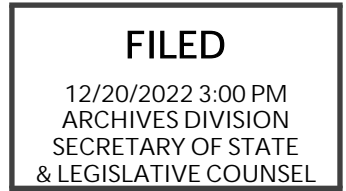




PERMANENT ADMINISTRATIVE ORDER

BP 52-2022
CHAPTER 855
BOARD OF PHARMACY



FILING CAPTION: Applicant for Drug Distribution Agent (DDA) renewal; annual due date

EFFECTIVE DATE: 12/21/2022

AGENCY APPROVED DATE: 12/15/2022

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AMEND: 855-062-0020

NOTICE FILED DATE: 10/21/2022

RULE SUMMARY: Amendment removes outdated due date of "August 31" and revises it to "September 30" in OAR 855-062-0020.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 dDivision 60 of this chapter of rules; or¶
 - (b) A wholesaler under dDivision 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 Board and submit it to the Board 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 Board, with the appropriate fee.¶
- (6) The Board 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 ~~shall~~ 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 ~~shall~~ 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 ~~shall~~ only be effective when issued in writing.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.155