RULE CAPTION
Div. 043 - Dispensing Practitioner Drug Outlet Rules and Div. 110 - Fees
Not more than 15 words that reasonably identifies the subject matter of the agency's intended action.

RULEMAKING ACTION
Secure approval of rule numbers with the Administrative Rules Unit prior to filing.

ADOPT:
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

AMEND:
855-110-0007

REPEAL:
None

RENUMBER: Secure approval of new rule numbers with the Administrative Rules Unit prior to filing.
None

AMEND AND RENUMBER: Secure approval of new rule numbers with the Administrative Rules Unit prior to filing.
None

Statutory Authority:
ORS 689.205 & 291.055

Other Authority:
None

Statutes Implemented:
ORS 689.155, 689.305

RULE SUMMARY
The Board proposes these revised Division 043 rules for a third time after incorporating multiple edits made to address comments and input received during the stakeholder's workgroup meetings from 2012 to 2016 and the rulemaking public comment periods in November 2016 and March 2017.

These rules are specific to practitioner outlets dispensing certain FDA approved human prescription drug therapies greater than a 72 hours’ supply or any medication refill. The rules exclude the registration for outlets engaged in only dispensing samples, MAP drugs, small amounts of drugs incidental to procedure/office visit, homeopathic, and natural thyroid products. Additionally, the Board does not intend to register those sites whose practitioner licensing board annually inspects the dispensing facilities to the standards of the Board.

Prescription drug dispensing has changed significantly in the last 5 years with increased access outside the pharmacy model. The process is also more sophisticated around the access to drugs, compounded drugs, supply and the chain of custody; i.e. how drugs are acquired, stored, labeled, when they expire etc. The Board of Pharmacy is charged with the regulation of the practice of pharmacy, as well as the risks and public safety related to the distribution and dispensing of prescription drugs. Dispensing Practitioner Drug Outlets are not currently regulated or inspected as all other dispensing locations. The Board wants to facilitate and ensure safe dispensing practices occur for the public.

These rules are intended to describe the Board's registration and compliance expectations for a practitioner who has been granted dispensing privileges from their licensing board and engages in drug dispensing from their practice location. A practitioner's outlet that engages in
dispensing certain FDA-approved human prescription drug therapies greater than a 72 hours’ supply or any medication refill will be required to register their dispensing site as a drug outlet with the Board as a Dispensing Practitioner Drug Outlet (DPDO).

The rule identifies: (1) purpose (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' implementation and enforcement of these rules and, as always, plans to approach regulation per its 'Compliance through Education' axiom. This means that the Board intends to educate practitioners over the next 18-24 months with the goal to have qualified outlets registered and in compliance with these rules. The Board expects qualifying facilities to self-identify. The rules will be effective September 2017 to allow the Board to accept applications, but will not charge a fee until the winter 2019 renewal.

The Board also proposes the associated fee in Division 110.

A full text file of this notice and the proposed rules are on the Oregon Board of Pharmacy website at: http://www.oregon.gov/pharmacy/Pages/Laws_Rules.aspx

Questions and public comments regarding this proposed rule can be sent to: Pharmacy.Rulemaking@state.or.us.

The Agency requests public comment on whether other options should be considered for achieving the rule’s substantive goals while reducing negative economic impact of the rule on business.

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<th>07-27-2017 4:30 p.m.</th>
<th>Mo Klein</th>
<th><a href="mailto:mo.klein@state.or.us">mo.klein@state.or.us</a></th>
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<td>Last Day (m/d/yyyy) and Time for public comment</td>
<td>Rules Coordinator Name</td>
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*The Oregon Bulletin is published on the 1st of each month and updates the rule text found in the Oregon Administrative Rules Compilation.
Need for the Rule(s):
These rules are intended to describe the Board's registration and compliance expectations for a practitioner who has been granted dispensing privileges from their licensing board and engages in drug dispensing from their practice location. 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 the dispensing site as a drug outlet with the Board as a Dispensing Practitioner Drug Outlet (DPDO). These rules are needed to allow the Board to register and inspect drug outlets to ensure compliance and safe medication dispensing to patients.

The Board regularly receives questions and inquiries from practitioners regarding registration and compliance requirements for their practice setting when they want to dispense drugs, as the Board of Pharmacy is seen as the 'drug expert'. Safe and compliant drug dispensing is multifaceted and complex.

In 2013, the Board received confirmation through DOJ Opinion 2013-1 of its statutory authority and responsibility to register dispensing practitioner drug outlets. These rules are specific to the dispensing of certain FDA approved human drugs from an outlet that is not a registered pharmacy. Prescription drug dispensing has changed significantly in the last 5 years with increased access outside the pharmacy model. The process is also more sophisticated around the access to drugs, compounded drugs, supply and the chain of custody; i.e. how drugs are acquired, stored, labeled, when they expire etc. The Board of Pharmacy wants to ensure that safe dispensing practices occur within these outlets. The Board intends to be a resource to dispensing practitioners and will inspect outlets to ensure safety standards are met.

The public has an expectation that prescription drugs provided to them are acquired from legitimate sources and are dispensing in a manner consistent with safety.

Fiscal and Economic Impact:
This rule has the potential to impact health care practitioners who decide to routinely dispense FDA approved drugs as part of their day-to-day practice and business model. Practitioners who decide to dispense on a large scale as part of their practice and business model will trigger required compliance with this rule. This may be a revenue producing activity for the practitioner, though the license will cost $100 per year.

Statement of Cost of Compliance:
1. Impact on state agencies, units of local government and the public (ORS 183.335(2)(b)(E)):
There is no anticipated impact on state agencies or units of local government. Impact on the public is positive, creating a safer drug delivery system.

2. Cost of compliance effect on small business (ORS 183.336):
a. Estimate the number of small business and types of businesses and industries with small businesses subject to the rule:
The Board has not been able to determine the number of practitioners that will choose to offer this service.
Because the intent is to identify and register large scale dispensing, we do not anticipate a high number of practitioner facilities who would be required to register. The Board has identified 3 of 76 rural health practitioner facilities that do not have a registered pharmacy within 25 miles. These 3 facilities may likely register and be required to pay the proposed $100 fee. Other facilities can choose to dispense and will also be required to pay the registration fee.

In all cases, the businesses that choose to register may be positively economically impacted because they will have an effective, on site, safe method for providing drugs to their patients.

b. Projected reporting, recordkeeping and other administrative activities required for compliance, including costs of professional services:
Division 043 rules for Dispensing Practitioner Drug Outlets (DPDOs) have requirements for reporting, record keeping and other administrative activities associated with dispensing drugs that may not be part of current practice. The cost of an annual license is proposed to be $100 in Division 110. Outlets will be required to complete a self-inspection form for Board Inspectors to review with them upon arrival for inspection. Their responsibility will be to adhere to best practices for storing and handling drugs.

c. Equipment, supplies, labor and increased administration required for compliance:
Licensees will be required to maintain records of their inventory transactions, and will be required to file an annual self inspection form. It is anticipated that this form will take 2 hours to complete each year.

How were small businesses involved in the development of this rule?
Representatives from each of the health care regulatory boards and associations with licensees and members that may potentially be affected by the DPDO registration requirements have been meeting as a work group for the past few years to build consensus, eliminate barriers and develop workable solutions. Each of these boards represent practitioners in a variety of practice settings, including small businesses.

Administrative Rule Advisory Committee consulted?: No
If not, why?:
A formal advisory committee was unnecessary based on the nature of the rules being implemented and as noted above, the ongoing work group that has met specifically regarding the DPDOs has served as an advisory work group on the development of these rules. The Board has worked with the following stakeholders including communications to their licensees and members 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).

07-27-2017 4:30  p.m.  Mo Klein  mo.klein@state.or.us
Last Day (m/d/yyyy) and Time for public comment  Printed Name  Email Address

Administrative Rules Unit, Archives Division, Secretary of State, 800 Summer Street NE, Salem, Oregon 97310.  ARC 925-2007
These rules are intended to describe the Board’s registration and compliance expectations for a practitioner who has been granted dispensing privileges from their licensing board and engages in drug dispensing from their practice location. 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 the dispensing site as a drug outlet with the Board as a Dispensing Practitioner Drug Outlet (DPDO).

The rule (1) identifies purpose (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 the 2013 DOJ Opinion OP-2013-1 and Non Pharmacy Dispensing Concept approved by the Oregon Board of Pharmacy 12/4/2014.

### Dispensing Practitioner Drug Outlets

**855-043-0505**

**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).

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

**855-043-0510**

**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. 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.

(8) The DPDO 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.

(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.

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

Oregon Board of Pharmacy 6.8.2017
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.

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) 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.

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 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.

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 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.
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 refer notify the practitioner’s licensing Board of any disciplinary action taken against a DPDO.
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.


(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.


(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.


Stat. Auth.: ORS 689.205 & 291.055
Stats. Implemented: ORS 689.135, 689.774 & 2689.305