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**NOTICE OF PROPOSED RULEMAKING**  
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855  
BOARD OF PHARMACY

**FILED**

08/17/2023 1:46 PM  
ARCHIVES DIVISION  
SECRETARY OF STATE

FILING CAPTION: Short-acting Opioid Antagonist; Labeling exemption

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 09/27/2023 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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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: 09/27/2023

TIME: 9:30 AM

OFFICER: Rachel Melvin

HEARING LOCATION

ADDRESS: Oregon Board of Pharmacy - Virtual Meeting , 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/](http://www.oregon.gov/pharmacy/pages/)

rulemaking-information or email your first and last name, email address and phone number 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 September 27, 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

CONFERENCE ID: 764448015

NEED FOR THE RULE(S)

Proposed rule incorporates the newly defined term "short-acting opioid antagonist" from 2023 HB 2395 and adds labeling exemption requirements that apply when a prescriber personally dispenses a short-acting opioid antagonist in the form of a nasal spray per directives of from 2023 SB 450.

## DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

2023 SB 450 <https://olis.oregonlegislature.gov/liz/2023R1/Downloads/MeasureDocument/SB0450/Enrolled>

2023 HB 2395 <https://olis.oregonlegislature.gov/liz/2023R1/Downloads/MeasureDocument/SB0450/Enrolled>

Narcan (naloxone) package insert <https://dailymed.nlm.nih.gov/dailymed/getFile.cfm?setid=724df050-5332-4d0a-9a5f-17bf08a547e1&type=pdf>

Opvee (nalfemene) package insert <https://dailymed.nlm.nih.gov/dailymed/getFile.cfm?setid=999a4269-9e54-4801-b2ac-2a7276f0b94f&type=pdf>

Spencer MR, Miniño AM, Warner M. Drug overdose deaths in the United States, 2001–2021. NCHS Data Brief, no 457. Hyattsville, MD: National Center for Health Statistics. 2022. DOI: <https://stacks.cdc.gov/view/cdc/122556>

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

The proposed rule may have a positive impact on racial equity in Oregon. According to the CDC, Black, Indigenous, and people of color and American Indian/Alaska Native (BIPOC-AI/AN) people are disproportionately likely to die from opioid overdoses. By making short-acting opioid antagonists more accessible, reducing stigma, and improving access to care, the rules could help to reduce the number of opioid overdose deaths in the state, particularly among BIPOC-AI/AN people.

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## FISCAL AND ECONOMIC IMPACT:

None anticipated.

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## 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.

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## DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

Small businesses were not involved with the development of proposed rules.

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

Proposed rules are legislative mandates of 2023 SB 450 and 2023 HB 2395.

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ADOPT: 855-115-0350

**RULE SUMMARY:** Proposed amendments relocate and revise OAR 855-019-0460 to OAR 855-115-0350. Revisions include striking the term “naloxone” and alternatively utilizing “short-acting opioid antagonist” as defined in 2023 HB 2395, adds labeling exemptions when a Pharmacist personally dispenses a FDA approved short-acting opioid antagonist in the form of a nasal spray as mandated in 2023 SB 450 and removes requirement for Pharmacist to determine individual seeking naloxone understands educational materials related to opioid overdose prevention and repeals duplicative rule concerning counseling that is contained in OAR 855-019-0230.

## CHANGES TO RULE:

**855-115-0350**

Services: Prescribing Practices - Short-acting Opioid Antagonist

(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.¶

(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 450