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TEMPORARY ADMINISTRATIVE ORDER
INCLUDING STATEMENT OF NEED & JUSTIFICATION

BP 35-2023
CHAPTER 855
BOARD OF PHARMACY

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ARCHIVES DIVISION
SECRETARY OF STATE
& LEGISLATIVE COUNSEL

FILING CAPTION: Institutional Drug Outlet Labeling Requirements for Short-acting Opioid Antagonist Temporary Rules

EFFECTIVE DATE: 01/01/2024 THROUGH 06/28/2024

AGENCY APPROVED DATE: 12/14/2023

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NEED FOR THE RULE(S):

Temporarily amends 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.

JUSTIFICATION OF TEMPORARY FILING:

Rule amendments are necessary by 1/1/2024 to comply with the legislative directives of 2023 SB 450, 2023 SB 1043 and 2023 HB 2395.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

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

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

AMEND: 855-041-6270

RULE SUMMARY: Temporarily amends 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 1/1/2024.

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: Temporarily amends (1)(d) and (e) by adding labeling exemptions pursuant to 2023 SB 450, effective 1/1/2024.

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