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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

I, Byron Mallott, Lieutenant Governor for the State of Alaska, certify that on October 27, 2016 at 105p .m., I filed the attached regulations according to the provisions of AS 44.62.040 – 44.62.120.



Byron Mallott, Lieutenant Governor

Effective: November 26, 2016

Register: 220, January 2017

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. 11/26/2016, Register 220)

Authority: AS 08.80.030 AS 08.80.168 AS 08.80.480

MEMORANDUM

State of Alaska Department of Law

To: The Honorable Byron Mallott
Lieutenant Governor

Date: October 24, 2016

File No.: JU2016200754

Tel. No.: 465-3600

From: Susan R. Pollard *SPP*
Chief Assistant Attorney General
and Regulations Attorney
Legislation and Regulations Section

Re: Board of Pharmacy Regulation re: 12
AAC 52.994; Board of Pharmacy:
Standards for Independent
Dispensing by a Pharmacist of an
Opioid Overdose Drug

We have reviewed the attached Board of Pharmacy regulations to implement AS 08.80.168 and 08.80.480 relating to the independent dispensing of opioid overdose drugs by a pharmacist. The regulations provide the standards established by the board under AS 08.80.168.

The Department of Law has reviewed the attached regulations against the statutory standards of the Administrative Procedure Act. Based upon our review, we find no legal problems. This memorandum constitutes the written statement of approval under AS 44.62.060(b) and (c) that authorizes your office to file the attached regulations.

The regulations were adopted by the Board of Pharmacy on October 7, 2016 after the close of the public comment period. The August 30, 2016 public notice and the October 7, 2016 certification order both state that this action is not expected to require an increased appropriation. Therefore, a fiscal note under AS 44.62.195 is not required.

We have made minor technical corrections to conform the regulations in accordance with AS 44.62.125. The corrections are shown on the attached copy of the regulations.

SRP:srp

Cc /encl: (via email)

John Cotter, R. Ph., Chair
Board of Pharmacy (via email through Jun Maiquis)

Micaela Fowler, Regulations Contact
Department of Commerce, Community, and Economic Development

Janey Hovenden, Director
Division of Corporation, Business, and Professional Licensing
Department of Commerce, Community, and Economic Development

Sara Chambers, Operations Manager
Division of Corporation, Business, and Professional Licensing
Department of Commerce, Community, and Economic Development

Jun Maiquis, Regulations Specialist
Division of Corporation, Business, and Professional Licensing
Department of Commerce, Community, and Economic Development

Harriet D. Milks, Assistant Attorney General
Commercial and Fair Business Section

**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



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:** 
Jun Maiquis, Regulations Specialist

STATE OF ALASKA)
FIRST JUDICIAL DISTRICT) ss.

**AFFIDAVIT OF NOTICE OF PROPOSED ADOPTION OF REGULATIONS
AND FURNISHING OF ADDITIONAL INFORMATION**

I, Jun Maiquis, Regulations Specialist, of the Department of Commerce, Community, and Economic Development, Division of Corporations, Business and Professional Licensing, being sworn, state the following:

As required by AS 44.62.190, notice of the proposed adoption of changes to 12 AAC 52.994, dealing with independent dispensing of opioid overdose drugs by pharmacists, has been given by being:

1. published in a newspaper or trade publication;
2. furnished to interested persons;
3. furnished to appropriate state officials;
4. furnished to the Department of Law, along with a copy of the proposed regulations;
5. electronically transmitted to incumbent State of Alaska legislators;
6. furnished to the Legislative Affairs Agency, Legislative Legal and Research Services;
7. posted on the Alaska Online Public Notice System as required by AS 44.62.175(a)(1) and (b) and 44.62.190(a)(1);
8. furnished electronically, along with a copy of the proposed regulations, to the Legislative Affairs Agency, the chair of the Labor and Commerce Committee of the Alaska Senate and House of Representatives, the Administrative Regulation Review Committee, and the legislative council.

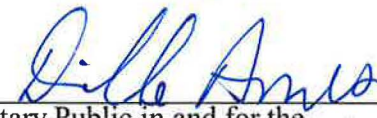
As required by AS 44.62.190(d), additional regulations notice information regarding the proposed adoption of the regulation changes described above has been furnished to interested persons and those in (5) and (6) of the list above. The additional regulations notice information also has been posted on the Alaska Online Public Notice System.

DATE: 10/11/16
Juneau, Alaska


Jun Maiquis, Regulations Specialist

SUBSCRIBED AND SWORN TO before me this 11th day of October, 2016.




Notary Public in and for the
State of Alaska
My commission expires: 11/1/17

STATE OF ALASKA

FIRST JUDICIAL DISTRICT

SS.

AFFIDAVIT OF AGENCY RECORD OF PUBLIC COMMENT

I, Jun Maiquis, Regulations Specialist for the Department of Commerce, Community, and Economic Development, Division of Corporations, Business and Professional Licensing, being duly sworn, state the following:

In compliance with AS 44.62.215, the Board of Pharmacy has kept a record of its use or rejection of factual or other substantive information that was submitted in writing as public comment and that was relevant to the accuracy, coverage, or other aspect of the Board of Pharmacy regulations on dealing with independent dispensing of opioid overdose drugs by pharmacists.

DATE: 10/11/16
Juneau, Alaska


Jun Maiquis, Regulations Specialist

SUBSCRIBED AND SWORN TO before me this 11th day of October, 2016.



Dale Ames
Notary Public in and for the
State of Alaska
My commission expires: *4/1/2016*

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RECEIVED
Juneau
SEP 06 2016

CBPL

AFFIDAVIT OF PUBLICATION

STATE OF ALASKA
THIRD JUDICIAL DISTRICT

Emma Dunlap
being first duly sworn on oath deposes and
says that he/she is a representative of the
Alaska Dispatch News, a daily newspaper.
That said newspaper has been approved
by the Third Judicial Court, Anchorage,
Alaska, and it now and has been published
in the English language continually as a
daily newspaper in Anchorage, Alaska, and
it is now and during all said time was
printed in an office maintained at the
aforesaid place of publication of said
newspaper. That the annexed is a copy of
an advertisement as it was published in
regular issues (and not in supplemental
form) of said newspaper on

August 30, 2016

and that such newspaper was regularly
distributed to its subscribers during all of
said period. That the full amount of the fee
charged for the foregoing publication is not
in excess of the rate charged private
individuals.

Signed



Subscribed and sworn to before me
this 30th day of August, 2016



Notary Public in and for
The State of Alaska.
Third Division
Anchorage, Alaska
MY COMMISSION EXPIRES

2/23/2019
Notary Public
BRITNEY L. THOMPSON
State of Alaska
My Commission Expires Feb 23, 2019

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

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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

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Published: August 30, 2016

STATE OF ALASKA

FIRST JUDICIAL DISTRICT

$$\left. \begin{array}{l}) \\) \\) \end{array} \right\} \text{SS.}$$

AFFIDAVIT OF BOARD ACTION

I, Donna Bellino, Licensing Examiner for the Board of Pharmacy, being duly sworn, state the following:


The attached motion dealing with independent dispensing of opioid overdose drugs by pharmacists was passed by the Board of Pharmacy during its October 7, 2016 teleconference meeting.

Date: 10/10/16
Juneau, Alaska

Donna Bellino
Donna Bellino, Licensing Examiner

SUBSCRIBED AND SWORN TO before me this 10 day of October, 2016.




Notary Public in and for the
State of Alaska
My commission expires: with office

On a motion duly made by Taryl Giessel, seconded by Rich Holt, and approved unanimously, it was

RESOLVED to accept the agenda as written.

Agenda Item 3 Ethics

The Board had no ethics disclosures.

Agenda Item 4 - Review written comments received regarding: 12 AAC 52.994 Independent dispensing of opioid overdose drugs by pharmacists

The Board of Pharmacy reviewed and discussed the written public comments received from the 30 day public comment period that closed on September 30th, 2016. After review of the comments received Board of Pharmacy did not make any changes to the draft regulation and voted to approve the regulation as is.

On a motion duly made by Taryl Giessel, seconded by Anne Gruening and approved unanimously, it was

RESOLVED to adopt regulation 12 AAC 52.994 Independent dispensing of opioid overdose drugs by pharmacists as approved for public notice, and without changes.

Agenda Item 5 – Other Board of Pharmacy Business

The Board of Pharmacy reviewed and discussed other board business and the following is a recap of the Board's discussion:

1) November 17-18, 2016 Board of Pharmacy meeting –

The Board continued their discussion from the August Board meeting on how to proceed with remaining Board meetings. Due to travel restrictions, the BOP can only meet in person two times per fiscal year. The Board provided Ms. Bellino with some meeting suggestions at August meeting that Ms. Bellino researched. Ms. Bellino had advised the Board that the previously suggested monthly Board meetings could not be achieved as it would create conflict with current processing work flow.

In lieu of holding a day and half teleconference in November the Board opted to hold two half day teleconferences. The Board will meet via teleconference on Thursday November 17th, 2016 from 9:00 am until noon, and will reconvene on Friday November 18th, 2016 from 9:00 am until noon. The Board also requested that Ms. Bellino research to see if utilizing WebEx would be possible for the November meeting.

2) CSAC(Controlled Substance Advisory Committee) Meeting –

This meeting requires that a member from the Board of Pharmacy participate. Previously, Mr. CJ Kim was the Board representative and he is no longer on the Board. A new representative was chosen, and Ms. Lana Bell, RPh will attend when the next meeting is scheduled. Mr. Kim will