OFFICE OF THE SECRETARY OF STATE

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CHERYL MYERS
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ARCHIVES DIVISION

STEPHANIE CLARK DIRECTOR

800 SUMMER STREET NE SALEM, OR 97310 503-373-0701

NOTICE OF PROPOSED RULEMAKING

INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855 BOARD OF PHARMACY **FILED**

12/21/2022 9:26 AM ARCHIVES DIVISION SECRETARY OF STATE

FILING CAPTION: Registration Fee for Pharmacy Prescription Kiosk (PPK)

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 01/26/2023 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

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: 01/26/2023 TIME: 9:30 AM

OFFICER: Rachel Melvin

HEARING LOCATION

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 virtually 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.

You must submit written comments before 4:30PM on January 26, 2023. Email written comments to pharmacy.rulemaking@bop.oregon.gov.

REMOTE MEETING DETAILS

MEETING URL: Click here to join the meeting

PHONE NUMBER: 503-446-4951

SPECIAL INSTRUCTIONS:

Phone Conference ID = 294 493 511#

NEED FOR THE RULE(S)

Creates new registration fee for the new registration type of Pharmacy Prescription Kiosk.

None available.

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

It is anticipated that these amendments will not impact any group of people differently than others.

FISCAL AND ECONOMIC IMPACT:

No fiscal or economic impact is known; pharmacies are not required to operate a Pharmacy Prescription Kiosk (PPK). If a pharmacy chooses to operate a PPK, the PPK Affiliated Pharmacy will be required to apply and pay a registration fee of \$120 for the PPK and be required to comply with all Oregon Administrative Rules and Oregon Revised Statutes. We do anticipate that registered drug outlets will be financially impacted in order to comply with the proposed rules. Pharmacies that choose to deploy kiosks will generate revenue from prescription and over-the-counter drug sales to help offset the cost of compliance with these proposed rules.

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).

OBOP- Fiscal impact is estimated to be minimal for the agency and limited to administrative and compliance costs. There is no anticipated fiscal impact to other state agencies, units of local government or the public. There are approximately 113 small business drug outlet pharmacies registered with the board. It is not anticipated that the cost of compliance for small business would be different from that of a non-small business.

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?

New registration type requires appropriate registration fee.

AMEND: 855-110-0007

RULE SUMMARY: Adds "Prescription Kiosk Retail Drug Outlet Pharmacy. Expires March 31 annually - \$120. Due by March 31 annually." as a new type of Retail Drug Outlet and requires appropriate registration fees.

CHANGES TO RULE:

855-110-0007

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

- (1) Drug Distribution Agent. Expires September 30 annually \$400. Late renewal fee (received after September 30) \$100.
- (2) Drug Room (including Correctional Facility). Expires March 31 annually \$100. Late renewal fee (received after March 31) \$75.¶
- (3) 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.¶
- (4) Nonprescription Drug Outlet. Expires January 31 annually \$75. Late renewal fee (received after January 31) $$25.\P$
- (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: ¶
- (A) Nonprescription Class D. Expires January 31 annually \$100. Late renewal fee (received after January 31) $$25.\P$
- (B) Nonprescription Class E. Expires January 31 annually \$0. Late renewal fee (received after January 31) \$0.¶
- (5) Prophylactic and/or Contraceptive Wholesaler and/or Manufacturer \$50. Expires December 31 annually.¶
- (6) Re-inspection fee \$100. Applies to any re-inspection of a drug outlet occasioned to verify corrections of violations found in an initial inspection.¶
- (7) Retail or Institutional Drug Outlet Pharmacy. Expires March 31 annually \$225. Late renewal fee (received after March 31) \$75.¶
- (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 March 31 annually \$75. Late renewal fee (received after March 31) \$25.¶
- (B) Community Health Clinic (CHC) Retail Drug Outlet Pharmacy. Expires March 31 annually \$100. Late renewal fee (received after March 31) \$25.¶
- (C) Dispensing Practitioner Drug Outlet (DPDO) Retail Drug Outlet Pharmacy. Expires March 31 annually \$100. Late renewal fee (received after March 31) \$25.¶
- (D) Reserved Prescription Kiosk Retail Drug Outlet Pharmacy. Expires March 31 annually \$120. Due by March 31 annually.
- (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 Institutional Drug Outlet Pharmacy. Expires March 31 annually \$120. Due by March 31 annually. \P
- (8) Wholesalers (including Wholesaler Class I, Wholesaler Class II and Wholesaler Class III). Expires September 30 annually \$525. Late renewal fee (received after September 30) \$100.

Statutory/Other Authority: ORS 689.205, ORS 291.055

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