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OFFICE OF THE LIEUTENANT GOVERNOR ALASKA

MEMORANDUM

TO:

Jun Maiquis

Department of Commerce, Community and Economic Development

FROM:

Scott Meriwether, Office of the Lieutenant Governor

465.4081

DATE:

October 27, 2016

RE:

Filed Permanent Regulations: Board of Pharmacy

Board of Pharmacy Regulation re: Standards for Independent Dispensing by a

Pharmacist of an Opioid Overdose Drug (12 AAC 52.994)

Attorney General File:

JU2016200754

Regulation Filed:

October 27, 2016

Effective Date:

November 26, 2016

Print:

220, January 2017

cc with enclosures:

Linda Miller, Department of Law

Micaela Fowler, Department of Commerce, Community & Economic

Development

Dianne Blumer, Administrative Regulation Review Committee

Judy Herndon, LexisNexis

ORDER CERTIFYING THE CHANGES TO REGULATIONS OF THE BOARD OF PHARMACY

The attached three pages of regulations, dealing with independent dispensing of opioid overdose drugs by pharmacists, are hereby certified to be a correct copy of the regulation changes that the Board of Pharmacy adopted at its October 7, 2016 teleconference meeting, under the authority of AS 08.80.030, AS 08.80.168, and AS 08.80.480 and after compliance with the Administrative Procedure Act (AS 44.62), specifically including notice under AS 44.62.190 and 44.62.200 and opportunity for public comment under AS 44.62.210.

This action is not expected to require an increased appropriation.

On the record, in considering public comments, the Board of Pharmacy paid special attention to the cost to private persons of the regulatory action being taken.

The regulation changes described in this order take effect on the 30th day after they have been filed by the lieutenant governor, as provided in AS 44.62.180.

DATE: 10/7/16
Fairbanks, Alaska

John Cotter, R.Ph., Chairman Board of Pharmacy

FILING CERTIFICATION

Byron Mallott, Lieutenant Governor

Effective: November 26, 2016

Register: 220, January 2017

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Chapter 52. Board of Pharmacy.

12 AAC 52 is amended by adding a new section to read:

12 AAC 52.994. Independent dispensing of opioid overdose drugs by pharmacists.

- (a) A pharmacist may independently dispense an opioid overdose drug approved for use as an opioid overdose drug by the United States Food and Drug Administration. Before a pharmacist independently dispenses an opioid overdose drug to a recipient, the pharmacist shall
- (1) in accordance with 12 AAC 52.340, complete a single training session that consists of one hour of continuing education specific to the use of an opioid overdose drug;
- (2) question the recipient to determine if there are any known contraindications to opioid overdose drug usage for the potential user; and
- (3) provide the recipient information about opioid overdose prevention, recognition, and response to opioid overdose drugs.
 - (b) A pharmacist may
 - (1) supply an opioid overdose drug as
 - (A) an intramuscular injection;
 - (B) an intranasal spray;
 - (C) an auto-injector; or
 - (D) any other product forms approved by the United States Food and Drug Administration; and
 - (2) recommend other optional items when appropriate, including
 - (A) alcohol pads;
 - (B) rescue breathing masks; or
 - (C) rubber gloves.

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- (c) When dispensing an opioid overdose drug
 - (1) the pharmacist shall
 - (A) label the drug in accordance with 12 AAC 52.480;
- (B) ensure that the label includes appropriate directions; the label may not consist of the sole direction "use as directed";
- (C) ensure that the label includes directions to call 911 or other available emergency services; and
- (D) document the drug as a prescription in the medication record of the recipient in accordance with 12 AAC 52.450; (m)
 - (2) the pharmacist may
- (A) in accordance with 12 AAC 52.585, provide the recipient with counseling and information on the drug furnished, including
 - (i) dosing;
 - (ii) administration;
 - (iii) effectiveness;
 - (iv) adverse effects;
 - (v) storage conditions;
 - (vi) shelf life; and
 - (vii) safety;
- (B) offer the recipient information or referrals to appropriate resources including information about addiction treatment, recovery services, or medication disposal resources, if the recipient indicates interest in that information.
- (d) Nothing in this section restricts the ability of a pharmacist to furnish an opioid overdose drug by means of an authorized practitioner prescription under 12 AAC 52.460 or

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12 AAC 52.490.

- (e) In this section,
 - (1) "opioid overdose drug"
 - (A) has the meaning given in AS 08.80.168;
 - (B) includes naloxone hydrochloride;
 - (2) "recipient" means the person to whom an opioid overdose drug is furnished.

(Eff. 11/26 Do16, Register 220)

Authority: AS 08.80.030

AS 08.80.168

AS 08.80.480