

OFFICE OF THE SECRETARY OF STATE

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ARCHIVES DIVISION

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NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855
BOARD OF PHARMACY

FILED

10/21/2022 9:59 AM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Applicant for DDA renewal; annual due date

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 11/22/2022 4:30 PM

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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800 NE Oregon St., Suite 150
Portland, OR 97232

pharmacy.rulemaking@bop.oregon.gov

Filed By:
Rachel Melvin
Rules Coordinator

HEARING(S)

Auxiliary aids for persons with disabilities are available upon advance request. Notify the contact listed above.

DATE: 11/22/2022

TIME: 9:30 AM

OFFICER: Rachel Melvin

ADDRESS: Oregon Board of Pharmacy

800 NE Oregon St., Suite 150

Portland, OR 97232

SPECIAL INSTRUCTIONS:

This hearing meeting will be held virtually via Microsoft Teams.

If you wish to present oral testimony during this hearing, sign up on our website at www.oregon.gov/pharmacy/pages/rulemaking-information or email your contact information to pharmacy.rulemaking@bop.oregon.gov to receive the link to join the virtual meeting. Please indicate which rule(s) you would like to comment on.

Alternatively, you may dial

503-446-4951

Phone Conference ID:

146 611 440#

for audio only.

You must submit written comments before 4:30PM on November 22, 2022. Email written comments to pharmacy.rulemaking@bop.oregon.gov.

NEED FOR THE RULE(S)

Amends the current Drug Distribution Agent registration due date from August 31 to reflect the proper due date of September 30 to provide clarity to licensees and registrants.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

None available.

STATEMENT IDENTIFYING HOW ADOPTION OF RULE(S) WILL AFFECT RACIAL EQUITY IN THIS STATE

Proposed amendments provide clarity, transparency for licensees/registrants, no effects on racial equity are anticipated.

FISCAL AND ECONOMIC IMPACT:

No fiscal impact is anticipated.

COST OF COMPLIANCE:

(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).

There are no known economic impacts to the agency, other state or local government, small businesses, or members of the public.

DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

Small businesses were not involved with the development of proposed rule amendments.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? NO IF NOT, WHY NOT?

Board staff recommend amending the due date for transparency and clarity for licensees and registrants.

AMEND: 855-062-0020

RULE SUMMARY: Proposed amendment removes outdated due date of "August 31" and revises it to "September 30" in OAR 855-062-0020. DDA applicants for renewal must complete and submit the form to the board by September 30 annually.

CHANGES TO RULE:

855-062-0020

Registration ¶¶

- (1) Any person engaged in any part of the process of manufacture or wholesale distribution of a drug into, out of, or within Oregon must be registered with the Board. A person must register as either:¶¶
- (a) A manufacturer under ~~d~~Division 60 of this chapter of rules; or¶¶
 - (b) A wholesaler under ~~d~~Division 65 of this chapter of rules; or¶¶
 - (c) A Drug Distribution Agent under this division of rules.¶¶
- (2) A person that is required to register as a Drug Distribution Agent must be registered before commencing business in Oregon and before any drug for which they provide a manufacturing, marketing or distribution service, may be sold, distributed, dispensed or administered in Oregon.¶¶
- (3) A person that is required to register as a Drug Distribution Agent must apply for registration on a form provided by the Board and must provide information required by the Board that ~~shall~~includes but is not limited to:¶¶
- (a) The name, business address, social security number or federal tax identification number of each owner, officer, and stockholder owning more than 10 per cent of the stock of the company, unless the stock of the company is publicly traded;¶¶
 - (b) Every trade or business name used by the applicant;¶¶

- (c) Any disciplinary action taken by any state or federal authority against the applicant or any other distributor under common ownership or control, or any owner, principal or designated representative of the applicant, in connection with the drug laws or regulations of any state or the federal government.¶
- (4) An applicant for renewal must complete the form provided by the Bboard and submit it to the Bboard with the appropriate fee by ~~August~~September 31 annually.¶
- (5) An applicant that provides a manufacturing or distribution service in respect of a controlled substance as defined in Division 80 of this chapter of rules must also complete and submit the Controlled Substance registration form provided by the Bboard, with the appropriate fee.¶
- (6) The Bboard may require a criminal history and financial background check of each principal, owner or officer of the applicant prior to initial registration and prior to any renewal unless the applicant is publicly traded. Any such checks ~~sh~~will be at the applicant's expense.¶
- (7) The Bboard may require a physical inspection of each facility prior to initial registration and prior to any renewal.¶
- (8) Each separate business entity and each location that does business in Oregon must be separately registered by the Bboard.¶
- (9) The registrant must notify the Bboard, within 15 days, of any substantial change to the information provided on the registration application. Substantial change ~~sh~~includes but is not limited to:¶
- (a) Change of ownership;¶
- (b) Change of business address;¶
- (c) Any disciplinary action taken or pending by any state or federal authority against the registrant, or any of its principals, owners, directors, officers.¶
- (10) The registration certificate is issued to a specific person and is non-transferable. Any addition or deletion of an owner or partner constitutes a change of ownership.¶
- (11) The Bboard may waive any requirement of this rule if, in the Bboard's judgment, a waiver will further public health or safety. A waiver granted under this section ~~sh~~will only be effective when issued in writing.
- Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155