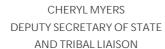
OFFICE OF THE SECRETARY OF STATE

LAVONNE GRIFFIN-VALADE SECRETARY OF STATE





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**

04/17/2024 9:55 AM **ARCHIVES DIVISION** SECRETARY OF STATE

FILING CAPTION: Amends rule to limit labeling exemption to nasal sprays consistent with 2023 SB 450

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 05/22/2024 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.

CONTACT: Rachel Melvin

971-673-0001

pharmacy.rulemaking@bop.oregon.gov

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: 05/22/2024 TIME: 9:30 AM

OFFICER: Rachel Melvin

REMOTE HEARING DETAILS

MEETING URL: Click here to join the meeting

PHONE NUMBER: 503-446-4951 **CONFERENCE ID: 392711816** 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 first and last name and email address to

pharmacy.rulemaking@bop.oregon.gov to receive a calendar invitation to join the virtual hearing. Please indicate which rule(s) you would like to comment on.

You must submit written comments before 4:30PM on May 22, 2024. Email written comments to pharmacy.rulemaking@bop.oregon.gov.

NEED FOR THE RULE(S)

Proposes to amend rule by adding requirements that limit labeling exemption to nasal sprays consistent with the directives of 2023 SB 450.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

2023 SB 450 https://olis.oregonlegislature.gov/liz/2023R1/Downloads/MeasureDocument/SB450/Enrolled

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

The proposed amendment is not expected to affect racial equity in this state.

FISCAL AND ECONOMIC IMPACT:

The proposed amendment has no anticipated fiscal and economic impact.

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 amendment to the rules.

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

Proposed amendments are consistent with the legislative mandate of 2023 SB 450, a RAC was not necessary.

AMEND: 855-115-0350

RULE SUMMARY: Proposes amending existing rule by adding that the labeling exemption only applies to nasal sprays as stated in 2023 SB 450.

CHANGES TO RULE:

855-115-0350

Services: Prescribing Practices - Short-acting Opioid Antagonists

- (1) A Pharmacist may prescribe any FDA approved short-acting opioid antagonist (e.g., naloxone, nalmefene) and the necessary medical supplies to administer a short-acting opioid antagonist for opiate overdose:¶
- (a) When dispensing any opiate or opioid prescription in excess of 50 morphine milligram equivalents (MME); ¶
- (b) To an individual seeking a short-acting opioid antagonist; ¶
- (c) To an entity seeking a short-acting opioid antagonist.¶
- (2) A Pharmacist is not required to label the prescription according to OAR 855-041-1130 if dispensing a FDA approved short-acting opioid antagonist in the form of a nasal spray. \P
- (3) The Pharmacist must document the encounter, the prescription and maintain records according to OAR 855-104-0055.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.305, ORS 689.681, ORS 689.682, ORS 689.684, 2023 HB 2395, 2023 SB 450ORS 689.802, ORS 689.813