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NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855
BOARD OF PHARMACY

FILED
12/22/2023 8:38 AM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Institutional Drug Outlet Labeling Requirements for Short-acting Opioid Antagonists

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 01/24/2024 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.

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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: 01/24/2024
TIME: 9:30 AM
OFFICER: Rachel Melvin

HEARING LOCATION
ADDRESS: Oregon Board of Pharmacy - Virtual Hearing , 800 NE Oregon St., Suite 150, Portland , OR 97232

REMOTE MEETING DETAILS
MEETING URL: Click here to join the meeting
PHONE NUMBER: 503-446-4951
CONFERENCE ID: 618712182
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, 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 January 24, 2024. Email written comments to pharmacy.rulemaking@bop.oregon.gov.

NEED FOR THE RULE(S)

Proposes to amend Emergency Department labeling requirements related to short-acting opioid antagonist for practitioners with prescriptive authority in Oregon. Incorporates legislative mandates of 2023 HB 2395, 2023 SB 450, 2023 SB 1043 related to short-acting opioid antagonist.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

2023 SB 450 https://olis.oregonlegislature.gov/liz/2023R1/Downloads/MeasureDocument/HB2023/A-Engrossed
2023 SB 1043 https://olis.oregonlegislature.gov/liz/2023R1/Downloads/MeasureDocument/SB1043/Enrolled
2023 HB 2395 https://olis.oregonlegislature.gov/liz/2023R1/Downloads/MeasureDocument/HB2395/Enrolled

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

The proposed rule amendments are not expected to affect racial equity in this state.

FISCAL AND ECONOMIC IMPACT:

No fiscal anticipated. Licensees, registrants and interested parties will have an opportunity to provide fiscal and economic impact statements during the open comment period.

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).

(1) The proposed rule amendments will have no additional economic impact on state agencies, units of local government, or the public.
(2)(a) The proposed rule amendments apply to registrants of the Oregon Board of Pharmacy. Approximately 30 % of Drug Outlet Pharmacy (RP & IP) registrants identify as a small business.
(b) The rulemaking imposes no additional mandatory reporting, recordkeeping or other administrative requirements on small businesses.
(c) The rulemaking imposes no additional requirements regarding equipment, supplies, labor or administration.

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

Licensees and registrants who identify as a small business will receive an email notice of proposed rulemaking via GovDelivery and will have an opportunity to provide public comment on the proposed rules for the board's consideration.

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

The resources involved in convening a RAC were not necessary to amend this rule. This rule enacts the mandates of 2023 SB 450, 2023 SB 1043, or 2023 HB 2395 and does not contain further decisions or requirements by the Board beyond what is in the legislation itself.

RULES PROPOSED:
855-041-6270, 855-041-6410

AMEND: 855-041-6270

RULE SUMMARY: Proposes to amend rule by adding (8) that states that nothing in the rule is intended to restrict or conflict with the directives of 2023 SB 450, 2023 SB 1043, or 2023 HB 2395, effective upon filing.

CHANGES TO RULE:

855-041-6270
Institutional Drug Outlet Pharmacy Prescription Labeling ¶

(1) Each pharmacy record keeping system must identify all pharmacy personnel involved in the repackaging including the pharmacist who verified the repackaged drug.¶
(2) Each repackaged drug, prepared by the pharmacy and intended for use within the facility must be in an appropriate container with a label that meets the requirements of OAR 855-041-1135 and includes:¶
(a) The brand or generic name and expiration date;¶
(b) The manufacturer and lot number, or an internal pharmacy code that references manufacturer and lot number;¶
(c) The strength of the drug.¶
(3) In-patient: Each drug dispensed to an in-patient other than in a unit-dose or manufacturer's unit-of-use packaging must be labeled with the following information:¶
(a) Name and location of patient;¶
(b) Name and strength of drug;¶
(c) Route of administration, when necessary for clarification;¶
(d) Manufacturer and lot number, or internal pharmacy code;¶
(e) Auxiliary labels as needed, and¶
(f) Expiration date.¶
(4) A drug that is provided for outpatient use must be dispensed by a retail drug outlet. ¶
(5) When a new barcode or electronic label is used to identify a drug the pharmacist must verify and document the accuracy of the identification with all electronic verification systems prior to distribution.¶
(6) When a drug is added to a parenteral solution under the direct supervision of a pharmacist, the admixture must be labeled with a distinctive supplementary label that includes the:¶
(a) Name, quantity and concentration of the drug added and the primary solution;¶
(b) Date and time of addition;¶
(c) Expiration date;¶
(d) Scheduled time for administration;¶
(e) Infusion rate, when applicable;¶
(f) Name or initials of person performing admixture;¶
(g) Identification of the pharmacy where the admixture was performed; and¶
(h) Name or initials of the verifying pharmacist.¶
(7) The label applied at a secondary storage or remote storage area by a nurse or physician must include: the patient name or patient identifier, quantity and concentration of the drug added and the primary IV solution; the date and time of addition and the initials of the nurse or physician adding the drug.¶
(8) Nothing in this rule is intended to restrict or conflict with HB 2395 (2023), SB 450 (2023), SB 1043 (2023).
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.505, 2023 HB 2395, 2023 SB 450, 2023 SB 1043

AMEND: 855-041-6410

RULE SUMMARY: Proposes amending (1)(d) and (e) by adding exemptions and incorporates a reference to 2023 SB450 and adding (11) that states that nothing in the rule is intended to restrict or conflict with the directives of 2023 SB 450, 2023 SB 1043, or 2023 HB 2395, effective upon filing.

CHANGES TO RULE:

855-041-6410
Emergency Department Distribution ¶

(1) A practitioner or associate practitioner with prescriptive authority in Oregon who is a member of the hospital's medical staff may dispense an emergency supply of drugs to a patient examined by them or by an associate practitioner subject to the following requirements:¶
(a) The prescriber ~~shall~~must offer the patient the option of being provided a prescription that may be filled at the pharmacy of the patient's choice;¶
(b) During consultation with the patient or the patient's caregiver, the prescriber ~~shall~~must clearly explain the appropriate use of the drug supplied and the need to have a prescription for any additional supply of the drug filled at a pharmacy of the patient's choice;¶
(c) The patient must be given instructions on the use and precautions for taking the drug;¶
(d) ~~T~~Except as described in SB 450 (2023), the drug is in a manufacturer's unit-of-use container, such as an inhaler, or hospital pre-pack that has been labeled by the pharmacy with:¶
(A) Name of drug, strength, and number of units. When a generic name is used, the label must also contain the identifier of the manufacturer or distributor;¶
(B) Accessory cautionary information as required for patient safety;¶
(C) Product identification label if the drug is not in unit-of-use packaging;¶
(D) An expiration date after which the patient should not use the drug; and¶
(E) Name, address and phone number of the hospital pharmacy.¶
(e) ~~T~~Except as described in SB 450 (2023), the following information must be added to the drug container by the practitioner or nurse before dispensing to the patient:¶
(A) Name of patient;¶
(B) Directions for use by the patient;¶
(C) Date of issue;¶
(D) Unique identifying number as determined by policy and procedure;¶
(E) Name of prescribing practitioner; and¶
(F) Initials of the dispensing nurse or practitioner.¶
(f) A prescription or record of the distribution must be completed by the practitioner or nurse. This record must contain:¶
(A) Name of patient;¶
(B) Date of issuance;¶
(C) Drug name and strength distributed;¶
(D) Units issued;¶
(E) Name of practitioner;¶
(F) Initials of the dispensing nurse or practitioner; and¶
(G) Instructions given to the patient as labeled.¶
(g) Any additional information required by state and federal laws and regulations for the distribution of a drug to an outpatient;¶
(h) The record must be reviewed and documented by a pharmacist for accuracy and completeness. The pharmacist ~~shall~~must review the record of dispensing of drugs within 24 hours. However, if the pharmacy is closed, records shall be reviewed during the first day the pharmacy is open but not to exceed 72 hours following the dispensing; and¶
(i) Errors and discrepancies will be included in hospital and pharmacy QA review process and available to the board.¶
(2) A controlled substance may only be distributed or dispensed to an outpatient by the examining practitioner after the patient has been examined by the practitioner and a legitimate medical purpose for a controlled substance has been determined. Distribution of a controlled substance must comply with all applicable state and federal laws and regulations.¶
(3) The CPO or PIC and appropriate hospital committee will establish a limited selection and quantity of drugs to be included in the Emergency Department formulary and the amount contained in each pre-pack that may be

distributed to meet only the acute care needs of a patient; for example, an emergency supply of drugs. The amount dispensed may not exceed a 48 hour supply except for:¶
(a) A drug in the manufacturer's unit-of-use packaging such as an inhalant or a topical drug;¶
(b) A full course of therapy that may be dispensed if in the professional judgment of the pharmacist or practitioner this would be in the patient's best interest such as an antibiotic;¶
(4) Any additional preparation for use of the medication must be completed prior to discharge; for example, reconstituting antibiotics;¶
(5) For the purpose of this rule an Automated Dispensing Machine (ADM) is a machine or contrivance which will prepare a completed and labeled prescription which is ready for dispensing to the patient or patient's representative.¶
(6) An Automated Dispensing Machine; may only be located within the Emergency Department in a secure environment that has no direct public access, and when used, must be part of the discharge procedure;¶
(7) When the patient or patient's representative receives the prescription from an ADM;¶
(a) A registered nurse or practitioner or pharmacist must be present at the time of dispensing; and¶
(b) A registered nurse or practitioner or pharmacist will grant access to the ADM for the release of the drugs to be dispensed using a password protected or biometric access; and¶
(c) The patient or patient's representative will obtain the drug using a specific patient access code.¶
(8) Only a pharmacy technician, certified pharmacy technician, intern or pharmacist may access the drug supply in the ADM.¶
(9) The CPO or PIC will establish policies and procedures for use of the ADM including, but not limited to emergency access and down time procedures for the ADM.¶
(10) Upon written request, the board may waive any of the requirements of this rule if a waiver will further public health or safety. A waiver granted under this section ~~shall~~must only be effective when it is issued in writing and will be time limited.¶
(11) Nothing in this rule is intended to restrict or conflict with HB 2395 (2023), SB 450 (2023), SB 1043 (2023).
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.505, 2023 HB 2395, 2023 SB 450, 2023 SB 1043