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NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855
BOARD OF PHARMACY

FILED
04/25/2022 12:06 PM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Reorganizes drug outlet categories by registration type

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 05/24/2022 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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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: 05/24/2022

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: 114 068 944# for audio only.

You may file written comments before 4:30PM on May 24, 2022 by emailing your comments to pharmacy.rulemaking@bop.oregon.gov

NEED FOR THE RULE(S)

Proposed amendments will reorganize drug outlet categories in OAR 855-110-0007 by itemizing by registration type and removes outdated language.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

None available.

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

Reorganizing proposed rules may provide clarity, transparency and promote patient safety, no effects on racial equity are anticipated. Ensuring registrants and licensees can easily locate proper fees and registration types will positively impact all Oregonians in all communities.

FISCAL AND ECONOMIC IMPACT:

Minimal fiscal impact is anticipated by adding Remote Dispensing Site Retail Drug Outlet Pharmacy and Pharmacy Prescription Lockers Retail Drug Outlet Pharmacy; registrant categories are being reorganized.

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).

No anticipated costs to the agency or small businesses. Proposed amendments impose no additional mandatory reporting, recordkeeping, or other administrative requirements on small businesses.

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

Small businesses were not involved in the development of proposed amendments to these rules.

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

Board staff suggests amending the current rule for transparency and clarity for registrants.

AMEND: 855-110-0007

RULE SUMMARY: Proposed amendments add Remote Dispensing Site Retail Drug Outlet Pharmacy and Pharmacy Prescription Lockers Retail Drug Outlet Pharmacy registration types. Reorganizes categories for nonprescription drug outlets and retail drug outlets by registration type. When applying for a new registration or when renewing their existing registration, registrants will be able to easily find and determine which fee registration type is applicable.

CHANGES TO RULE:

855-110-0007

Fees for Registration, Renewal, and Reinspection of Drug Outlets ¶

~~(1) Community Health Clinic. Expires March 31 annually - \$100. Late renewal fee (received after March 31) - \$25. ¶~~

~~(2) Drug Distribution Agent. Expires September 30 annually - \$400. Late renewal fee (received after September 30) - \$100. ¶~~

~~(3) Drug Room (including Correctional Facility). Expires March 31 annually - \$100. Late renewal fee (received after March 31) - \$75. ¶~~

~~(4) Manufacturers (including Manufacturer Class I, Manufacturer Class II and Manufacturer Class III). Expires September 30 annually - \$525. Late renewal fee (received after September 30) - \$100. ¶~~

~~(5) Medical Device, Equipment & Gas Class C Nonprescription Drug Outlet. Expires January 31 annually - \$75. Late renewal fee (received after January 31) - \$25. ¶~~

~~(6) Nonprescription Class A. Expires January 31 annually - \$75. Late renewal fee (received after January 31) - \$25. a) This includes the following categories of registration: ¶~~

~~(A) Nonprescription Class A. ¶~~

~~(B) Nonprescription Class B. ¶~~

~~(C) Medical Device, Equipment & Gas Class C. ¶~~

~~(b) Other nonprescription Drug Outlet registration category fees are as follows: ¶~~

(7A) Nonprescription Class ~~B~~D. Expires January 31 annually - ~~\$75~~100. Late renewal fee (received after January 31) - \$25.¶

(8B) Nonprescription Class ~~D~~E. Expires January 31 annually - \$100. Late renewal fee (received after January 31) - ~~\$250~~¶

(95) Prophylactic and/or Contraceptive Wholesaler and/or Manufacturer - \$50. Expires December 31 annually. ¶

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

(117) Retail, or Institutional, or Consulting, or "Drugless" Pharmacy Drug Outlet Pharmacy. Expires March 31 annually - \$225. Late renewal fee (received after March 31) - \$75. ¶

(12) Wholesalers (including Wholesaler Class I, Wholesaler Class II and Wholesaler Class III)a) This includes the following categories of registration:¶

(A) Consulting "Drugless" Drug Outlet Pharmacy¶

(B) Home Dialysis Retail Drug Outlet Pharmacy¶

(C) Institutional Drug Outlet Pharmacy¶

(D) Remote Dispensing Site Retail Drug Outlet Pharmacy ¶

(E) Retail Drug Outlet Pharmacy¶

(b) Other Retail/Institutional Drug Outlet registration category fees are as follows:¶

(A) Charitable Retail Drug Outlet Pharmacy. Expires ~~September~~March 301 annually - ~~\$52~~75. Late renewal fee (received after ~~September~~March 301) - \$100.¶

(13) Remote Dispensing Machine or Remote Distribution Facility25.¶

(B) Community Health Clinic (CHC) Retail Drug Outlet Pharmacy. Expires March 31 annually - ~~\$1200~~. Due by March 31 annually. ¶

(14) CharitabLate renewal fee (received after March 31) - \$25. ¶

(C) Dispensing Practitioner Drug Outlet (DPDO) Retail Drug Outlet Pharmacy. Expires March 31 annually - ~~\$75~~. ~~\$100~~. Late renewal fee (received after March 31) - \$25.¶

(15) Home Dialysis. Expires March 31 annually - \$225. Late renewal fee (received after March 31) - \$75. ¶

(16) Dispensing PracæD) Reserved. ¶

(E) Prescription Lockers Retail Drug Outlet Pharmacy. Expires March 31 annually - \$120. Due by March 31 annually. ¶

(F) Remote Dispensing Machine Institutional Drug Outlet Pharmacy. Expires March 31 annually - \$120. Due by March 31 annually. ¶

(G) Remote Distribution Facility Institutionæal Drug Outlet Pharmacy. Expires March 31 annually - ~~\$100~~20. Due by March 31 annually. ¶

(8) Wholesalers (including Wholesaler Class I, Wholesaler Class II and Wholesaler Class III). Expires ~~September 30~~ annually - ~~\$525~~. Late renewal fee (received after ~~March~~September 310) - ~~\$25~~100.

Statutory/Other Authority: ORS 689.205, ORS 291.055

Statutes/Other Implemented: ORS 689.135, ORS 689.774, ORS 689.305