NOTICE OF PROPOSED CHANGES RELATING TO THE DISPENSING OF OPIOID OVERDOSE DRUGS BY A PHARMACIST IN THE REGULATIONS OF THE BOARD OF PHARMACY

BRIEF DESCRIPTION: The Board of Pharmacy proposes to establish standards for the independent dispensing by a pharmacist of an opioid overdose drug.

The Board of Pharmacy (Board) proposes to adopt regulation changes in Title 12, Chapter 52, of the Alaska Administrative Code, dealing with independent dispensing of opioid overdose drugs by pharmacists, including the following:

12 AAC 52.994, Independent dispensing of opioid overdose drugs by pharmacists, is a proposed new section that establishes standards for independent dispensing of opioid overdose drugs by a pharmacist.

You may comment on the proposed regulation changes, including the potential costs to private persons of complying with the proposed changes, by submitting written comments to Jun Maiquis, Regulations Specialist, Division of Corporations, Business and Professional Licensing, P.O. Box 110806, Juneau, AK 99811-0806. Additionally, the Board will accept comments by facsimile at (907) 465-2974 and by electronic mail at RegulationsAndPublicComment@alaska.gov. Comments may also be submitted through the Alaska Online Public Notice System by accessing this notice on the system at http://notice.alaska.gov/182656, and using the comment link. **The comments must be received not later than 5:00 p.m. on September 30, 2016.** Comments received after this deadline will not be considered by the Board.

You may submit written questions relevant to the proposed action to Jun Maiquis, Regulations Specialist, Division of Corporations, Business and Professional Licensing, P.O. Box 110806, Juneau, AK 99811-0806 or by e-mail at jun.maiquis@alaska.gov. **The questions must be received at least 10 days before the end of the public comment period.** The Board will aggregate its response to substantially similar questions and make the questions and responses available on the Board's website at https://www.commerce.alaska.gov/web/cbpl/ProfessionalLicensing/BoardofPharmacy.aspx or on the Alaska Online Public Notice System. The Board may, but is not required to, answer written questions received after the 10-day cut-off date and before the end of the comment period.

If you are a person with a disability who needs a special accommodation in order to participate in this process, please contact Jun Maiquis at (907) 465-2537 or jun.maiquis@alaska.gov not later than September 23, 2016 to ensure that any necessary accommodations can be provided.

A copy of the proposed regulation changes is available on the Alaska Online Public Notice System and by contacting Jun Maiquis at (907) 465-2537 or jun.maiquis@alaska.gov, or go to https://www.commerce.alaska.gov/web/portals/5/pub/PHA-0816.pdf.

After the public comment period ends, the Board will either adopt the proposed regulation changes or other provisions dealing with the same subject, without further notice, or decide to take no action. The language of the final regulation may be different from that of the proposed regulation. **You should comment during the time allowed if your interests could be affected.** Written comments and questions received are public records and are subject to public inspection.

Statutory Authority: AS 08.80.030; AS 08.80.168; AS 08.80.480
Statutes Being Implemented, Interpreted, or Made Specific: AS 08.80.030; AS 08.80.168; AS 08.80.480

Fiscal Information: The proposed regulation changes are not expected to require an increased appropriation.

DATE: 8/29/16

/s/
Jun Maiquis, Regulations Specialist
Division of Corporations, Business and
Professional Licensing

For each occupation regulated under the Division of Corporations, Business and Professional Licensing, the Division keeps a list of individuals or organizations who are interested in the regulations of that occupation. The Division automatically sends a Notice of Proposed Regulations to the parties on the appropriate list each time there is a proposed change in an occupation's regulations in Title 12 of the Alaska Administrative Code. If you would like your address added to or removed from such a list, send your request to the Division at the address above, giving your name, either your e-mail address or mailing address (as you prefer for receiving notices), and the occupational area in which you are interested.

ADDITIONAL REGULATION NOTICE INFORMATION
(AS 44.62.190(d))

1. **Adopting agency:** Board of Pharmacy – Department of Commerce, Community, and Economic Development, Division of Corporations, Business and Professional Licensing.

2. **General subject of regulation:** Independent dispensing of opioid overdose drugs by pharmacists.

3. **Citation of regulation:** 12 AAC 52.994.

4. **Department of Law file number:** To be assigned.

5. **Reason for the proposed action:** Compliance with new state statute.

6. **Appropriation/Allocation:** Corporations, Business and Professional Licensing – #2360.

7. **Estimated annual cost to comply with the proposed action to:**
   A private person: Single training session that consists of one hour of continuing education $25 to $50.
   Another state agency: None known.
   A municipality: None known.

8. **Cost of implementation to the state agency and available funding (in thousands of dollars):**
   No costs are expected in FY 2017 or in subsequent years.

9. **The name of the contact person for the regulation:**
   Jun Maiquis, Regulations Specialist
   Division of Corporations, Business and Professional Licensing
   Department of Commerce, Community, and Economic Development
   Telephone: (907) 465-2537
   E-mail: jun.maiquis@alaska.gov

10. **The origin of the proposed action:** Board of Pharmacy.

11. **Date:** 8/29/16 **Prepared by:** /s/
    Jun Maiquis, Regulations Specialist

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.

(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; and

(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

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. ___/___/____, Register ____)

Authority: AS 08.80.030 AS 08.80.168 AS 08.80.480