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ARCHIVES DIVISION
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NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855
BOARD OF PHARMACY

FILED
04/26/2018 9:08 AM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Amend naloxone prescribing rules related to possession, distribution and counseling

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 05/23/2018 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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Portland, OR 97232

Filed By:
Mo Klein
Rules Coordinator

HEARING(S)

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

DATE: 05/23/2018

TIME: 9:30 AM

OFFICER: Staff

ADDRESS: Portland State Office

Building

800 NE Oregon St. Conference Room

1A

Portland, OR 97232

NEED FOR THE RULE(S):

Implements 2017 HB 3440 to increase access to naloxone.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

<https://olis.leg.state.or.us/liz/2017R1/Downloads/MeasureDocument/HB3440/Enrolled>

FISCAL AND ECONOMIC IMPACT:

None

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).

Provision of naloxone services by a pharmacy/pharmacist prescribed is voluntary. Minimal costs to comply with labeling and recordkeeping if a pharmacy or other business chooses to provide naloxone services.

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

Small businesses were not involved in the development of these rules.

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

The Oregon Board of Pharmacy is required to write rules that comply with the statutory mandates put forth in 2017 HB 3440.

AMEND: 855-019-0460

RULE SUMMARY: Prescribing and dispensing naloxone including counseling requirements and who may possess, distribute, or administer the drug.

CHANGES TO RULE:

855-019-0460

Naloxone - Delivery of Care ¶¶

- (1) A pharmacist can prescribe naloxone and the necessary medical supplies for opiate overdose training.¶¶
- (2) A pharmacist can prescribe naloxone and the necessary medical supplies to an individual or entity seeking naloxone.¶¶
- (3) The pharmacist shall determine that the individual (or the individual on behalf of an entity) seeking naloxone demonstrates understanding of educational materials related to opioid overdose prevention, recognition, response, and the administration of naloxone.¶¶
- (4) The pharmacist may prescribe naloxone in any FDA approved dosage form and the necessary medical supplies needed to administer naloxone.¶¶
- (5) The pharmacist shall dispense the naloxone product in a properly labeled container.¶¶
- (6) Naloxone may not be ~~dispensed~~ prescribed without offering to provide oral counseling to the authorized recipient, ~~to which may~~ include dose, effectiveness, adverse effects, storage conditions, and safety.¶¶
- (7) The pharmacist must document the encounter and the prescription, and maintain records for three years.¶¶
- (8) Any person, having once lawfully obtained naloxone may possess, distribute or administer it for the purpose of reversing opiate overdose.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.305, ~~689.681~~, 2016 OL Ch. 100, 2017 OL Ch. 684, ORS 689.305, ORS 689.681, ORS ~~689.683~~2