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NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855
BOARD OF PHARMACY

FILED
10/21/2022 9:57 AM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Retail Drug Outlet Pharmacy Prescription Labeling; Expiration date requirements

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

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)

Permanently adopts temporary rule from 10/2022 related to expiration date requirements.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

OAR 855-041-1130 Temporary Administrative Order https://www.oregon.gov/pharmacy/Documents/855-041-1130-Temp_BP_45-2022TrackedChanges.pdf

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

Proposed rule language will increase patient access, especially for life saving medications such as naloxone and inhalers for asthma. The rule provides clarity and transparency to licensees and registrants.

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 labeling requirements to increase patient access and for transparency and clarity for licensees/registrants.

AMEND: 855-041-1130

RULE SUMMARY: Permanently adopts temporary rule from 10/2022. Proposed amendments allow prescription drugs dispensed in manufacturer's container to be labeled with the expiration date on the container and not limited to one year. Includes striking language in (10) and adding (a) (b) (A) (B), and (11). Adds clarifying language related to expiration date requirements on prescription labels including manufacturer's expiration date or one year from the date the drug was repackaged and dispensed. The current rule as written may limit patient access due to prescription medication expiration dates being limited to one year. Amendments are necessary to allow licensees and registrants the ability to label prescriptions dispensed in the manufacturer's container with the manufacturer's expiration date and not being limited to one year from dispensing.

CHANGES TO RULE:

855-041-1130
Retail Drug Outlet Pharmacy Prescription Labeling ¶

Prescriptions must be labeled with the following information:¶
(1) Name, address and telephone number of the pharmacy;¶
(2) Date of fill;¶
(3) Identifying number;¶
(4) Name of patient;¶
(5) Name of drug, strength, and quantity dispensed; when a generic name is used, the label must also contain the identifier of the manufacturer or distributor;¶
(6) Directions for use by the patient;¶

(7) Name of practitioner;¶
(8) Required precautionary information regarding controlled substances;¶
(9) Such other and further accessory cautionary information as required for patient safety;¶
(10) An expiration date after which the patient should not use the drug or medicine. Expiration dates on prescriptions must ~~be the same as that on the original container or one year from the date the drug was originally dispensed and placed in the new container, whichever date is earlier.~~not exceed:¶
(a) That on the manufacturer's container if dispensed in the manufacturer's container; or¶
(b) The earliest date of either:¶
(A) The manufacturer's expiration date; or¶
(B) One year from the date the drug was repackaged and dispensed. ¶
(11) Any drug expiring before the expected length of time for the course of therapy must not be dispensed.¶
(1~~1~~2) Any dispensed prescription medication, other than those in unit dose or unit of use packaging, must be labeled with its physical description, including any identification code that may appear on tablets and capsules.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.505, ORS 689.515