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ARCHIVES DIVISION

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TEMPORARY ADMINISTRATIVE ORDER

INCLUDING STATEMENT OF NEED & JUSTIFICATION

BP 45-2022

CHAPTER 855

BOARD OF PHARMACY

FILED

10/17/2022 2:25 PM ARCHIVES DIVISION SECRETARY OF STATE & LEGISLATIVE COUNSEL

FILING CAPTION: Prescription Labeling; Expiration date requirements

EFFECTIVE DATE: 10/17/2022 THROUGH 04/14/2023

AGENCY APPROVED DATE: 10/13/2022

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NEED FOR THE RULE(S):

Temporarily amends current rule by clarifying prescription expiration date requirements for licensees and registrants.

JUSTIFICATION OF TEMPORARY FILING:

The current rule as written may limit patient access due to prescription medication expiration dates being limited to one year. Prompt action is 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. This will increase patient access, especially for life saving medications such as naloxone and inhalers for asthma.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

None available.

AMEND: 855-041-1130

RULE SUMMARY: 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.

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 <u>the</u> course of therapy must not be dispensed. ¶ (142) 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