Hearing Date | Time | Location | Hearings Officer
---|---|---|---
3-7-17 | 9:30 a.m. | 800 NE Oregon St., Portland, OR 97232 Conf Rm 1E | Staff

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

ADOPT:
855-043-0505, 855-043-0515, 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:

RENUMBER: Secure approval of new rule numbers with the Administrative Rules Unit prior to filing.

AMEND AND RENUMBER: Secure approval of new rule numbers with the Administrative Rules Unit prior to filing.

Statutory Authority:
ORS 689.205 & 291.055

Other Authority:

Statutes Implemented:
ORS 689.155, 689.305

RULE SUMMARY
The Board proposes these revised Division 043 rules for a second time after incorporating various edits made to address comments and input received during the public comment period in November 2016, with the goal to register the large volume Dispensing Practitioner Drug Outlets (DPDO).

These rules are specific to the dispensing of FDA approved human drugs. The rules exclude the dispensing of homeopathic and natural thyroid products.

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 of prescription drugs. Practitioner Dispensing 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 who 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 also proposes a fee in Division 110.

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.

<table>
<thead>
<tr>
<th>Last Day (m/d/yyyy) and Time</th>
<th>Rules Coordinator Name</th>
<th>Email Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>03-07-2017 4:30 p.m.</td>
<td>Karen MacLean</td>
<td><a href="mailto:Karen.S.MacLean@state.or.us">Karen.S.MacLean@state.or.us</a></td>
</tr>
</tbody>
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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.*
Board of Pharmacy

Agency and Division

Division 043, Dispensing Practitioner Drug Outlet Rules

Rule Caption (Not more than 15 words that reasonably identifies the subject matter of the agency's intended action.)
In the Matter of:
Division 043, Dispensing Practitioner Drug Outlet Rules

Statutory Authority:
ORS 689.205 & 291.055

Other Authority:

Statutes Implemented:
ORS 689.155, 689.305

Need for the Rule(s):
The Board regularly receives questions or inquiries from practitioners regarding registration requirements for their practice setting when they want to dispense drugs. Some are complex in their dispensing practices; others are more standard, but are increasing the amount they are dispensing.

In 2013, the Board received confirmation through DOJ Opinion 2013-1 of its statutory authority to register dispensing practitioner drug outlets. These rules are specific to the dispensing of 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 drug, 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.

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 who 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).

There is a nominal fee associated with this license type and necessary to ensure compliance resources are available to support the registered drug outlets.

The public has an expectation that prescription drugs provided to them are safe.

Documents Relied Upon, and where they are available:
2/13/2013 Department of Justice Opinion OP-2013-1
12/4/2014 Non Pharmacy Dispensing Concept

Fiscal and Economic Impact:
Proposed rules in Division 043 establish a new type license category called Dispensing Practitioner Drug Outlet. This has the potential to impact health care practitioners who routinely dispense FDA approved drugs as part of their day-to-day practice. The proposed fiscal/economic impact is difficult to determine, because the number of practitioners who dispense is unknown.

Statement of Cost of Compliance:
1. Impact on state agencies, units of local government and the public (ORS 183.335(2)(b)(E)):
The cost of compliance and impact on state agencies and local governments is assumed to be minimal or none, as these outlets are currently registered with the Board. If any state agency Board of Pharmacy licensees or local governments make access available to the new opportunities with public health emergency/drug room, naloxone, drug take back or charitable pharmacy activities, the cost of compliance
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 Dispensing Practitioner Drug Outlets that exist which will qualify to register and
   would be impacted by the rules in Division 043, nor how many of those are small businesses. 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.

   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) will have a variety of new requirements for reporting, recordkeeping and
   other administrative activities associated with dispensing drugs that are not likely part of current practice. The cost of an annual license is
   proposed to be $100 or less for each outlet. Outlets will be required to complete a self-inspection form for Board Inspectors to review with
   them upon arrival for inspection.

   c. Equipment, supplies, labor and increased administration required for compliance:
The Division 043 rules for DPDO's as noted above will likely have increases associated with compliance for outlets that qualify for licensure.
   An example of possible cost increases could include software modifications or labor costs for staff time to maintain records.

   How were small businesses involved in the development of this rule?
Representatives from the each of the health care regulatory Boards and associations with licensees and members that may potentially be
   effected 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. This was done at the Board's request initially and again at the Legislature's request.

   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
   workgroup that has met specifically regarding the DPDO's has served as an advisory workgroup on the development of these rules.