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NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855
BOARD OF PHARMACY

FILED
10/25/2021 5:11 PM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Addresses fee changes pursuant to 2021 HB 2074 and 2021 HB 3036; Procedural rule review

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 11/23/2021 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)

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

DATE: 11/23/2021
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.

Alternatively, you may dial (503) 446-4951 Phone Conference ID: 472 815 435# for audio only.

You may file written comments before 4:30PM on November 23, 2021 by emailing your comments to pharmacy.rulemaking@bop.oregon.

NEED FOR THE RULE(S)

Revisions to Division 110 are necessary to incorporate annual Prescription Drug Monitoring Program (PDMP) fee increase of $25 to $35 set forth in 2021 HB 2074 and to repeal all rules related to Supervising Physician Dispensing Outlets (SPDOs) as a result of 2021 HB 3036 effective 3/31/2022. To appropriately reference and reflect current regulations, amends and repeals outdated regulations in alignment with the board's 2020-2024 strategic plan.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

https://olis.oregonlegislature.gov/liz/2021R1/Downloads/MeasureDocument/HB2074/Enrolled 2021 HB 2074 and related statutes
https://olis.oregonlegislature.gov/liz/2021R1/Downloads/MeasureDocument/HB3036/Enrolled 2021 HB 3036 and related statutes
ORS 475.125 https://www.oregonlegislature.gov/bills_laws/ors/ors475.html

FISCAL AND ECONOMIC IMPACT:

2021 HB 2074 increases the PDMP fee from $25 to $35 annually resulting in a $20 increase in fees paid by a pharmacist at the time of biennial licensure renewal. Increasing the fee will result in increased revenue by the agency of approximately $172,200 ($10 per year or $20 x 8600 RPH renewals). 90% of the revenue is passed through to the PDMP program and 10% is retained by the agency for administrative costs, resulting in an agency revenue increase of $17,200.

There are currently 52 Supervising Physician Dispensing Outlets (SPDO) and 49 Dispensing Practitioner Dispensing Outlets (DPDO) currently active. As a result of 2021 HB 3036, SPDO will be discontinued effective 3/31/2022. 6 SPDOs also have an active DPDO registration. The discontinued SPDOs may now meet the requirements for registration as a "DPDO". The current SPDO registration fee is $175 annually and the current DPDO registration fee is $100 annually. There are 6 locations that hold both registrations.

The use of NABP's eProfile and eGov processes have reduced many of the manual processes and created licensing efficiencies such as re-examination fees for NAPLEX. This has become an obsolete fee that is no longer assessed. With the new exam processes, applicants do not apply for licensure with the board until after they have passed the NAPLEX exam. No anticipated fiscal. Score Transfer is applicable to new graduates and has similar workload to licensure via exam (NAPLEX), so the fee should be equivalent to the current NAPLEX fee. The Board receives approximately 125 Score Transfer applications in a biennium. Reducing this fee from $250 to $50 will result in a biennial revenue reduction of $25,000.

Reciprocity (Licensure Transfer) is applicable to applicants who are licensed as a pharmacist in another state and meet the requirements listed in ORS 689.265 and OAR 855-019-0130. There are approximately 850 Reciprocity applications received in a biennium. Reducing this fee from $250 to $100 will result in a biennial revenue reduction of $127,500.

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).

OAR 855-060-0001, OAR 855-110-0003- No anticipated fiscal.

OAR 855-110-0005(1) and (3)
There are approximately 125 Score Transfer applications received in a biennium. Reducing this fee from $250 to $50 will result in a biennial revenue reduction of $25,000 for the Oregon Board of Pharmacy. There are approximately 850 Reciprocity applications received in a biennium. Reducing this fee from $250 to $100 will result in a biennial revenue reduction of $127,500 for the Oregon Board of Pharmacy.

OAR 855-110-0005(6)(b)
$20 increase in fees paid by a pharmacist at the time of biennial licensure renewal will result in increased revenue by the

agency of approximately $172,200 ($10 per year or $20 x 8600 RPH renewals).

OAR 855-110-0007(16)

52 currently registered SPDO licenses will be discontinued as of March 31, 2022. These registrants may need to register as a DPDO in the future and will be subject to all required licensing/registration fees and requirements related to applying to become a DPDO.

There are no known economic impacts to small businesses or members of the public related to the directives of 2021 HB 2074 and 2021 HB 3036.

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?

Legislative directives of 2021 HB 2074 and 2021 HB 3036.

RULES PROPOSED:

855-060-0001, 855-110-0003, 855-110-0005, 855-110-0007, 855-110-0010

AMEND: 855-060-0001

RULE SUMMARY: Revisions to Division 060 are procedural rule review to appropriately reference and reflect current regulations and amend outdated regulations in alignment with the board's 2020-2024 strategic plan.

CHANGES TO RULE:

855-060-0001
Application ¶

No place of manufacturing, wholesaling or repackaging of drugs or medicines, as defined in ORS 689.005(20), (35), and (36) ~~shall~~may be conducted or operated until it has been registered by the State Board of Pharmacy~~, except that compounding or repackaging, as a part of a Shared Pharmacy Services agreement as defined in OAR 855-006-0005(20), does not constitute manufacturing. Manufacturing registration expires September 30th annually:~~.¶
(1) All applications for registration of a new or relocated manufacturer shall be accompanied by the required fees as set forth in OAR 855-110-~~0007(3)~~.¶
(2) Application ~~shall~~must specify the location of the manufacturer premises. When the applicant is not the owner of the business, the application shall indicate the owner and the applicant's affiliation with the owner;¶
(a) If the owner is a partnership or other multiple owner, the names of the partners or person holding the five largest interests shall be indicated on the application.¶
(b) If the owner is a corporation, the name filed ~~shall~~must be the same as filed with the Corporation Commissioner. The name of the corporation, the names of the corporation officers and the names of the stockholders who own the five largest interests shall be indicated on the application.¶
(c) Upon request by the ~~B~~board, the applicant ~~shall~~must furnish such information as required by the ~~B~~board regarding the partners, stockholders, or other persons not named in the application.¶
(3) All registration renewal applications ~~shall~~must be accompanied by the annual fee and contain the same information required in subsection (2)(a), (b), and (c) of this rule.¶
(4) A change of ownership or location requires a new application, fee, and registration within 15 days.¶
(5) The registration certificate is issued to a person or firm and is non-transferable. Additions or deletions of a partner/partners ~~shall~~must be considered as a change of ownership.¶
(6) Manufacturer registration expires September 30th annually. The registration cannot be prorated.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.305, ORS 689.315, ORS 689.325

AMEND: 855-110-0003

RULE SUMMARY: Revisions to Division 110 include incorporating the annual PDMP fee increase of $25 to $35 set forth in 2021 HB 2074.

CHANGES TO RULE:

855-110-0003
General ¶

(1) All fees paid under these rules are non-refundable.¶
(2) Fees cannot be prorated.¶
(3) Fees for initial licensure as a Pharmacist or Certified Oregon Pharmacy Technician may be reduced to one-half of a biennial rate, if the application is received ~~or the mailing date of the application is postmarked~~ within 180 days of expiration.¶
(4) A ~~delinquent~~late fee must be paid~~:~~¶
~~(a) When an~~ when a renewal application is ~~postmark~~received after the date specified in these rules~~; or~~¶
~~(b) When the Board requests additional information from an applicant and this information is not provided within 30 days.¶~~
~~(5) A delinquent fee may be assessed when an application is submitted incomplete and the Board requests the missing information~~.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.135

AMEND: 855-110-0005

RULE SUMMARY: Revisions to Division 110 include incorporating the annual PDMP fee increase of $25 to $35 set forth in 2021 HB 2074. Repeals all rules related to Supervising Physician Dispensing Outlets (SPDOs) as a result of 2021 HB 3036 effective 3/31/2022. Appropriately references and reflects current regulations, amends and repeals outdated regulations in alignment with the board's 2020-2024 strategic plan.

CHANGES TO RULE:

855-110-0005
Licensing Fees ¶

(1) Pharmacist license examination (NAPLEX) ~~and re-examination~~ fee - $50.¶
(2) Pharmacist jurisprudence (MPJE) re-examination fee - $25.¶
(3) Pharmacist licensing by reciprocity fee - $~~25~~100. ¶
(4) Pharmacist licensing by score transfer fee - $~~2~~50. ¶
(5) Intern license fee. Expires November 30 every two years - $100.¶
(6) Pharmacist:¶
(a) Biennial license fee. Expires June 30 each odd numbered year. The biennial license fee is - $250. Late renewal fee (received after June 30) - $50.¶
(b) Electronic Prescription Monitoring Fund fee. Due by June 30 biennially - $~~5~~70. (This is a mandatory fee, required by ORS 431~~.972~~A.880 that must be paid with the pharmacist license renewal fee).¶
(c) Workforce Data Collection fee. Due by June 30 biennially - $4. (This is a mandatory fee as required by OAR 409-026-0130 that must be paid with the Pharmacist license renewal fee.)¶
(7) Certification of approved provider of continuing education course fee, none at this time.¶
(8) Pharmacy Technician license fee - $100.¶
(9) Certified Oregon Pharmacy Technician:¶
(a) Biennial license fee. Expires June 30 each even numbered year - $100. Late renewal fee (received after June 30) - $20.¶
(b) Workforce Data Collection fee. Due by June 30 biennially - $4. (This is a mandatory fee as required by OAR 409-026-0130 that must be paid with the Certified Oregon Pharmacy Technician license renewal fee.)
Statutory/Other Authority: ORS 689.205, ORS 291.055, ORS 183.705
Statutes/Other Implemented: ORS 689.135, ORS 676.410, ORS 431A.880

AMEND: 855-110-0007

RULE SUMMARY: Revisions to Division 110 include incorporating the annual PDMP fee increase of $25 to $35 set forth in 2021 HB 2074. Repeals all rules related to Supervising Physician Dispensing Outlets (SPDOs) as a result of 2021 HB 3036 effective 3/31/2022. Appropriately references and reflects current regulations, amends and repeals outdated regulations in alignment with the board's 2020-2024 strategic plan.

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 ~~c~~Correctional ~~f~~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. 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.¶
(7) Nonprescription Class B. Expires January 31 annually - $75. Late renewal fee (received after January 31) - $25.¶
(8) Nonprescription Class D. Expires January 31 annually - $100. Late renewal fee (received after January 31) - $25.¶
(9) Prophylactic and/or Contraceptive Wholesaler and/or Manufacturer - $50. Expires December 31 annually. ¶
(10) Re-inspection fee - $100. Applies to any re-inspection of a drug outlet occasioned to verify corrections of violations found in an initial inspection.¶
(11) Retail, Institutional, or Consulting/"Drugless" Pharmacy Drug Outlet. 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). Expires September 30 annually - $525. Late renewal fee (received after September 30) - $100.¶
(13) Remote Dispensing Machine or Remote Distribution Facility. Expires March 31 annually - $120. Due by March 31 annually. ¶
(14) Charitable Pharmacy. Expires March 31 annually - $75. 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) ~~Supervising Physician Dispensing Outlet. Expires March 31 annually - $175. Late renewal fee (received after March 31) - $75. ¶~~
~~(17)~~ Dispensing Practitioner Drug Outlet. Expires March 31 annually - $100. Late renewal fee (received after March 31) - $25.
Statutory/Other Authority: ORS 689.205, ORS 291.055
Statutes/Other Implemented: ORS 689.135, ORS 689.774, ORS 689.305

AMEND: 855-110-0010

RULE SUMMARY: Revisions to Division 110 include incorporating the annual PDMP fee increase of $25 to $35 set forth in 2021 HB 2074. Repeals all rules related to Supervising Physician Dispensing Outlets (SPDOs) as a result of 2021 HB 3036 effective 3/31/2022. Appropriately references and reflects current regulations, amends and repeals outdated regulations in alignment with the board's 2020-2024 strategic plan.

CHANGES TO RULE:

855-110-0010
Fees for Registration for Controlled Substances ~~under ORS 475.095~~ ¶

(1) Animal Euthanasia controlled substance registration fee - $75 annually.¶
(2) Drug Distribution Agent controlled substance registration fee - $100 annually. ¶
(3) Drug Room (including ~~c~~Correctional ~~f~~Facility) controlled substance registration fee - $100 annually. ¶
(4) Manufacturer controlled substance registration fee - $100 annually. ¶
(5) Retail or Institutional Drug Outlet controlled substance registration fee - $100 annually. ¶
(6) Schedule II Precursor registration fee - $75 annually. ¶
(7) Wholesaler controlled substance registration fee - $100 annually. ¶
(8) Remote Distribution Facility controlled substance registration fee - $100 annually.
Statutory/Other Authority: ORS 689.205, ORS 291.055
Statutes/Other Implemented: ORS 689.135