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## PERMANENT ADMINISTRATIVE ORDER

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**BOARD OF PHARMACY**

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FILING CAPTION: Div. 043 - Dispensing Practitioner Drug Outlet Rules and Div. 110 - Fees

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### RULES:

855-043-0505, 855-043-0510, 855-043-0520, 855-043-0525, 855-043-0530, 855-043-0535, 855-043-0540, 855-043-0545, 855-043-0550, 855-043-0555, 855-043-0560, 855-110-0007

ADOPT: 855-043-0505

NOTICE FILED DATE: 06/14/2017

RULE SUMMARY: These rules are intended to describe the Board's registration and compliance expectations for a practitioner's facility that engages in dispensing certain FDA-approved human prescription drug therapies greater than a 72 hours supply or any medication refill. The facility dispensing site must be registered as a drug outlet with the Board as a Dispensing Practitioner Drug Outlet (DPDO).

### CHANGES TO RULE:

#### 855-043-0505

##### Dispensing Practitioner Drug Outlets - Purpose

A practitioner's facility that engages in dispensing certain FDA-approved human prescription 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 Dispensing Practitioner Drug Outlet (DPDO).

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.155, ORS 689.305

ADOPT: 855-043-0510

NOTICE FILED DATE: 06/14/2017

RULE SUMMARY: Div.043-Dispensing Practitioner Drug Outlet Rules and Div. 110-Fees (Registration)

CHANGES TO RULE:

855-043-0510

Dispensing Practitioner Drug Outlets - Registration

(1) A practitioner's facility that engages in dispensing FDA-approved human prescription 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's facility is exempt from this registration requirement if the practitioner and facility only engages in:¶

(A) Dispensing FDA approved drug samples; or¶

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

(C) Dispensing homeopathic products; or¶

(D) Dispensing natural thyroid supplemental products; or¶

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

(F) 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 bottle of fluoride rinse; 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. ¶

(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. ¶

(8) The DPDO registration expires March 31, annually. If the annual renewal fee 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. ¶

(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, or supervising practitioner. ¶

(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.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.155, 689.305

ADOPT: 855-043-0520

NOTICE FILED DATE: 06/14/2017

RULE SUMMARY: Div. 043-Dispensing Practitioner Drug Outlet Rules and Div. 110-Fees (Policies and Procedures)

CHANGES TO RULE:

855-043-0520

Dispensing Practitioner Drug Outlets - Policies and Procedures

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.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.155, 689.305

ADOPT: 855-043-0525

NOTICE FILED DATE: 06/14/2017

RULE SUMMARY: Div.043 - Dispensing Practitioner Drug Outlet Rules and Div. 110 - Fees (Security)

CHANGES TO RULE:

855-043-0525

Dispensing Practitioner Drug Outlets - 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) A drug dispensing machine cannot be placed in a waiting room or an area that is accessible by the public.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.155, 689.305

ADOPT: 855-043-0530

NOTICE FILED DATE: 06/14/2017

RULE SUMMARY: Div. 043 - Dispensing Practitioner Drug Outlet Rules and Div. 110 - Fees (Drug acquisition)

CHANGES TO RULE:

855-043-0530

Dispensing Practitioner Drug Outlets - Drug Acquisition

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

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.155, 689.305

ADOPT: 855-043-0535

NOTICE FILED DATE: 06/14/2017

RULE SUMMARY: Div. 043 - Dispensing Practitioner Drug Outlet Rules and Div. 110 - Fees (Drug Storage)

CHANGES TO RULE:

855-043-0535

Dispensing Practitioner Drug Outlets - 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.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.155, 689.305

ADOPT: 855-043-0540

NOTICE FILED DATE: 06/14/2017

RULE SUMMARY: Div 043 - Dispensing Practitioner Drug Outlet Rules and Div. 110 - Fees (Labeling)

CHANGES TO RULE:

855-043-0540

Dispensing Practitioner Drug Outlet - Labeling

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

(a) Name of patient; ¶

(b) Name of prescriber; ¶

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

(d) Date of dispensing; ¶

(e) 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; ¶

(f) Quantity dispensed; ¶

(g) Directions for use; ¶

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

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

(j) 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.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.155, 689.305



ADOPT: 855-043-0545

NOTICE FILED DATE: 06/14/2017

RULE SUMMARY: Div. 043 - Dispensing Practitioner Drug Outlet Rules and Div. 110 - Fees (Dispensing and Drug Delivery)

CHANGES TO RULE:

855-043-0545

Dispensing Practitioner Drug Outlets - Dispensing and Drug Delivery

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

(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. ¶

(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 shall maintain a list of sites in Oregon where drugs may be disposed.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.155, 689.305

ADOPT: 855-043-0550

NOTICE FILED DATE: 06/14/2017

RULE SUMMARY: Div 043 - Dispensing Practitioner Drug Outlet Rules and Div. 110 Fees (Disposal of Drugs)

CHANGES TO RULE:

855-043-0550

Dispensing Practitioner Drug Outlets - 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.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.155, 689.305

ADOPT: 855-043-0555

NOTICE FILED DATE: 06/14/2017

RULE SUMMARY: Div. 043 - Dispensing Practitioner Drug Outlet Rules and Div. 110 - Fees (Record Keeping)

CHANGES TO RULE:

855-043-0555

Dispensing Practitioner Drug Outlets - Record Keeping

(1) A unique dispensing record shall be maintained, be readily retrievable, and kept for a minimum of three years.

The record must show, at a minimum, the following:¶

(a) Name of patient; ¶

(b) Dose, dosage form, quantity dispensed and either the brand name of drug, or generic name and name of manufacturer or distributor; ¶

(c) Directions for use; ¶

(d) Date of dispensing; and ¶

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

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.155, 689.305

ADOPT: 855-043-0560

NOTICE FILED DATE: 06/14/2017

RULE SUMMARY: Div. 043 - Dispensing Practitioner Drug Outlet Rules and Div. 110 - Fees (Inspections)

CHANGES TO RULE:

855-043-0560

Dispensing Practitioner Drug Outlets - Inspections

(1) The DPDO must complete the Board Self Inspection Form by February 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 notify the practitioner's licensing Board of any disciplinary action taken against a DPDO.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.155, 689.305

AMEND: 855-110-0007

NOTICE FILED DATE: 06/14/2017

RULE SUMMARY: Div. 043 - Dispensing Practitioner Drug Outlet Rules and Div. 110 - Fees (Fees)

CHANGES TO RULE:

855-110-0007

Fees for Registration, Renewal, and Reinspection of Drug Outlets ¶¶

- (1) Community Health Clinic. Expires March 31 annually - \$75\*. Delinquent renewal fee (postmarked after February 28) - \$25. (\*Temporary revenue surplus fee reduction pursuant to ORS 291.055(3)). Fee reduction shall be effective retroactive to July 1, 2013.¶¶
- (2) Drug Distribution Agent. Expires September 30 annually - \$400. Delinquent renewal fee (postmarked after August 31) - \$100.¶¶
- (3) Drug Room (including correctional facility). Expires March 31 annually - \$75\*. Delinquent renewal fee (postmarked after February 28) - \$75. (\*Temporary revenue surplus fee reduction pursuant to ORS 291.055(3)). Fee reduction shall be effective retroactive to July 1, 2013.¶¶
- (4) Manufacturers (including Manufacturer Class I, Manufacturer Class II and Manufacturer Class III). Expires September 30 annually - \$400. Delinquent renewal fee (postmarked after August 31) - \$100.¶¶
- (5) Medical Device, Equipment & Gas Class C. Expires January 31 annually - \$50. Delinquent renewal fee (postmarked after December 31) - \$25.¶¶
- (6) Nonprescription Class A. Expires January 31 annually - \$50. Delinquent renewal fee (postmarked after December 31) - \$25.¶¶
- (7) Nonprescription Class B. Expires January 31 annually - \$50. Delinquent renewal fee (postmarked after December 31) - \$25.¶¶
- (8) Nonprescription Class D. Expires January 31 annually - \$100. Delinquent renewal fee (postmarked after December 31) - \$25.¶¶
- (9) Prophylactic and/or Contraceptive Wholesaler and/or Manufacturer - \$50\*. Expires December 31 annually. (\*Temporary revenue surplus fee reduction pursuant to ORS 291.055(3)). Fee reduction shall be effective retroactive to July 1, 2013.¶¶
- (10) Re-inspection fee - \$100. Applies to any re-inspection of a drug outlet occasioned to verify corrections of violations found in an initial inspection.¶¶
- (11) Retail or Institutional Drug Outlet. Expires March 31 annually - \$175\*. Delinquent renewal fee (postmarked after February 28) - \$75. (\*Temporary revenue surplus fee reduction pursuant to ORS 291.055(3)). Fee reduction shall be effective retroactive to July 1, 2013.¶¶
- (12) Wholesalers (including Wholesaler Class I, Wholesaler Class II and Wholesaler Class III). Expires September 30 annually - \$400. Delinquent renewal fee (postmarked after August 31) - \$100.¶¶
- (13) Remote Dispensing Machine or Remote Distribution Facility. Expires March 31 annually - \$100. Due by February 28 annually.¶¶
- (14) Charitable Pharmacy. Expires March 31 annually - \$75. Delinquent renewal fee (postmarked after February 28) - \$25.¶¶
- (15) Home Dialysis. Expires March 31 annually - \$175\*. Delinquent renewal fee (postmarked after February 28) - \$75. (\*Temporary revenue surplus fee reduction pursuant to ORS 291.055(3)). Fee reduction shall be effective retroactive to July 1, 2013.¶¶
- (16) Supervising Physician Dispensing Outlet. Expires March 31 annually - \$175\*. (\*Temporary revenue surplus fee reduction pursuant to ORS 291.055(3)). Delinquent renewal fee (postmarked after February 28) - \$75.¶¶
- (17) Dispensing Practitioner Drug Outlet. Expires March 31 annually --- \$100\*. Delinquent renewal fee (postmarked after February 28) --- \$25\*. (\*This fee will be waived until the 2019 renewal cycle that begins January 1, 2019.)

Statutory/Other Authority: ORS 689.205, 291.055

Statutes/Other Implemented: ORS 689.135, 689.774, 2689.305