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NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855
BOARD OF PHARMACY

FILED
08/17/2023 10:12 AM
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
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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/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 amendments are legislative mandates of 2023 SB 450 and 2023 HB 2395. Amends existing rules related to naloxone by utilizing the newly defined term “short-acting opioid antagonist” instead of “naloxone” per directives of 2023 HB 2395. Amends existing rules for Pharmacies, Dispensing Practitioner Drug Outlet (DPDO), Correctional

Facility (CF), Community Health Clinic (CHC) and Charitable Pharmacies by incorporating 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 2023 SB 450. Repeals OAR 855-041-2340 Naloxone and OAR 855-139-0720 Naloxone General Requirements as these requirements can be found in other existing rules.

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

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

Proposed amendments and repeals would possibly 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.

FISCAL AND ECONOMIC IMPACT:

None anticipated.

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 amendments.

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

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

RULES PROPOSED:
855-019-0460, 855-041-1035, 855-041-1130, 855-041-2340, 855-043-0540, 855-043-0630, 855-043-0735, 855-044-0060, 855-139-0155, 855-139-0720

AMEND: 855-019-0460

RULE SUMMARY: Proposed amendments in OAR 855-019-0460 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:

855-019-0460
~~Naloxone - Delivery of Care and Prescribing~~Short-acting Opioid Antagonist ¶

(1) A ~~p~~Pharmacist~~, having determined that there is an identified medical need, can prescribe naloxone~~ may prescribe any FDA-approved short-acting opioid antagonist (e.g., naloxone, nalmefene) and the necessary medical supplies to administer ~~naloxone~~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 ~~naloxone; ¶~~
~~(c) To an entity seeking naloxone.¶~~
~~(2) The pharmacist shall determine that the individual (or the individual on behalf of~~a short-acting opioid antagonist; ¶
(c) To an entity~~)~~ seeking ~~naloxone demonstrates understanding of educational materials related to opioid overdose prevention, recognition, response, and the administration of naloxone~~a short-acting opioid antagonist.¶
(~~3~~2) ~~The p~~A Pharmacist ~~may prescribe naloxone in any FDA approved dosage form and the necessary medical supplies needed to administer naloxone.¶~~
~~(4) The pharmacist shall dispense the naloxone product~~ is not required to label the prescription according to OAR 855-041-1130 if dispensing a ~~properly labeled container.¶~~
~~(5) Naloxone may not be prescribed without offering to provide oral counseling to the authorized recipient, which may include dose, effectiveness, adverse effects, storage conditions, and safet~~FDA-approved short-acting opioid antagonist in the form of a nasal spray. ¶
(~~6~~3) The ~~p~~Pharmacist must document the encounter~~ and,~~ the prescription~~,~~ and maintain records for three years.¶
~~(7) 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 689.684, ORS 689.305, ORS 689.681, ORS 689.682, 20~~19 OL Ch.~~23 HB 2395, 2023 SB 4~~7~~50

AMEND: 855-041-1035

RULE SUMMARY: Proposed amendments include striking the term "naloxone" and replacing it with "short-acting opioid antagonist" due to directives from 2023 HB 2395.

CHANGES TO RULE:

855-041-1035
Minimum Equipment Requirements ¶

(1) Each retail drug outlet and institutional drug outlet must have the following:¶
(a) Appropriate and current pharmaceutical references (e.g., pharmacology, injectables, and veterinary drugs) based on services offered by the outlet; ¶
(b) Appropriate and current Oregon Revised Statutes, Oregon Administrative Rules, United States Code, Code of Federal Regulations, standards adopted by reference (e.g., USP) based on services offered by the outlet and a minimum of three years of the Board of Pharmacy quarterly newsletters;¶
(c) Access to appropriate electronic reporting databases (e.g., PDMP, NPLEx, OHA ALERT-IIS) based on the services offered by the outlet;¶
(d) Appropriate equipment to maintain the proper storage of drugs;¶
(e) Appropriate equipment and supplies as required by Oregon Revised Statutes, Oregon Administrative Rules, United States Code, Code of Federal Regulations, and standards adopted by reference (e.g., USP) based on services offered by the outlet;¶
(f) A sink with running hot and cold water;¶
(g) Signage in a location easily seen by the public where prescriptions are dispensed or administered: ¶
(A) Stating "This pharmacy may be able to substitute a less expensive drug which is therapeutically equivalent to the one prescribed by your doctor unless you do not approve." The printing on this sign must be in block letters not less than one inch in height. ¶
(B) Providing notification in each of the languages required in OAR 855-041-1132 of the right to free, competent oral interpretation and translation services, including translated prescription labels, for patients who are of limited English proficiency, in compliance with federal and state regulations if the pharmacy dispenses prescriptions for a patient's self-administration;¶
(C) Providing notification by posting a closed sign at the entrances stating the hours of the pharmacy's operation when a pharmacist is not in attendance if the pharmacy operates as a double set-up pharmacy per OAR 855-041-2100; ¶
(D) Providing written notice in a conspicuous manner that ~~naloxone~~short-acting opioid antagonists (e.g., naloxone, nalmefene) and the necessary medical supplies to administer ~~naloxone~~short-acting opioid antagonists are available at the pharmacy if ~~naloxone~~short-acting opioid antagonist services are provided by the pharmacy ~~per OAR 855-041-2340~~; and¶
(E) Providing notification of accurate hours of operation at each pharmacy entrance; and¶
(h) Accurate hours of operation on each telephone greeting and pharmacy-operated internet (e.g. website, social media, mobile applications).¶
(i) Additional equipment and supplies that are determined as necessary by the Pharmacy or Pharmacist-in-Charge.¶
(2) Failure to have, use and maintain required equipment constitutes unprofessional conduct under ORS 689.405(1)(a).
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.508, ORS 689.515, ORS 689.564, ORS 689.686, 2023 HB 2395

AMEND: 855-041-1130

RULE SUMMARY: Proposes amending OAR 855-041-1130 by incorporating statutory reference “2023 SB 450” labeling exemptions when dispensing an FDA approved short-acting opioid antagonist in the form of a nasal spray on behalf of a prescribing pharmacist.

CHANGES TO RULE:

855-041-1130
Retail Drug Outlet Pharmacy Prescription Labeling ¶

~~P~~Except as described in SB 450 (2023), prescriptions must be labeled with the following information:¶
(1) Name, address and telephone number of the pharmacy;¶
(2) Date of fill;¶
(3) Identifying number;¶
(4) Name of patient;¶
(5) Name of drug, strength, and quantity dispensed; when a generic name is used, the label must also ¶~~¶~~ contain the identifier of the manufacturer or distributor;¶
(6) Directions for use by the patient;¶
(7) Name of practitioner;¶
(8) Required precautionary information regarding controlled substances;¶
(9) Such other and further accessory cautionary information as required for patient safety;¶
(10) An expiration date after which the patient should not use the drug or medicine. Expiration dates on prescriptions must not exceed: ¶
(a) That on the manufacturer's container if dispensed in the manufacturer's container; or¶
(b) The earliest date of either:¶
(A) The manufacturer's expiration date; or¶
(B) One year from the date the drug was repackaged and dispensed.¶
(11) Any drug expiring before the expected length of time for the course of therapy must not be dispensed.¶
(12) Any dispensed prescription medication, other than those in unit dose or unit of use packaging, must be labeled with its physical description, including any identification code that may appear on tablets and capsules.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.505, ORS 689.515, 2023 SB 450

REPEAL: 855-041-2340

RULE SUMMARY: Repeals OAR 855-041-2340 as these rules are duplicative with rules in OAR 855-041-1035 and OAR 855-041-1040.

CHANGES TO RULE:

~~855-041-2340~~
~~Naloxone ¶~~

~~Pharmacies providing naloxone services must establish, maintain and enforce written procedures including, but not limited to:¶~~
~~(1) Providing a workflow process and physical location that maintains confidentiality and is not susceptible to distraction; ¶~~
~~(2) Documentation and recordkeeping: and¶~~
~~(3) Provide written notice in a conspicuous manner that naloxone and the necessary medical supplies to administer naloxone are available at the pharmacy.~~
~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.305, ORS 689.681, ORS 689.682, 2019 OL Ch. 470~~

AMEND: 855-043-0540

RULE SUMMARY: Amends OAR 855-043-0540 by incorporating statutory reference to the labeling exemptions contained in 2023 SB 450 that apply to a Dispensing Practitioner Drug Outlet (DPDO) when a prescriber personally dispenses a FDA approved short-acting opioid antagonist in the form of a nasal spray.

CHANGES TO RULE:

855-043-0540
Dispensing Practitioner Drug Outlet - Labeling
(1) ~~A~~Except as described in SB 450 (2023), a prescription must be labeled with the following information:¶
(a) Name of patient; ¶
(b) Name of prescriber; ¶
(c) Name, address, and phone number of the clinic; ¶
(d) Date of dispensing; ¶
(e) Name and strength of the drug. If the drug does not have a brand name, then the generic name of the drug and the drug manufacturer must be stated; ¶
(f) Quantity dispensed; ¶
(g) Directions for use; ¶
(h) Cautionary statements, if any, as required by law; and ¶
(i) An expiration date after which the patient should not use the drug or medicine. Expiration dates on prescriptions must be the same as that on the original container or one year from the date the drug was originally dispensed and placed in the new container, whichever date is earlier. Any drug expiring before the expected length of time for course of therapy must not be dispensed. ¶
(j) Any dispensed prescription medication, other than those in unit dose or unit of use packaging, must be labeled with its physical description, including any identification code that may appear on tablets and capsules.¶
(2) Not withstanding any other requirements in this rule, when a drug is dispensed in the practice of an Expedited Partner Therapy treatment protocol, as described in OAR 855-043-0004, the name of the patient may be omitted.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.305, 2023 SB 450

AMEND: 855-043-0630

RULE SUMMARY: Amends OAR 855-043-0630 by incorporating statutory reference to the labeling exemptions contained in 2023 SB 450 that apply to a Correctional Facility (CF) when a prescriber personally dispenses a FDA approved short-acting opioid antagonist in the form of a nasal spray.

CHANGES TO RULE:

855-043-0630
Correctional Facility - Drug Delivery and Control ¶

(1) Policies and Procedures: The ~~þ~~Pharmacist and the practitioner representing the facility ~~shall b~~are responsible for establishing written policies and procedures for medication management including, but not limited to, drug procurement, dispensing, administration, labeling, medication counseling, drug utilization review, medication records, parenterals, emergency and nonroutine dispensing procedures, stop orders, over-the-counter drugs, security, storage and disposal of drugs withing the facility. Policies and procedures ~~shall~~must be reviewed and updated annually by the ~~þ~~Pharmacist and the practitioner, maintained in the facility; and be made available to the ~~B~~board for inspection. The facility ~~shall~~must submit to the ~~B~~board for approval, the name of any employee ~~þ~~Pharmacist or a written agreement between the ~~þ~~Pharmacist and the facility regarding drug policies and procedures. The facility ~~shall~~must notify the ~~B~~board of any change of ~~þ~~Pharmacist within 15 days of the change.¶
(2) Dispensing: Prescription drugs ~~shall~~must be dispensed by a ~~þ~~Pharmacist or by a practitioner authorized to dispense in either an individual container, medication card, or in a unit dose system. ¶
(3) Unit Dose Dispensing System. The "Unit Dose Dispensing System" is that drug distribution system which is pharmacy based and which uses unit dose packaging in a manner which removes traditional drug stock from patient care areas and enables the selection and distribution of unit dose packaging to be pharmacy based and controlled:¶
(a) A unit dose dispensing system ~~shall~~must:¶
(A) By nature of the system;¶
(i) Provide for separation of medications by patient name and location; and¶
(ii) Provide for separating medications by day of administration.¶
(B) By means of an individual patient medication record:¶
(i) Record the drug and dosing regimen of those drugs dispensed by the pharmacy;¶
(ii) Record the actual doses dispensed and returned to the pharmacy;¶
(iii) Record the date of the original order and the date the order is discontinued;¶
(iv) Provide a means for the ~~þ~~Pharmacist to verify the prescriber's original order;¶
(v) Provide a means for the ~~þ~~Pharmacist to certify the accuracy of the selected medication before the dose is delivered for administration to the patient; and¶
(vi) Provide a mechanism to easily identify those drugs dispensed by pharmacy that are controlled substances.¶
(b) Each ~~correctional facility~~CF utilizing a unit dose dispensing system ~~shall~~must establish written policies specifying the categories of drugs which will or will not be dispensed under the unit dose distribution system. Such policies ~~shall~~must be available in the pharmacy for inspection by the ~~B~~board:¶
(A) Proper utilization of the unit dose system requires that, in as far as is practicable, all medications be in unit dose packaging when dispensed.¶
(B) Controlled substances may be included in the unit dose system if the methods of including such drugs in the system are in compliance with applicable federal and state laws and rules.¶
(C) Drugs not dispensed in unit dose packaging must be labeled in accordance with ~~OAR 855-041-0177~~(4).¶
(c) The ~~þ~~Pharmacist ~~shall~~must certify the accuracy of the selected unit dose packages before the dose is delivered for administration to the patient.¶
(d) All medication ~~shall~~must be stored in a locked area or locked cart.¶
(4) Labeling: ~~P~~Except as described in SB 450 (2023), prescription drugs dispensed in individual containers or medication cards ~~shall~~must be labeled with the following information:¶
(a) Name and identifying number of the patient/inmate;¶
(b) Name, strength, and quantity of the drug dispensed. If the drug does not have a brand name, then the generic name of the drug and the drug manufacturer must be stated;¶
(c) Name of the prescriber;¶
(d) Initials of the dispenser and the date of dispensing;¶
(e) Directions for use;¶
(f) Auxiliary labels and cautionary statements as required;¶
(g) Manufacturer's expiration date, or an earlier date if preferable; and¶

(h) Name of the pharmacy.¶
(5) Patient counseling:¶
(a) Upon receipt of a prescription drug order and following review by the ~~p~~Pharmacist of the patient's record, the ~~p~~Pharmacist ~~shall~~must initiate and provide oral counseling to the patient or to the patient's agent or care giver in all ambulatory care settings and for discharge medications in institutions:¶
(A) Upon request; or¶
(B) On matters which a reasonable and prudent ~~p~~Pharmacist would deem significant; or¶
(C) Whenever the drug prescribed has not previously been dispensed to the patient; or¶
(D) Whenever the patient's medication record shows the drug has not been previously dispensed to the patient in the same dosage, form, strength or with the same written directions.¶
(b) When counseling is provided it ~~shall~~must include information that a reasonable and prudent ~~p~~Pharmacist would deem necessary to provide for the safe and effective use of the drug. Such information may include the following:¶
(A) The name and description of the drug;¶
(B) The dosage form, dose, route of administration, and duration of drug therapy;¶
(C) The intended use of the drug and expected actions;¶
(D) Special directions and precautions for preparation, administration, and use by the patient;¶
(E) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;¶
(F) The possible dangers of taking the drug with alcohol, or taking the drug and then operating a motor vehicle or other hazardous machinery;¶
(G) Techniques for self-monitoring drug therapy;¶
(H) Proper storage;¶
(I) Prescription refill information;¶
(J) Action to be taken in the event of a missed dose; and¶
(K) Pharmacist comments relevant to the patient's drug therapy, including any other information peculiar to the specific patient or drug.¶
(c) Patient counseling ~~shall~~must be in person whenever practicable. Whenever the prescription is delivered outside the confines of the pharmacy by mail or other third party delivery, counseling ~~shall~~must be in writing and by free access to the ~~p~~Pharmacist by phone.¶
(d) Subsections (a) and (b) of this section ~~shall~~must not apply to those prescription drug orders for inpatients in hospitals or institutions where the drug is to be administered by a nurse or other individual authorized to administer drugs.¶
(e) Notwithstanding the requirements set forth in subsection (a), a ~~p~~Pharmacist is not required to provide oral counseling when a patient refuses the ~~p~~Pharmacist 's attempt to counsel, or when the ~~p~~Pharmacist, on a case by case basis and in the exercise of professional judgment, determines that another form of counseling would be more effective.¶
(f) Board rules for patient counseling must be observed for patient/inmates who self administer or who are given prescription drugs when they are released from the ~~correctional facility~~CF.¶
(6) Administration: Drugs ~~shall~~must be administered to inmate/ patients by a practitioner or nurse, or by an unlicensed person who has been trained to administer drugs as defined ~~in Nursing Board administrative rule~~by the Oregon State Board of Nursing in OAR 851-04~~7~~5-00~~2~~60. Drugs selected by registered nurses from manufacturer's or ~~p~~Pharmacist's bulk drug containers ~~shall~~must not be administered by unlicensed persons, except under certain emergency and nonroutine situations as described in the facility's policies and procedures.
Statutory/Other Authority: ~~:~~ ORS 689.205
Statutes/Other Implemented: ORS 689.155, 2023 SB 450

AMEND: 855-043-0735

RULE SUMMARY: Amends OAR 855-043-0735 by incorporating statutory reference to the labeling exemptions contained in 2023 SB 450 that apply to a Community Health Clinic (CHC) when a prescriber personally dispenses a FDA approved short-acting opioid antagonist in the form of a nasal spray.

CHANGES TO RULE:

855-043-0735
Community Health Clinic (CHC) - Labeling ¶

(1) ~~A~~Except as described in SB 450 (2023), a prescription must be labeled with the following information:¶
(a) Unique identifier (i.e. prescription number);¶
(b) Name of patient;¶
(c) Name of prescriber;¶
(d) Name, address, and phone number of the clinic;¶
(e) Date of dispensing;¶
(f) Name of drug, strength, and quantity dispensed; when a generic name is used, the label must also contain the identifier of the manufacturer or distributor;¶
(g) Quantity dispensed;¶
(h) Directions for use;¶
(i) Initials of the practitioner who has been given dispensing privileges by their licensing Board or the Registered Nurse;¶
(j) Cautionary statements, if any, as required by law; and¶
(k) Manufacturer's expiration date, or an earlier date if preferable, after which the patient should not use the drug.¶
(2) Notwithstanding any other requirements in this rule, when a drug is dispensed in the practice of an Expedited Partner Therapy treatment protocol, the name of the patient may be omitted from the label, the patient's name may be omitted from the records and a drug may be dispensed to the patient to be given to the patient's partner even if the partner has not been examined by a licensed health care provider acting within their scope of practice.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.305, 2023 SB 450

AMEND: 855-044-0060

RULE SUMMARY: Amends OAR 855-044-0060 by incorporating statutory reference to the labeling exemptions contained in 2023 SB 450 that apply to Charitable Pharmacies when a prescriber personally dispenses a FDA approved short-acting opioid antagonist in the form of a nasal spray.

CHANGES TO RULE:

855-044-0060
Labeling ¶

(1) ~~T~~Except as defined in SB 450 (2023), the label on a drug dispensed or distributed from a charitable pharmacy must meet all federal rules and laws and must contain:¶
(a) The name, address and telephone number of the pharmacy;¶
(b) The name of the prescribing practitioner;¶
(c) The initials of the dispensing practitioner;¶
(d) Date dispensed;¶
(e) The name of the patient;¶
(f) Name and manufacturer of drug, drug strength, the quantity dispensed;¶
(g) Directions for use;¶
(~~i~~h) The expiration date;¶
(~~j~~i) A unique identifier; and¶
(~~k~~j) Any further cautionary information required for patient safety.¶
(2) All original patient identification must be removed.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.774, 2023 SB 450

AMEND: 855-139-0155

RULE SUMMARY: Proposed amendments include striking the term "naloxone" and replacing it with "short-acting opioid antagonist" due to directives of 2023 HB 2395.

CHANGES TO RULE:

855-139-0155
Outlet: Minimum Equipment Requirements
(1) Each Oregon Retail Drug Outlet RDSP must have the following:¶
(a) Appropriate and current pharmaceutical references (e.g., pharmacology, injectables, and veterinary drugs) services offered by the outlet; ¶
(b) Appropriate and current Oregon Revised Statutes, Oregon Administrative Rules, United States Code, Code of Federal Regulations, standards adopted by reference (e.g., USP) based on services offered by the outlet and a minimum of three years of the Board of Pharmacy quarterly newsletters;¶
(c) Access to appropriate electronic reporting databases (e.g., PDMP, NPLEx, OHA ALERT-IIS) based on the services offered by the outlet;¶
(d) Appropriate equipment to maintain the proper storage of drugs;¶
(e) Appropriate equipment and supplies as required by Oregon Revised Statutes, Oregon Administrative Rules, United States Code, Code of Federal Regulations, and standards adopted by reference (e.g., USP) based on services offered by the outlet;¶
(f) A sink with running hot and cold water;¶
(g) Signage in a location easily seen by the public where prescriptions are dispensed or administered: ¶
(A) Stating "This pharmacy may be able to substitute a less expensive drug which is therapeutically equivalent to the one prescribed by your doctor unless you do not approve." The printing on this sign must be in block letters not less than one inch in height. ¶
(B) Providing notification in each of the languages required in OAR 855-139-0410 of the right to free, competent oral interpretation and translation services, including translated prescription labels, for patients who are of limited English proficiency, in compliance with federal and state regulations if the pharmacy dispenses prescriptions for a patient's self-administration;¶
(C) Providing written notice in a conspicuous manner that ~~naloxone~~short-acting opioid antagonists (e.g., naloxone, nalmefene) and the necessary medical supplies to administer ~~naloxone~~short-acting opioid antagonists are available at the pharmacy if ~~naloxone~~short-acting opioid antagonist services are provided by the pharmacy ~~per OAR 855-139-0720~~; ¶
(D) Stating "This location is a Remote Dispensing Site Pharmacy, supervised by an Oregon licensed Pharmacist from (insert name of RDSP Affiliated Pharmacy, address, and telephone number)." The printing on the sign must be in block letters not less than one inch in height; and¶
(E) Providing notification of accurate hours of operation at each pharmacy entrance; and¶
(h) Accurate hours of operation on each telephone greeting and pharmacy-operated internet (e.g. website, social media, mobile applications).¶
(i) Additional equipment and supplies that are determined as necessary by the Pharmacy or Pharmacist-in-Charge.¶
(2) Failure to have, use and maintain required equipment constitutes unprofessional conduct under ORS 689.405(1)(a).
Statutory/Other Authority: ORS 689.205, ORS 689.686, ORS 689.515, 2021 SB 629
Statutes/Other Implemented: ORS 689.155, 2023 HB 2395

REPEAL: 855-139-0720

RULE SUMMARY: Repeals OAR 855-139-0720 as these rules are duplicative with rules in OAR 855-139-0155 and OAR 855-139-0500.

CHANGES TO RULE:

~~855-139-0720~~
~~Service: Naloxone- General Requirements~~
~~Pharmacies providing naloxone services must establish, maintain and enforce written procedures including, but not limited to:¶~~
~~(1) Providing a workflow process and physical location that maintains confidentiality and is not susceptible to distraction; ¶~~
~~(2) Documentation and recordkeeping: and¶~~
~~(3) Provide written notice in a conspicuous manner that naloxone and the necessary medical supplies to administer naloxone are available at the pharmacy.~~
~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.305, ORS 689.681, ORS 689.682~~