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PERMANENT ADMINISTRATIVE ORDER

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FILING CAPTION: Amend naloxone prescribing rules per 2017 HB 3440.

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RULES:

855-019-0455, 855-019-0460, 855-041-2310, 855-041-2330, 855-041-2340

AMEND: 855-019-0455

RULE TITLE: Naloxone - Qualifications

NOTICE FILED DATE: 10/30/2017

RULE SUMMARY: The Naloxone rule amendments in Div 019 and Div 041 incorporate edits put forth in 2017 HB 3440. The new law removes all previous Oregon Health Authority (OHA) training mandates. Edits clarify that a pharmacist can prescribe naloxone to an entity or an individual seeking naloxone and any necessary supplies to administer the naloxone.

RULE TEXT:

A pharmacist acting in good faith, exercising reasonable care and who is educated in opiate overdose and naloxone rescue can prescribe naloxone and the necessary medical supplies to administer the naloxone.

STATUTORY/OTHER AUTHORITY: ORS 689.205

STATUTES/OTHER IMPLEMENTED: ORS 689.305, 689.681, 2016 OL Ch. 100, 2017 OL Ch. 683

AMEND: 855-019-0460

RULE TITLE: Naloxone - Delivery of Care

NOTICE FILED DATE: 10/30/2017

RULE SUMMARY: The Naloxone rule amendments in Div 019 and Div 041 incorporate edits put forth in 2017 HB 3440. The new law removes all previous Oregon Health Authority (OHA) training mandates. Edits clarify that a pharmacist can prescribe naloxone to an entity or an individual seeking naloxone and any necessary supplies to administer the naloxone.

RULE TEXT:

- (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 without providing oral counseling to the authorized recipient, to 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.

STATUTORY/OTHER AUTHORITY: ORS 689.205

STATUTES/OTHER IMPLEMENTED: ORS 689.305, 689.681, 2016 OL Ch. 100, 2017 OL Ch. 683

AMEND: 855-041-2310

RULE TITLE: Naloxone - Definitions

NOTICE FILED DATE: 10/30/2017

RULE SUMMARY: The Naloxone rule amendments in Div 019 and Div 041 incorporate edits put forth in 2017 HB 3440. The new law removes all previous Oregon Health Authority (OHA) training mandates. Edits correct rule reference numbers and remove certain definitions that are no longer applicable for Naloxone prescribing.

RULE TEXT:

The following words and terms, when used in OAR 855-041-2300 through 855-041-2320 shall have the following meanings, unless the context clearly indicates otherwise.

- (1) "Allergic reaction" means a medical condition caused by exposure to an allergen, with physical symptoms that may be life threatening, ranging from localized itching to severe anaphylactic shock and death.
- (2) "Authorization to Obtain Epinephrine" means a certificate that contains the name, signature, and license number of the supervising professional authorizing the dispensing of epinephrine to the individual whose name appears on the certificate. Additionally, the certificate contains a record of the number of epinephrine orders filled to date.
- (3) "Statement of Completion" means a certificate that states the specific type of emergency the trainee was trained to respond to, the trainee's name and address, the name of the authorized trainer and the date that the training was completed.
- (4) "Trainee" means an individual who has attended and successfully completed the formal training pursuant to the protocols and criteria established by the Oregon Health Authority, Public Health Division.

STATUTORY/OTHER AUTHORITY: ORS 689.205, ORS 689.681

STATUTES/OTHER IMPLEMENTED: ORS 689.155, ORS 689.681

REPEAL: 855-041-2330

RULE TITLE: Naloxone

NOTICE FILED DATE: 10/30/2017

RULE SUMMARY: This Naloxone rule is repealed and removes the rules no longer required with the edits put forth in 2017 HB 3440.

RULE TEXT:

- (1) A Pharmacy may fill orders for unit-of-use naloxone to be used by trainees for opiate overdose emergencies. Individuals must successfully complete a training program approved by the Oregon Health Authority, Public Health Division. Upon successful completion, the trainee will receive the following certificates:
- (a) Statement of Completion; and
 - (b) Authorization to Obtain Naloxone.
- (2) Distribution of naloxone from a pharmacy to be used for opiate overdose emergencies may occur in the following ways:
- (a) A supervising professional may obtain a supply of naloxone for a program pursuant to a request by the supervising professional and a pharmacy sale by invoice. The pharmacy shall keep the invoice on record for three (3) years.
 - (b) A trainee may obtain naloxone upon presentation of the Statement of Completion and Authorization to Obtain Naloxone certificate to a pharmacy which:
 - (A) A pharmacist may generate a prescription for, and dispense up to two (2) unit-of-use doses of naloxone as specified by the supervising professional whose name, signature, and license number appear on the Authorization to Obtain Naloxone certificate.
 - (B) The pharmacist who generates the hardcopy prescription for naloxone in this manner shall reduce the prescription to writing and file the prescription in a manner appropriate for a non-controlled substance.
 - (C) Once the pharmacist generates the naloxone prescription, the pharmacist shall write in the appropriate space provided on the Authorization to Obtain Naloxone certificate the date and the number of doses dispensed, and return the certificate to the trainee.
- (3) The Statement of Completion and Authorization to Obtain Naloxone certificate may be used to obtain naloxone up to six (6) times within three (3) years from the date of the initial training.
- (a) Both the Statement of Completion and the Authorization to Obtain Naloxone certificate expire three (3) years from the date of the trainee's last Oregon Health Authority, Public Health Division approved naloxone training.
 - (b) Upon completion of the training, the trainee will receive a new Statement of Completion and Authorization to Obtain Naloxone, with a valid duration of three (3) years.
- (4) The naloxone container must be labeled with the following information:
- (a) A statement that the naloxone is intended for use in the Oregon Opiate Overdose Treatment program;
 - (b) Trainees name; and
 - (c) Trainer; or
 - (d) Supervising Professional.

STATUTORY/OTHER AUTHORITY: ORS 689.205, 2013 OL Ch. 340

STATUTES/OTHER IMPLEMENTED: ORS 689.155, 2013 OL Ch. 340

AMEND: 855-041-2340

RULE TITLE: Naloxone - Pharmacist Prescribing of Naloxone

NOTICE FILED DATE: 10/30/2017

RULE SUMMARY: The Naloxone rule amendments in Div 019 and Div 041 incorporate edits put forth in 2017 HB 3440. The new law removes all previous Oregon Health Authority (OHA) training mandates.

RULE TEXT:

The pharmacy 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; and
- (2) Documentation and recordkeeping.

STATUTORY/OTHER AUTHORITY: ORS 689.205

STATUTES/OTHER IMPLEMENTED: ORS 689.305, 689.681, 2016 OL Ch. 100, 2017 OL Ch. 683