pharmacist must:

(a) Develop policies and procedures for the outlet in collaboration with the supervising physician; and

(b) Work in consultation with the supervising physician in the development of the formulary of drugs and classes of drugs for the outlet.

855-043-0420

Policies and Procedures

(1) The registered SPDO must:

(a) Maintain written policies and procedures for drug management, including storage, security, integrity, access, dispensing, disposal, record keeping and accountability;

(b) Maintain all drug records required by federal and state law;

(c) Establish procedures for procurement of drugs; and

(d) Establish procedures to train physician assistants who dispense drugs and to ensure the continued competence of physician assistants who dispense drugs.

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855-043-0425

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) No drug dispensing machines may be placed in waiting rooms or areas that are accessible by the public.

855-043-0430

Storage of Drugs

All drugs, including drug samples, must be stored under conditions that ensure proper sanitation, temperature, light, ventilation, moisture control, and any other condition recommended by the manufacturer.

855-043-0435

Labeling

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

(a) Unique identifier;

(b) Name of patient;

(c) Name of prescriber;

(d) Name, address, and phone number of the clinic;

(e) Date of dispensing;

(f) Name and strength of the drug. If the drug does not have a brand name, then the generic name of the drug and the drug manufacturer must be stated;

(g) Quantity dispensed;

(h) Directions for use;

(i) Initials of the person dispensing;

(i) Cautionary statements, if any, as required by law; and

(j) Manufacturer's expiration date, or an earlier date if preferable, after which the patient should not use the drug; and

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(k) Any dispensed prescription medication, other than those in unit dose or unit of use packaging, shall be labeled with its physical description, including any identification code that may appear on tablets and capsules.

(2) Notwithstanding any other requirements in this rule, when a drug is dispensed in the practice of an Expedited Partner Therapy treatment protocol, as described in OAR 855-041-4000 through 4005, the name of the patient may be omitted.

855-043-0440

Dispensing and Drug Delivery

(1) Drugs dispensed by a practitioner or physician assistant with dispensing authority under this section must be personally dispensed by the practitioner or physician assistant.

(2) Prior to dispensing a medication a drug utilization review must be performed by the practitioner which includes but is not limited to drug interactions, drug allergies and duplicate drug therapy.

(3) The practitioner or physician assistant must orally counsel the patient concerning all new drugs, unless circumstances would render oral counseling ineffective.

(4) When dispensed, a drug must be accompanied by written information that contains at least the following information:

(a) Drug name, class and indications;

(b) Proper use and storage;

(c) Common side effects;

(d) Precautions and contraindications; and

(e) Significant drug interactions.

(5) Each authorized dispenser of a prescription drug product for which a Medication Guide is required must provide the Medication Guide directly to each patient or each patient's agent when the product is dispensed, unless an exemption applies.

(6) Any other requirements when required by federal law.

(7) A SPDO must dispense drugs in new containers that comply 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.

(8) Drugs must be prepackaged by a pharmacy or manufacturer registered with the Board.

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(9) A SPDO 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.

(10) 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.

855-043-0445

Drug Dispensing Training Program

A physician assistant must complete a drug dispensing training program jointly developed by the Oregon Medical Board and the Board of Pharmacy before dispensing drugs to patients.

855-043-0450

Disposal of Drugs

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

855-043-0455

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;

(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) Records documenting training required by OAR 855-043-0445 must be kept for three years.

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