The proposed rules to *Div 043 Dispensing Practitioner Drug Outlets* \are intended to distinguish between traditional and non-traditional dispensing of drugs by a health care practitioner who has been granted dispensing privileges from their licensing board and dispenses from their practice location. A health care practitioner who participates in non-traditional dispensing must register the dispensing outlet with the Board as a Dispensing Practitioner Drug Outlet (DPDO).

The rule (1) identifies purpose and scope (2) registration criteria and requirements (3) policies and procedures, (4) security (5) drug acquisitions (6) drug storage (7) labeling (8) dispensing and drug delivery (9) disposal of drugs (10) recordkeeping and (11) inspections.

The Board plans a "soft-launch" of enforcement of these rules and, as always, plans to approach regulation per its "Compliance through Education" axiom.

The Board has worked with the following stakeholders in the development of these rules: Oregon Medical Board, Oregon State Board of Nursing, Oregon Board of Pharmacy, Oregon Dental Board, Oregon Veterinary Board, Oregon Board of Naturopathic Medicine, Oregon Optometry Board, Oregon Medical Association, Oregon Nurses Association, Oregon State Pharmacy Association, Oregon Dental Association, Oregon Veterinary Medical Association, Oregon Association of Naturopathic Physicians, Oregon Optometric Physicians Association, and the Drug Enforcement Agency (DEA).

Supporting documents include: 2013 DOJ Opinion OP-2013-1 and Non Pharmacy Dispensing Concept approved by the Oregon Board of Pharmacy 12/4/2014.

Proposed

Dispensing Practitioner Drug Outlets

855-043-0505

Purpose and Scope

These rules are intended to distinguish between traditional and non-traditional dispensing of drugs by a practitioner who has been granted dispensing privileges from their licensing board and dispenses from their practice location. A practitioner who participates in non-traditional dispensing must register the dispensing outlet with the Board as a Dispensing Practitioner Drug Outlet (DPDO).

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.305

855-043-0515

Registration

(1) A practitioner who engages in dispensing drug therapies greater than a 72 hours supply or any medication refill must register their dispensing site as a drug outlet with the Board as a DPDO on a form provided by the Board, and must renew its registration annually on a renewal form provided by the Board.

(2) A practitioner is exempt from this registration requirement if the practitioner only engages in:

(A) Dispensing FDA approved drug samples; or

(B) Dispensing Medication Assistance Program (MAP) drugs; or

(C) Dispensing a small amount of drugs to start therapy or incidental to a procedure or office visit, up to a 72 hour supply; or

(D) An amount greater than a 72 hour supply if the drug is:

(i) A drug in the manufacturer's original unit-of-use packaging, such as a metered-dose-inhaler; or

(ii) A full course of therapy, if in the professional judgment of the practitioner would be in the patient's best interest, such as a course of antibiotic therapy.

(3) The initial application must state the location of the DPDO 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 more than one individual owns the dispensing site, the names and addresses of the partners or persons holding the three largest ownership interests in the dispensing site 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.

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

(5) An initial application must be accompanied by the fee established in division 110 of this chapter. The fee is not to exceed $100.

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

(7) 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.

Proposed Rules

(8) The DPDO registration expires December 31, annually. If the annual renewal fee referred to in section (5) of this rule is not paid by November 30 of the current year, the applicant for renewal must submit the delinquent fee established in division 110 of this chapter with the renewal application.

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

(10) The registrant must notify the Board, within 15 days, of any substantial change to the information provided on the registration application. Substantial change shall include but not be limited to: change of ownership; change of business name; 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, consultant pharmacist or supervising physician.

(11) 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.

(12) The Board may grant a time-limited waiver exempting DPDO registration when a practitioner licensing board submits a request to the Board with a plan to annually inspect the dispensing facility to the standards of the Board.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.305

Policies and Procedures

855-043-0520

The registered DPDO must maintain written policies and procedures for the management of drugs intended for dispensing, to include security, acquisition, storage, dispensing and drug delivery, disposal and record keeping .

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.305

855-043-0525

Security

Proposed Rules

(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) A drug dispensing machine cannot be placed in a waiting room or an area that is accessible by the public.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.305,

855-043-0530

Drug Acquisition

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

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.305,

855-043-0535

Drug Storage

All drugs must be stored according to 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 689.155, 689.305

855-043-0540

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;

Proposed Rules

(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) 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

(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) Not withstanding 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.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.305

855-043-0545

Dispensing and Drug Delivery

(1) Drugs dispensed from DPDO by a practitioner shall be dispensed in compliance with the practitioner's Board requirements.

(2) A DPDO must comply with all requirements of State or federal law.

(3) A DPDO must dispense a drug 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.

Proposed Rules

(4) Drugs must be packaged by the practitioner, a pharmacy, or a manufacturer registered with the Board.

(5) A DPDO 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.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.305

855-043-0550

Disposal of Drugs

Drugs that are recalled, 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 689.155, 689.305

855-043-0555

Record Keeping

(1) A dispensing record shall 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.

Proposed Rules

(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 689.155, 689.305

855-043-0560

Inspections

(1) The DPDO must complete the Board Self Inspection Form by January 1, annually.

(2) Each DPDO will be inspected on a routine basis and shall be scheduled in advance with the practitioner, to occur during normal business hours.

(3) The inspection shall focus on the acquisition, storage, labeling and recordkeeping of drugs intended for dispensing and any violation will apply to the DPDO registration and not to the practitioner.

(4) The Board of Pharmacy shall refer any disciplinary action taken against a DPDO to the practitioner's licensing Board.

Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155, 689.305

Proposed Rules