



Oregon

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TO: Dispensing Practitioner Drug Outlet Interested Parties

FROM: Oregon Board of Pharmacy

DATE: November 1, 2017

RE: Dispensing Practitioner Drug Outlet Rules

At the Board's August 10, 2017 Board meeting, the Board adopted rules for Dispensing Practitioner Drug Outlets (DPDOs) in OAR 855-043-0505 through 855-043-0560 and 855-110-0007. The 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).

The rules include requirements and best practices common to all pharmacy drug outlets: (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.

True to the Board's word, the intention is to have a "soft-launch" of enforcement and as always, plans to approach regulation through the "Compliance through Education" axiom. The Board intends to file and make these rules effective December 1, 2017. The Board will have an application for the DPDO license available on the Board's website by December 1st in order for outlets that inquire about license requirements to review and apply. The fee for this license will be waived until January 1, 2019 when we begin the renewal cycle for this category. This will allow the Board to begin scheduling inspections for licensed outlets and educating with the Board's Self Inspection form for this category.

This was the culmination of several years of collaboration on rule development, in addition to multiple rulemaking hearings, all with the input of the following stakeholders: 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).

The Board thanks all the above organizations for their input.

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

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

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

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

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

18 Dispensing Practitioner Drug Outlets

19 855-043-0505

20 Purpose

21 **A practitioner’s facility that engages in dispensing certain FDA-approved human**
 22 **prescription drug therapies greater than a 72 hours supply or any medication refill must**
 23 **register their dispensing site as a drug outlet with the Board as a Dispensing Practitioner**
 24 **Drug Outlet (DPDO).**

25 **Stat. Auth.: ORS 689.205**

26 **Stats. Implemented: ORS 689.155, 689.305**

27
 28 855-043-0510

29 Registration

30 **(1) A practitioner’s facility that engages in dispensing FDA-approved human prescription**
 31 **drug therapies greater than a 72 hours supply or any medication refill must register their**
 32 **dispensing site as a drug outlet with the Board as a DPDO on a form provided by the**
 33 **Board, and must renew its registration annually on a renewal form provided by the Board.**

34 **(2) A practitioner's facility is exempt from this registration requirement if the practitioner**
35 **and facility only engages in:**

36 **(A) Dispensing FDA approved drug samples; or**

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

38 **(C) Dispensing homeopathic products; or**

39 **(D) Dispensing natural thyroid supplemental products; or**

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

42 **(F) An amount greater than a 72 hour supply if the drug is:**

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

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

47 **(3) The initial application must state the location of the DPDO and the name of the person**
48 **applying for registration. When the person applying for registration is not the owner of the**
49 **dispensing site, the application must disclose the name and address of the owner and the**
50 **applicant's affiliation with the owner.**

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

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

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

60 **(5) An initial application must be accompanied by the fee established in division 110 of this**
61 **chapter.**

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

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

66 (8) The DPDO registration expires March 31, annually. If the annual renewal fee referred
67 to in section (5) of this rule is not paid by February 28 of the current year, the applicant for
68 renewal must submit the delinquent fee established in division 110 of this chapter with the
69 renewal application.

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

71 (10) The registrant must notify the Board, within 15 days, of any substantial change to the
72 information provided on the registration application. Substantial change shall include but
73 not be limited to: change of ownership; change of business name; change of business
74 address; change of normal business hours; any disciplinary action taken or pending by any
75 state or federal authority against the registrant, or any of its principals, owners, directors,
76 officers, or supervising practitioner.

77 (11) A new registration form is required for a change of ownership or location and must be
78 submitted to the Board with the fees as specified in division 110 of this chapter within 15
79 days of the change.

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

83 Stat. Auth.: ORS 689.205

84 Stats. Implemented: ORS 689.155, 689.305

85 Policies and Procedures

86 855-043-0520

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

90 Stat. Auth.: ORS 689.205

91 Stats. Implemented: ORS 689.155, 689.305

92 855-043-0525

93 **Security**

94 **(1) All drugs must be kept in a locked drug cabinet or designated drug storage area that is**
95 **sufficiently secure to deny access to unauthorized persons. The drug cabinet or designated**
96 **drug storage area must remain locked and secured when not in use.**

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

99 **Stat. Auth.: ORS 689.205**

100 **Stats. Implemented: ORS 689.155, 689.305,**

101 **855-043-0530**

102 **Drug Acquisition**

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

105 **Stat. Auth.: ORS 689.205**

106 **Stats. Implemented: ORS 689.155, 689.305**

107 **855-043-0535**

108 **Drug Storage**

109 **All drugs must be stored according to manufacturer's published guidelines and be stored**
110 **in appropriate conditions of temperature, light, humidity, sanitation, ventilation, and**
111 **space.**

112 **Stat. Auth.: ORS 689.205**

113 **Stats. Implemented: ORS 689.155, 689.305**

114 **855-043-0540**

115 **Labeling**

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

117 **(a) Name of patient;**

118 **(b) Name of prescriber;**

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

120 **(d) Date of dispensing;**

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

123 **(f) Quantity dispensed;**

124 **(g) Directions for use;**

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

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

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

131 **(2) Notwithstanding any other requirements in this rule, when a drug is dispensed in the**
132 **practice of an Expedited Partner Therapy treatment protocol, as described in OAR 855-**
133 **041-4000 through 4005, the name of the patient may be omitted.**

134 **Stat. Auth.: ORS 689.205**

135 **Stats. Implemented: ORS 689.155, 689.305**

136

137 **855-043-0545**

138 **Dispensing and Drug Delivery**

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

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

142 **(3) A DPDO must dispense a drug in a new container that complies with the current**
143 **provisions of the Federal Consumer Packaging Act (Public Law 91-601, 91st Congress, S.**
144 **2162) and rules or regulations and with the current United States Pharmacopoeia/National**
145 **Formulary monographs for preservation, packaging, storage and labeling.**

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

148 **(5) A DPDO may not accept the return of drugs from a previously dispensed prescription**
149 **and shall maintain a list of sites in Oregon where drugs may be disposed.**

150 **Stat. Auth.: ORS 689.205**

151 **Stats. Implemented: ORS 689.155, 689.305**

152 **855-043-0550**

153 **Disposal of Drugs**

154 **Drugs that are recalled, outdated, damaged, deteriorated, misbranded, adulterated, or**
155 **identified as suspect or illegitimate must be documented, quarantined and physically**
156 **separated from other drugs until they are destroyed or returned to the supplier.**

157 **Stat. Auth.: ORS 689.205**

158 **Stats. Implemented: ORS 689.155, 689.305**

159 **855-043-0555**

160 **Record Keeping**

161 **(1) A unique dispensing record shall be maintained, be readily retrievable, and kept for a**
162 **minimum of three years. The record must show, at a minimum, the following:**

163 **(a) Name of patient;**

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

166 **(c) Directions for use;**

167 **(d) Date of dispensing; and**

168 **(e) Initials of person dispensing the prescription.**

169 **(2) All records of receipt and disposal of drugs must be kept for a minimum of three years.**

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

172 **Stat. Auth.: ORS 689.205**
173 **Stats. Implemented: ORS 689.155, 689.305**

174 **855-043-0560**

175 **Inspections**

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

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

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

182 **(4) The Board of Pharmacy shall notify the practitioner's licensing Board of any**
183 **disciplinary action taken against a DPDO.**

184 **Stat. Auth.: ORS 689.205**
185 **Stats. Implemented: ORS 689.155, 689.305**

186

187

188 **855-110-0007**

189 **Fees for Registration, Renewal, and Reinspection of Drug Outlets**

190 (1) Community Health Clinic. Expires March 31 annually — \$75*. Delinquent renewal fee
191 (postmarked after February 28) — \$25. (*Temporary revenue surplus fee reduction pursuant to
192 ORS 291.055(3)). Fee reduction shall be effective retroactive to July 1, 2013.

193 (2) Drug Distribution Agent. Expires September 30 annually — \$400. Delinquent renewal fee
194 (postmarked after August 31) — \$100.

195 (3) Drug Room (including correctional facility). Expires March 31 annually — \$75*. Delinquent
196 renewal fee (postmarked after February 28) — \$75. (*Temporary revenue surplus fee reduction
197 pursuant to ORS 291.055(3)). Fee reduction shall be effective retroactive to July 1, 2013.

198 (4) Manufacturers (including Manufacturer Class I, Manufacturer Class II and Manufacturer
199 Class III). Expires September 30 annually — \$400. Delinquent renewal fee (postmarked after
200 August 31) — \$100.

201 (5) Medical Device, Equipment & Gas Class C. Expires January 31 annually — \$50. Delinquent
202 renewal fee (postmarked after December 31) — \$25.

203 (6) Nonprescription Class A. Expires January 31 annually — \$50. Delinquent renewal fee
204 (postmarked after December 31) — \$25.

205 (7) Nonprescription Class B. Expires January 31 annually — \$50. Delinquent renewal fee
206 (postmarked after December 31) — \$25.

207 (8) Nonprescription Class D. Expires January 31 annually — \$100. Delinquent renewal fee
208 (postmarked after December 31) — \$25.

209 (9) Prophylactic and/or Contraceptive Wholesaler and/or Manufacturer — \$50*. Expires
210 December 31 annually. (*Temporary revenue surplus fee reduction pursuant to ORS
211 291.055(3)). Fee reduction shall be effective retroactive to July 1, 2013.

212 (10) Re-inspection fee — \$100. Applies to any re-inspection of a drug outlet occasioned to verify
213 corrections of violations found in an initial inspection.

214 (11) Retail or Institutional Drug Outlet. Expires March 31 annually — \$175*. Delinquent
215 renewal fee (postmarked after February 28) — \$75. (*Temporary revenue surplus fee reduction
216 pursuant to ORS 291.055(3)). Fee reduction shall be effective retroactive to July 1, 2013.

- 217 (12) Wholesalers (including Wholesaler Class I, Wholesaler Class II and Wholesaler Class III).
218 Expires September 30 annually — \$400. Delinquent renewal fee (postmarked after August 31)
219 — \$100.
- 220 (13) Remote Dispensing Machine or Remote Distribution Facility. Expires March 31 annually —
221 \$100. Due by February 28 annually.
- 222 (14) Charitable Pharmacy. Expires March 31 annually — \$75. Delinquent renewal fee
223 (postmarked after February 28) — \$25.
- 224 (15) Home Dialysis. Expires March 31 annually — \$175*. Delinquent renewal fee (postmarked
225 after February 28) — \$75. (*Temporary revenue surplus fee reduction pursuant to ORS
226 291.055(3)). Fee reduction shall be effective retroactive to July 1, 2013.
- 227 (16) Supervising Physician Dispensing Outlet. Expires March 31 annually — \$175*.
228 (*Temporary revenue surplus fee reduction pursuant to ORS 291.055(3)). Delinquent renewal
229 fee (postmarked after February 28) — \$75.
- 230 **(17) Dispensing Practitioner Drug Outlet. Expires March 31 annually --- \$100*. Delinquent**
231 **renewal fee (postmarked after February 28) --- \$25. (*This fee will be waived until the 2019**
232 **renewal cycle that begins January 1, 2019.)**
- 233
- 234 Stat. Auth.: ORS 689.205 & 291.055
235 Stats. Implemented: ORS 689.135, 689.774 & 2689.305
- 236