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OFFICE OF THE LIEUTENANT GOVERNOR
ALASKA

MEMORANDUM

TO: Sara Chambers, Department of Commerce, Community and Economic Development

FROM: April Simpson, Office of the Lieutenant Governor
465.4081

DATE: August 29, 2024

RE: Filed Permanent Regulations: Board of Pharmacy

Board of Pharmacy regulations re: Certification, collaborative practice, guidelines, PDMP registration (12 AAC 52.235 - .995)

Attorney General File:	2024200135
Regulation Filed:	8/29/2024
Effective Date:	9/28/2024
Print:	251, October 2024

cc with enclosures: Colleen Bailey, Department of Law
Judy Herndon, LexisNexis
Sylvan Robb, Division Director
Stefanie Davis, Regulations Specialist

THE STATE
of ALASKA
GOVERNOR MIKE DUNLEAVY

Department of Law

CIVIL DIVISION

P.O. Box 110300
Juneau, Alaska 99811
Main: 907.465.3600
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August 27, 2024

The Honorable Nancy Dahlstrom
Lieutenant Governor
State of Alaska
P.O. Box 110015
Juneau, AK 99811-0015

Re: *12 AAC 52.235 - .995: Board of Pharmacy - Certification, collaborative practice, guidelines, PDMP registration*
Our file: 2024200135

Dear Lieutenant Governor Dahlstrom:

The Department of Law has reviewed the attached regulations of the Board of Pharmacy against the statutory standards of the Administrative Procedure Act. Based upon our review, we find no legal problems. This letter 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 after the close of the public comment period.

The regulations concern pharmacy technicians, collaborative practice authorities, sterile pharmaceutical guidelines, manufacturer license requirements, registration with the prescription drug monitoring program (PDMP) under AS 17.30.200 (controlled substance prescription database), establishment of an alternative to probation program, and definitions.

The June 6, 2024 public notice and the August 23, 2024 certification of adoption order both state that this action is not expected to require an increased appropriation. Therefore, a fiscal note under AS 44.62.060 is not required.

No technical corrections were necessary to conform the regulations in accordance with AS 44.62.060.

Sincerely,

TREG TAYLOR
ATTORNEY GENERAL

By: Rebecca C. Polizzotto
Digitally signed by Rebecca C. Polizzotto
Date: 2024.08.27 13:25:31 -08'00'

Rebecca C. Polizzotto
Chief Assistant Attorney General
Legislation, Regulations, and
Legislative Research Section

RCP/scw

CC w/enclosure: Stefanie Davis, Regulations Specialist 2
Department of Commerce, Community and Economic Development

Harriet D. Milks, Assistant Attorney General
Department of Law

Steven C. Weaver, Assistant Attorney General
Department of Law

ORDER CERTIFYING THE CHANGES TO
REGULATIONS OF THE BOARD OF PHARMACY

The attached eight pages of regulations, dealing with pharmacy technicians, collaborative practice authorities, sterile pharmaceutical guidelines, manufacturer license requirements, PDMP registration, alternative to probation program, and definitions, are certified to be a correct copy of the regulation changes that the Board of Pharmacy adopted at its August 20, 2024 meeting, under the authority of AS 08.01.075, AS 08.80.005, AS 08.80.030, AS 08.80.157, AS 08.80.159, AS 08.80.168, AS 08.80.261, AS 08.80.480, AS 11.71.900, AS 17.30.200, and AS 17.30.900, 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: August 23, 2024

Michael Bowles Digitally signed by Michael Bowles Date: 2024.08.23 07:57:47 -08'00'

Michael Bowles, Executive Administrator
Alaska Board of Pharmacy

FILING CERTIFICATION

April Simpson for

I, Nancy Dahlstrom, Lieutenant Governor for the State of Alaska, certify that on August 29, 2024 at 2:57 p.m., I filed the attached regulations according to the provisions of AS 44.62.040 - 44.62.120.

for Nancy Dahlstrom, Lieutenant Governor

Effective: September 28, 2024.

Register: 251, October 2024.

FOR DELEGATION OF THE LIEUTENANT GOVERNOR'S AUTHORITY

I, NANCY DAHLSTROM, LIEUTENANT GOVERNOR OF THE STATE OF ALASKA, designate the following state employees to perform the Administrative Procedures Act filing functions of the Office of the Lieutenant Governor:

April Simpson, Regulations and Initiatives Specialist

IN TESTIMONY WHEREOF, I have signed and affixed the Seal of the State of Alaska, in Juneau, on May 15th, 2023.

NANCY DAHLSTROM
LIEUTENANT GOVERNOR

12 AAC 52.235(a)(1)(C) is amended to read:

(C) the pharmacy uses software that displays the image or graphical description of the correct drug being verified**, or the institutional facility uses software that performs and verifies a barcode scan before administration** [; HOWEVER, IF THERE IS ANY DEVIATION BETWEEN THE IMAGE OR GRAPHICAL DESCRIPTION AND THE ACTUAL PRODUCT BEING DISTRIBUTED, A PHARMACIST MUST REVIEW AND DISPENSE THE ORDER]; and

(Eff. 4/3/2020, Register 234; am 8/30/2020, Register 235; am 5/19/2023, Register 246; am 9/28/2024, Register 251)

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.168

12 AAC 52.240(a) is amended to read:

(a) A pharmacist planning to exercise collaborative practice authority in the pharmacist's practice by initiating or modifying drug therapy, in accordance with a written protocol established and approved for the pharmacist's practice by a practitioner authorized to prescribe drugs under AS 08, must submit the completed written protocol to the board [AND BE APPROVED BY THE BOARD BEFORE IMPLEMENTATION].

12 AAC 52.240(d) is repealed:

(d) Repealed 9/28/2024 [UNLESS THE BOARD IS SATISFIED THAT THE PHARMACIST HAS BEEN ADEQUATELY TRAINED IN THE PROCEDURES OUTLINED IN THE WRITTEN PROTOCOL, THE BOARD WILL SPECIFY AND REQUIRE COMPLETION OF ADDITIONAL TRAINING THAT COVERS THOSE PROCEDURES BEFORE ISSUING APPROVAL OF THE PROTOCOL].

12 AAC 52.240(f) is amended to read:

(f) **An authorizing practitioner or a pharmacist may terminate the** [THE] written protocol [MAY BE TERMINATED] upon written notice [BY THE AUTHORIZING PRACTITIONERS OR PHARMACISTS]. The **pharmacist** [PHARMACISTS] shall notify the board in writing **not more than** [WITHIN] 30 days after a written protocol is terminated.

12 AAC 52.240(g) is amended to read:

(g) Any modification to the written protocol must be **submitted to** [APPROVED BY] the board as required by this section for a new written protocol.

12 AAC 52.240(i) is amended to read:

(i) A signed copy of the [APPROVED COLLABORATIVE PRACTICE APPLICATION AND] protocols must remain at the pharmacy location at all times. (Eff. 11/10/2001, Register 160; am 2/11/2004, Register 169; am 11/16/2012, Register 204; am 10/13/2019, Register 232; am 1/19/2024, Register 249; am 9/28/2024, Register 251)

Authority: AS 08.80.030 AS 08.80.480

12 AAC 52.430 is amended to read:

12 AAC 52.430. Standard of care [GUIDELINES] relating to preparation or dispensing of sterile pharmaceuticals. A pharmacy or pharmacist that prepares or dispenses sterile pharmaceuticals shall adhere to the **accepted standard of care** [GUIDELINES ESTABLISHED BY THE BOARD IN THE PAMPHLET TITLED *"STERILE PHARMACEUTICALS,"* DATED FEBRUARY 2008, AND INCORPORATED BY REFERENCE IN THIS SECTION]. (Eff. 1/16/98, Register 145; am 10/9/2008, Register 188;

am 9/28/2024, Register 251)

Authority: AS 08.80.030 AS 08.80.157

[**EDITOR'S NOTE:** THE PAMPHLET INCORPORATED BY REFERENCE IN 12 AAC 52.430, *"STERILE PHARMACEUTICALS"* MAY BE OBTAINED FROM THE DEPARTMENT OF COMMERCE, COMMUNITY, AND ECONOMIC DEVELOPMENT, DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING, BOARD OF PHARMACY, STATE OFFICE BUILDING, 9TH FLOOR, 333 WILLOUGHBY AVENUE, JUNEAU, ALASKA, 99801; PHONE (907) 465-2589.]

12 AAC 52.698(b) is amended to read:

(b) A manufacturer license will be issued to an applicant who

(1) submits a complete application on a form provided by the department;

(2) pays the applicable fees **set out under** [REQUIRED IN] 12 AAC 02.310;

(3) provides the name of the designated representative who will manage the manufacture of drugs or devices for the wholesale drug facility;

(4) submits an attestation that

(A) a self-inspection of the premises using the form provided by the department was completed within the last two years; or

(B) an inspection of the premises by a third party was completed within the last two years; [AND]

(5) submits an attestation that the applicant holds a license as a manufacturer in another jurisdiction and that the license is in good standing, if applicable**; and**

(6) submits the results of the applicant's most recent Good Manufacturing Practice (GMP) inspection by the United States Food and Drug Administration.

(Eff. 7/15/2023, Register 247; am 9/28/2024, Register 251)

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030

12 AAC 52.855(b) is amended to read:

(b) A licensed pharmacist **who dispenses** [PRACTICING IN THIS STATE SHALL REGISTER WITH THE PDMP. REGISTRATION MUST BE COMPLETED NOT LATER THAN 30 DAYS AFTER INITIAL LICENSURE IF THE PHARMACIST'S PRACTICE IS EXPECTED TO INVOLVE DISPENSING] a schedule II, III, or IV controlled substance [UNDER FEDERAL LAW. A PHARMACIST WHO WAS NOT DISPENSING A SCHEDULE II, III, OR IV CONTROLLED SUBSTANCE UNDER FEDERAL LAW AT THE TIME OF INITIAL LICENSURE BUT PLANS TO BEGIN DISPENSING A SCHEDULE II, III, OR IV CONTROLLED SUBSTANCE UNDER FEDERAL LAW SHALL REGISTER WITH THE PDMP BEFORE DISPENSING A SCHEDULE II, III, OR IV CONTROLLED SUBSTANCE UNDER FEDERAL LAW] in this state **shall register with the PDMP not more than 30 days after the pharmacist dispenses that substance for the first time**.

The introductory language of 12 AAC 52.855(c) is amended to read:

(c) Except as provided in (a) of this section, before dispensing, prescribing, or administering a schedule II, III, or IV controlled substance under federal law, a pharmacist or practitioner required to register with the PDMP **shall** [MUST]

...

12 AAC 52.855(e) is amended to read:

(e) A pharmacist or practitioner required to register with the PDMP **shall** [MUST] access information in the PDMP database using the credentials identified in (c)(1)(A) and (B) of this section.

(Eff. 12/29/2011, Register 200; am 6/7/2018, Register 226; am 5/6/2021, Register 238; am 3/17/2022; Register 241; am 7/15/2023, Register 247; am 9/28/2024, Register 251)

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

The introductory language of 12 AAC 52.930 is amended to read:

12 AAC 52.930. Terms of probation. The board **may** [WILL, IN ITS DISCRETION,] subject a licensee who is placed on probation to one or more of the following terms of probation, and to other relevant terms of probation, including those in 12 AAC 52.940 - 12 AAC 52.960:

...

(Eff. 1/16/98, Register 145; am 9/28/2024, Register 251)

The introductory language of 12 AAC 52.940(a) is amended to read:

(a) In addition to one or more of the terms of probation set out in 12 AAC 52.930, **the board may subject** a licensee placed on probation for the habitual use of alcohol or illegal use of controlled substances [MAY ALSO BE SUBJECT] to one or more of the following:

...

12 AAC 52.940(a)(3) is amended to read:

(3) **abstention** [ABSTAINING] from the personal use of alcohol or controlled substances in any form, except when lawfully prescribed by a practitioner licensed to practice in

the state [ALASKA];

12 AAC 52.940(b) is amended to read:

(b) **The board may restrict a licensee's access** [ACCESS] to a controlled substance in the work setting [WILL, IN THE BOARD'S DISCRETION, BE RESTRICTED].

12 AAC 52.940 is amended by adding a new subsection to read:

(c) The board may offer a licensee subject to this section an opportunity to participate in an alternative to probation program. A licensee that participates in an alternative to probation program shall meet the probation terms required by the board under the alternative to probation program. The board will keep a licensee's participation in an alternative to probation program confidential, except as required by law. (Eff. 1/16/98, Register 145; am 9/28/2024, Register 251)

Authority: AS 08.01.075 AS 08.80.030 AS 08.80.261
AS 08.80.005

12 AAC 52.995(a) is amended by adding new paragraphs to read:

(46) "owner", within the meaning given in AS 08.80.480, includes a person or entity who is the legal operator of a licensed pharmacy or facility and is assigned a unique federal employer identification number (EIN) for the transaction of business;

(47) "change of ownership"

(A) means a change in the federal employer identification number (EIN) at the parent level, or any transfer of a beneficial interest in a business entity licensed or registered by the board to any person or entity in which the transfer results in the

transferee's holding 50 percent or more of the beneficial interest in that license or registration; a person or entity that engages in a change of ownership includes

(i) an individual who sells a pharmacy or facility;

(ii) an individual who enters into a partnership with others;

(iii) an individual who becomes incorporated;

(iv) a partnership who sells a pharmacy or facility;

(v) a partnership whose membership changes and dissolves;

(vi) a partnership who becomes incorporated;

(vii) a corporation that sells or disposes all assets;

(viii) a corporation that changes from a limited liability corporation to a corporation; or

(ix) a corporation that merges into or consolidates with another corporation;

(B) does not include

(i) an individual incorporating only the individual incorporates only the individual, without other shareholders;

(ii) an individual or entity that engages in a stock change of 20 percent or less; or

(iii) a managing officer who transfers from or leaves the job position, and the change in managing officers does not result in a change described in (A) of this paragraph.

12 AAC 52.995(c)(3) is amended to read:

(3) ordering and evaluating the results of laboratory tests relating to drug therapy,

including blood chemistries and cell counts, drug levels in blood, urine, tissue, or other body fluids, and culture and sensitivity tests that are performed in accordance with a written protocol [APPROVED] under 12 AAC 52.240.

(Eff. 1/16/98, Register 145; am 5/5/2000, Register 154; am 11/10/2001, Register 160; am 8/21/2002, Register 163; am 2/15/2006, Register 177; am 8/12/2007, Register 183; am 9/11/2010, Register 195; am 12/29/2011, Register 200; am 8/1/2014, Register 211; am 6/7/2018, Register 226; am 10/31/2019, Register 232; am 4/3/2020, Register 234; am 8/30/2020, Register 235; am 7/15/2023, Register 247; am 1/19/2024, Register 249; am 5/19/2024, Register 250; am 9/28/2024, Register 251)

Authority: AS 08.80.005 AS 08.80.159 AS 17.30.200
AS 08.80.030 AS 11.71.900 AS 17.30.900
AS 08.80.157

(((Publisher: please replace the period that follows 12 AAC 52.995(a)(45) with a semicolon.)))