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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: December 20, 2023

RE: Filed Permanent Regulations: Board of Pharmacy

Board of Pharmacy regulations re: License Updates per HB 112 (12 AAC 52.010 -

52.995)

Attorney General File: 2023200336

Regulation Filed: 12/20/2023

Effective Date: 1/19/2024

Print: 249, April 2024

cc with enclosures: Colleen Bailey, Department of Law

Judy Herndon, LexisNexis Sylvan Robb, Division Director

Alison Osborne, Regulations Specialist Stefanie Davis, Regulations Specialist

Department of Law



CIVIL DIVISION

P.O. Box 110300 Juneau, Alaska 99811 Main: 907.465.3600 Fax: 907.465.2520

December 15, 2023

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

Re: 12 AAC 52.010 - 52.995: Board of Pharmacy License Updates per HB 112

Our file: 2023200336

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.

Reflecting the enactment of ch. 155, SLA 23 ((CSHB 112(L&C) am) and related changes to AS 08.80, the regulations streamline good moral character requirements, establish a retired status pharmacist license, make other conforming changes to 12 AAC 52, and ensure pharmacies are reporting all controlled substances that are dispensed by a pharmacist to include those prescribed by a veterinarian and dispensed through the pharmacist, but not regulating the prescribing and dispensing of controlled substances by a veterinarian.

The October 17, 2023, public notice and the December 8, 2023, 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.

So that these regulations become effective as close as possible to the November 26, 2023, effective date of the related legislation, we respectfully request that these regulations be filed as soon as possible and ideally on the same day as the related fee regulations (Department of Law file number 2023200337).

We have made some technical corrections to conform the regulations in accordance with AS 44.62.060. The corrections are incorporated into the attached copy of the regulations.

Sincerely,

TREG TAYLOR ATTORNEY GENERAL

Rebecca C. Polizzotto

Digitally signed by Rebecca C. Polizzotto Date: 2023.12.15 10:24:56 -09'00'

By:

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

RCP/SCW

CC w/enclosure: Stefanie Davis, Regulations Specialist

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 twenty-four pages of regulations, dealing with adding a retired status pharmacist license and implementing additional statutory changes to AS 08.80 under Chapter 15, SLA 2023 (HB 112), are certified to be a correct copy of the regulation changes that the Board of Pharmacy adopted at its December 7, 2023 meeting, under the authority of AS 08.01.075, AS 08.01.100, AS 08.80.005, AS 08.80.030, AS 08.80.110, AS 08.80.116, AS 08.80.147, AS 08.80.157, AS 08.80.159, AS 08.80.160, AS 08.80.165, AS 08.80.168, AS 08.80.261, AS 08.80.270, AS 08.80.315, AS 08.80.330, AS 08.80.460, 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: December 08, 2023

Michael Bowles Digitally signed by Michael Bowles Date: 2023.12.08 07:53:09 -09'00'

Michael Bowles, Executive Administrator Alaska Board of Pharmacy

April SI	impson 4	0	FILING CERTIFICATION t Governor for the State of Alaska, certify that					
I, Nancy I	Dahlstrom, l	Lieutenan	Governor	for the S	state of Ala	ska, certi	ify that	or
	7.50	_	172	1202				

December 20, 2023 at 9:17 a.m., I filed the attached regulations

according to the provisions of AS 44.62.040 - 44.62.120.

For Nancy Dahlstrom, Lieutenant Governor

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.

OF THE STATE OF ALASKA

NANCY DAHLSTROM LIEUTENANT GOVERNOR

12 AAC 52.010 is repealed:

12 AAC 52.010. Classifications of licensure. Repealed. (Eff. 1/16/98, Register 145; am 2/26/2000, Register 153; am 2/15/2006, Register 177; am 10/31/2019, Register 232; am 7/15/2023, Register 247; repealed 1 / 19/2024, Register 249)

12 AAC 52.020(b)(1) is amended to read:

(1) a complete [,] notarized application on a form provided by the department **that**includes

- (A) the ownership name and Alaska corporate entity number;
- (B) the pharmacy's "doing business as" name, if applicable;
- (C) the physical location of the facility;
- (D) a mailing address and telephone number;
- (E) the names of all partners or corporate officers;
- (F) the name, active Alaska license number, and contact information for the pharmacist-in-charge;
- (G) the names and active pharmacist license numbers in the current jurisdiction of all pharmacists employed by the pharmacy; and
 - (H) completion of the professional fitness section of the application;

12 AAC 52.020(b) is amended by adding a new paragraph to read:

- (5) for a pharmacy that is located outside of the state,
- (A) a copy of the active pharmacy license in good standing from the jurisdiction where the pharmacy is physically located; and

(B) an attestation that an inspection of the premises by a third party was completed within the last two years.

(((Publisher: Please change the period at the end of 12 AAC 52.020(b)(4) to a semicolon.)))

12 AAC 52.020(c) is repealed:

12 AAC 52.020(d) is amended to read:

(d) An application for a pharmacy license must include the name and specific location of each remote pharmacy that will be under that pharmacy's control, if applicable.

12 AAC 52.020(e) is repealed:

12 AAC 52.020(f) is amended to read:

(f) A pharmacy that has changed its name, ownership, or physical address shall notify the board in writing not later than 30 days after the change. A notification of a change of physical address must include an attestation that a new self-inspection will be completed not later than 30 days after the start of business in the new location.

12 AAC 52.020(g) is repealed:

12 AAC 52.020 is amended by adding new subsections to read:

- (h) An Internet-based pharmacy providing services within the meaning of the "practice of pharmacy" under AS 08.80.480 to residents in this state must obtain a license under this section.
- (i) To convert an existing out-of-state pharmacy registration previously registered under AS 08.80.158, as that statute existed on November 25, 2023, and 12 AAC 52.130 to an out-of-state pharmacy license under AS 08.80.030 and this section, the pharmacy shall submit an out-of-state pharmacy renewal application meeting the requirements of 12 AAC 52.300. (Eff. 1/16/98, Register 145; am 2/26/2000, Register 153; am 2/11/2004, Register 169; am 2/15/2006, Register 177; am 1/17/2007, Register 181; am 12/28/2022, Register 244; am 7/15/2023, Register 247; am 1/19/2024, Register 249)

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.270

AS 08.80.030 **AS 08.80.159** AS 08.80.330

[EDITOR'S NOTE: AS OF REGISTER 245 (APRIL 2023), THE REGULATIONS
ATTORNEY MADE TECHNICAL CORRECTIONS UNDER AS 44.62.125(b) TO 12 AAC
52.020(c).]

12 AAC 52.070(b)(3) is repealed:

(3) repealed 1 / 19 / 2024;

(Eff. 1/16/98, Register 145; am 2/15/2006, Register 177; am 7/1/2007, Register 182; am 10/31/2019, Register 232; am 12/28/2022, Register 244; am 1 / 19 / 2024, Register 249)

Authority: AS 08.80.005 AS 08.80.110 AS 08.80.270

AS 08.80.030 AS 08.80.116

12 AAC 52.075 is repealed:

12 AAC 52.075. Good moral character. Repealed. (Eff. 1/16/98, Register 145; am 1/17/2007, Register 181; repealed 1 / 19 / 2024, Register 249)

12 AAC 52.095(a) is amended to read:

12 AAC 52.095. Application for pharmacist license by reciprocity. (a) An applicant for a pharmacist license by reciprocity shall submit the items required in this section for review and approval by the executive administrator. An application that does not clearly demonstrate qualifications for licensure must be reviewed and approved by the board. An applicant for a pharmacist license shall submit

- (1) a complete [,] notarized application on a form provided by the department;
- (2) the applicable fees established in 12 AAC 02.310;
- (3) [TWO AFFIDAVITS FROM REPUTABLE CITIZENS WHO HAVE KNOWN THE APPLICANT FOR AT LEAST ONE YEAR ATTESTING TO THE APPLICANT'S GOOD MORAL CHARACTER;
- (4)] an application for license transfer through the National Association of Boards of Pharmacy; the license by which the applicant is seeking reciprocity from must be current, unencumbered, and in good standing; and

(4) verification that the applicant has engaged in the practice of pharmacy for at least one year immediately before applying for a license.

12 AAC 52.095(b) is amended to read:

(b) An applicant for licensure under this section who has not taken the Multistate

Pharmacy Jurisprudence Examination (MPJE) required under 12 AAC 52.090 is approved to sit for that examination if the applicant has submitted the documents required under (a)(1) - (4) [(a)(1)- (4)] of this section.

(Eff. 7/1/2007, Register 182; am 10/31/2019, Register 232; am 12/28/2022, Register 244; am

1 / 19 / 1004, Register 249)

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.145

12 AAC 52.120(f) is amended to read:

(f) <u>The board will not renew a</u> [A] pharmacist intern license [MAY NOT BE RENEWED]. An applicant who wishes to continue an internship in <u>the</u> [THIS] state after the license has expired must <u>apply</u> [REAPPLY] for a new pharmacist intern license in accordance with this section.

(Eff. 1/16/98, Register 145; am 2/11/2004, Register 169; am 2/15/2006, Register 177; am 1/17/2007, Register 181; am 11/16/2012, Register 204; am 7/9/2017, Register 223; am 6/29/2018, Register 226; am 10/31/2019, Register 232; am 12/28/2022, Register 244; am 7/15/2023, Register 247; am 1/19/2024, Register 249)

Authority: AS 08.80.005 AS 08.80.110 AS 08.80.116
AS 08.80.030

Editor's note: As of Register 245 (April 2023), the regulations attorney made technical corrections under AS 44.62.125(b) to 12 AAC 52.120(b)(1) and (2) (now 12 AAC 52.120(a)(1) and (2)).

12 AAC 52.130 is repealed:

12 AAC 52.130. Registration of pharmacies located outside of the state. Repealed. (Eff. 1/16/98, Register 145; am 6/2/2004, Register 170; am 2/15/2006, Register 177; am 6/29/2018, Register 226; am 12/28/2022, Register 244; repealed 1 / 10 / 2024, Register 249)

12 AAC 52.140(b) is amended to read:

- (b) A pharmacy technician license will be issued to an applicant who
 - (1) submits a completed form for application, including
 - (A) the applicant's name, mailing address, and telephone number; and
- (B) the applicant's date of birth that shows the applicant is at least 18 years of age, or at least 16 years of age and enrolled in a supervised high school, college, or apprenticeship pharmacy technician training program [OLD];
- (2) certifies that the applicant has not been convicted of a felony or another crime that affects the applicant's ability to perform the duties of a pharmacy technician safely and competently;
- (3) certifies that the applicant has earned a high school diploma or its equivalent and provides the name of the issuing institution and the date the diploma or its equivalent was issued, or is enrolled in a supervised high school, college, or apprenticeship pharmacy technician training program;
- (4) certifies that the applicant is fluent in the reading, writing, and speaking of the English language; and
 - (5) pays the applicable fees established in 12 AAC 02.310.

(Eff. 1/16/98, Register 145; am 2/15/2006, Register 177; am 1/17/2007, Register 181; am 7/7/2022, Register 243; am 12/28/2022, Register 244; am 1/19/2024, Register 249)

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52.200 is repealed and readopted to read:

- 12 AAC 52.200. Pharmacist-in-charge. (a) The responsibilities of the pharmacist-in-charge include
- (1) obtaining an Alaska pharmacist license before the facility's licensure in the state;
- (2) compliance with all laws and regulations governing the activities of the pharmacy;
 - (3) training of all pharmacy personnel;
- (4) ensuring adequate policies and procedures are in place for pharmacy operations;
 - (5) maintaining required records;
 - (6) storage of all materials, including drugs and chemicals;
 - (7) ensuring effective controls against theft or diversion of prescription drugs; and
- (8) maintaining an active pharmacist license in the jurisdiction where the facility is physically located.
- (b) A pharmacist designated to replace the pharmacist-in-charge of a licensed pharmacy shall notify the board not later than 30 days after that designation. A pharmacist who is not already licensed in the state shall apply for a pharmacist license not later than 30 days after the designation to replace the pharmacist-in-charge.

- (c) Notwithstanding 12 AAC 52.425(a), a pharmacist may not serve as a pharmacist-incharge unless the pharmacist is physically present in the pharmacy for a sufficient amount of time to provide supervision and control.
- (d) A pharmacist may not serve as pharmacist-in-charge for more than one pharmacy at any one time except upon obtaining written permission from the board. (Eff. 1/16/98, Register 145; am 2/26/2000, Register 153; am 2/15/2006, Register 177; am 6/29/2018, Register 226; am 12/28/2022, Register 244; am 7/15/2023, Register 247; am 1 / 14 / 2024, Register 249)

 Authority: AS 08.80.005 AS 08.80.157 AS 08.80.330

 AS 08.80.030 AS 08.80.160

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

12 AAC 52.205. General standards of pharmacy practice. (a) To determine whether a specific act is within the scope of pharmacy practice in or into the state, or whether an act can be delegated to other individuals under a licensee's supervision, the licensee must independently determine whether the act is

- (1) expressly prohibited by
 - (A) this chapter; or
 - (B) any applicable state or federal laws;
- (2) consistent with the licensee's education, training, and experience; and
- (3) within the accepted standard of care that would be provided in a similar setting by a reasonable and prudent licensee with similar education, training, and experience.
- (b) The pharmacist-in-charge shall make necessary changes or improvements to ensure patient safety and employee wellness in a pharmacy, as part of a continuous quality improvement

Register 249, April 2024 PROFESSIONAL REGULATIONS program for pharmacy services. (Eff. 1 /19 / 2024, Register 249)

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52.240(b)(9) is repealed:

(Eff. 11/10/2001, Register 160; am 2/11/2004, Register 169; am 11/16/2012, Register 204; am 10/31/2019, Register 232; am 1 / 19 / 2024, Register 249)

Authority: AS 08.80.030 AS 08.80.480

(((Publisher: Please move the "and" link at the end of former 12 AAC 52.240(b)(9) so that the link follows current 12 AAC 52.240(b)(8).)))

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

12 AAC 52.245. Retired status pharmacist license. (a) Upon retiring from practice, an individual holding an unencumbered pharmacist license in the state that is not under investigation with the board may apply for the conversion of an active or inactive pharmacist license to a retired status pharmacist license.

- (b) An individual holding a retired status pharmacist license may use the title "pharmacist-retired" but may not practice or indicate that the individual is practicing or soliciting to practice as a pharmacist in the state.
- (c) A retired status pharmacist license is valid for the life of the holder, does not require renewal, and is exempt from continuing education requirements.
- (d) The executive administrator or board will issue a retired status pharmacist license to an individual who meets the requirements of (a) of this section if the applicant

- (1) submits a completed retired status application on a form provided by the department; and
- (2) pays the retired status pharmacist license one-time fee set out under 12 AAC 02.310.
- (e) An individual who holds a retired status pharmacist license may apply to change the license from retired status to active status by
- (1) meeting the requirements of 12 AAC 52.310(b) if the license has been in retired status for less than two years;
- (2) meeting the requirements of 12 AAC 52.310(c) if the license has been in retired status for more than two years but less than five years; or
- (3) meeting the requirements of 12 AAC 52.070 if the license has been in retired status for more than five years. (Eff. 1 / 19 / 2024, Register 241)

 Authority: AS 08.01.100 AS 08.80.030 AS 08.80.147

12 AAC 52.300(b)(3) is amended to read:

(3) an attestation that a self-inspection of the premises using the form provided by the department was completed within the last two years or since the last time the license [OR REGISTRATION] was initially issued; the applicant must retain the self-inspection and make it available to the board upon request for the duration of the licensing period in which it was completed.

(Eff. 1/16/98, Register 145; am 2/26/2000, Register 153; am 5/5/2000, Register 154; am 5/26/2006, Register 178; am 4/3/2020, Register 234; am 8/30/2020, Register 235; am 7/7/2022, Register 243; am 7/15/2023, Register 247; am 1 / 19 / 2024, Register 249)

Authority: AS 08.01.100 AS 08.80.030 AS 08.80.157

AS 08.80.005 AS 08.80.147 AS 08.80.165

12 AAC 52.310 is amended to read:

12 AAC 52.310. Reinstatement of <u>a lapsed</u> [AN EXPIRED] pharmacist or pharmacy technician license. (a) If a pharmacist's or pharmacy technician's license has <u>lapsed</u> [EXPIRED] for any reason, that pharmacist or pharmacy technician may not practice pharmacy until <u>the</u>

board reinstates the license [IS REINSTATED BY THE BOARD].

- (b) The board will reinstate a pharmacist or pharmacy technician license that has been lapsed [EXPIRED] less than two years if the applicant submits
 - (1) a completed renewal application;
 - (2) any applicable license renewal fees required under [IN] 12 AAC 02.310; and
- (3) documentation that the applicant has <u>completed</u> [MET] all continuing education requirements <u>under</u> [OF] 12 AAC 52.320 12 AAC 52.350 <u>within the immediate</u> two years before applying for reinstatement [; AND
- (4) FOR A LICENSING PERIOD THAT BEGINS ON OR AFTER JULY 1, 2006, A COMPLETED JURISPRUDENCE QUESTIONNAIRE PREPARED BY THE BOARD, COVERING THE PROVISIONS OF AS 08.80 AND THIS CHAPTER].
- (c) The board will reinstate a pharmacist license that has been <u>lapsed more than</u>

 [EXPIRED] two years <u>but less than five years</u> [OR MORE] if the applicant
- (1) submits a completed application for reinstatement on a form provided by the department;
 - (2) pays any applicable license renewal fees required under [IN] 12 AAC 02.310

for the entire period the license has been <u>lapsed</u> [EXPIRED];

- (3) [REPEALED 5/5/2000;
- (4)] submits <u>documentation that the applicant has completed</u> [EVIDENCE OF COMPLETION OF] all continuing education requirements <u>under</u> [IN] 12 AAC 52.320 12 AAC 52.350 <u>within the immediate two years before applying for reinstatement</u> [THAT WOULD HAVE BEEN REQUIRED TO MAINTAIN A CURRENT LICENSE FOR THE ENTIRE PERIOD THE LICENSE HAS BEEN EXPIRED];
 - (4) [(5)] qualifies by
 - (A) retaking and passing the examinations required <u>under</u> [IN] 12 AAC 52.090(a); or
 - (B) providing verification that the applicant has continually practiced pharmacy in another state under a license issued by the authority of that state for the period that the license has been <u>lapsed</u> [EXPIRED], and by meeting the requirements of 12 AAC 52.090(a)(2); for purposes of AS 08.80.147 and this subparagraph, an applicant has continually practiced pharmacy if the pharmacist has actively practiced pharmacy in the other state for at least six months during each year that the license in this state was lapsed; and
- (5) [(6)] submits a verification issued directly to the board by each licensing jurisdiction where the applicant holds, or has ever held, a license as a pharmacist during the time period in which the applicant's license was lapsed in **the** [THIS] state that the applicant's license in the other jurisdiction was [WERE] not suspended, revoked, or otherwise restricted except for failure to apply for renewal or failure to obtain the required continuing education requirements.
 - (d) Repealed 8/1/2014.

(e) <u>The board will not reinstate</u> a [A] pharmacy technician license that has been <u>lapsed</u> [EXPIRED] for two years or more [WILL NOT BE REINSTATED].

(f) The board will not reinstate a pharmacist license that has been lapsed for five years or more. (Eff. 1/16/98, Register 145; am 5/5/2000, Register 154; am 8/21/2002, Register 163; am 2/11/2004, Register 169; am 5/26/2006, Register 178; am 9/17/2011, Register 199; am 8/1/2014, Register 211; am 1/19/2014, Register 249)

Authority: AS 08.01.100 AS 08.80.030 AS 08.80.165

AS 08.80.005 AS 08.80.147

12 AAC 52.423(a) is amended to read:

- (a) A central pharmacy that wishes to provide pharmacy services through a remote pharmacy in the state using a telepharmacy system as provided in 12 AAC 52.425 must apply to the board for a <u>remote pharmacy</u> license. The central pharmacy applying under this section for a remote pharmacy license must
- (1) submit to the department a complete [,] notarized application on a form provided by the department;
- (2) submit to the department the applicable fees established <u>under [IN] 12 AAC 02.310; [AND]</u>
 - (3) comply with the requirements of 12 AAC 52.020; and
- (4) provide the name and active or pending license number of the central pharmacy.

12 AAC 52.423(c) is repealed:

(c) Repealed 1/19/2024.

12 AAC 52.423(d) is amended to read:

(d) A remote pharmacy that has changed its name, physical address, or ownership must notify the board in writing not later than 30 days after the change. A notification of a change of physical address must include an attestation that a new self-inspection will be completed not later than 30 days after the start of business in the new location. (Eff. 9/17/2011, Register 199; am 10/31/2019, Register 232; am 7/15/2023, Register 247; am 1/19/2024, Register 249)

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.157

12 AAC 52.500(b) is amended to read:

(b) Original prescription drug order information for controlled substances listed in schedules <u>II</u>, III, IV, or V may be transferred only by the pharmacy that originally received the prescription drug order from the prescribing practitioner. The transfer must be communicated directly between two licensed pharmacists.

(Eff. 1/16/98, Register 145; am 7/9/2017, Register 223; am 10/31/2019, Register 232; am 4/3/2020, Register 234; am 8/30/2020, Register 235; am 10/31/2019, Register 232; am 4/3/2020, Register 234; am 8/30/2020, Register 235; am 10/31/2019, Register 232; am 4/3/2020, Register 234; am 8/30/2020, Register 235; am 10/31/2019, Register 232; am 4/3/2020, Register 235; am 10/31/2019, Register 232; am 4/3/2020, Register 236; am 10/31/2019, Register 232; am 10/31/2019, Register 232; am 4/3/2020, Register 233; am 10/31/2019, Register 232; am 4/3/2020, Register 234; am 8/30/2020, Register 235; am 10/31/2019, Register 249)

12 AAC 52.800(a) is amended to read:

12 AAC 52.800. Drug room license. (a) An institutional facility that does not maintain a pharmacy but prepares and administers prescription drugs from bulk supplies for patients receiving treatment within the facility must be licensed by the board as a drug room under [12 AAC 52.010 AND] 12 AAC 52.020.

(Eff. 1/16/98, Register 145; am 1/17/2007, Register 181; am 7/15/2023, Register 247; am

1 / 19 / 2024, Register 249)

Authority: AS 08.80,005 AS 08.80.157 AS 08.80.480

AS 08.80.030 AS 08.80.390

12 AAC 52.857(d) is amended to read:

(d) A pharmacy that obtains a DEA registration after its license [OR REGISTRATION] is initially granted by the board must notify the board on a form provided by the department not later than 10 days from the date [OF] the DEA registration is issued to the pharmacy. (Eff.

3/17/2022, Register 241; am 1 / 19 / 224, Register 249)

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

12 AAC 52.865(b) is amended to read:

(b) Unless excused from reporting under AS 17.30.200(t), a pharmacist or practitioner required to submit information under AS 17.30.200(b) must submit the information to the PDMP daily. Information regarding a schedule II, III, or IV controlled substance prescribed by a veterinarian and dispensed by a pharmacist must be submitted by the pharmacist. Nothing affects the inapplicability of this section to veterinarians under AS 17.30.200(u).

(Eff. 12/29/2011, Register 200; am 6/7/2018, Register 226; am 12/28/2022, Register 244; am

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

Editor's note: As of Register 233 (April 2020), the regulations attorney made a technical revision under AS 44.62.125(b)(6), to 12 AAC 52.865(b).

In 2018 the revisor of statutes, acting under AS 01.05.031, rearranged the subsections in AS 17.30.200. As a result, the subsection formerly designated as AS 17.30.200(o) is now designated as AS 17.30.200(n). As of Register 237 (April 2021), the regulations attorney made a conforming technical revision under AS 44.62.125(b)(6), to 12 AAC 44.445(d), so that the cross-reference now cites AS 17.30.200(n), formerly designated AS 17.30.200(o).

The regulations attorney made a technical revision under AS 44.62.125, to set out a cross-reference to AS 17.30.200(u). Sec. 5, ch. 14, SLA 2023 originally enacted the statutory subsection as AS 17.30.200(v), but the revisor of statutes, acting under AS 01.05.031, is expected upon final codification to assign that statutory material to AS 17.30.200(u), and assign AS 17.30.200(v) to the current section-specific definitions.

12 AAC 52.920(a)(15) is amended to read:

(15) acts or omissions within the practice of pharmacy that fail to meet the standard of care [FAILING TO USE REASONABLE KNOWLEDGE, SKILLS, OR JUDGMENT IN THE PRACTICE OF PHARMACY];

(Eff. 1/16/98, Register 145; am 6/7/2018, Register 226; am 1 / 19 / 2024, Register 249)

Authority: AS 08.01.075 AS 08.80.261 AS 08.80.460

AS 08.80.005 AS 08.80.315 AS 17.30.200

AS 08.80.030

12 AAC 52.991 is amended to read:

12 AAC 52.991. Disciplinary decision or conviction reporting requirement. (a) A

licensee shall report in writing to the board any disciplinary decision, felony charge, or criminal conviction [, INCLUDING CONVICTION OF A FELONY OR CONVICTION OF ANOTHER CRIME THAT AFFECTS THE APPLICANT'S OR LICENSEE'S ABILITY TO PRACTICE COMPETENTLY AND SAFELY,] issued against the licensee not later than 30 days after the date of the disciplinary decision, felony charge, or criminal conviction.

(b) A licensed [OR REGISTERED] facility shall report in writing to the board any disciplinary decision, including a voluntary suspension or revocation issued by a federal, state, or local government of a license currently or previously held [BY THE APPLICANT OR FACILITY FOR THE MANUFACTURE OR DISTRIBUTION OF DRUGS OR DEVICES, INCLUDING CONTROLLED SUBSTANCES], or any felony charge or criminal conviction under federal, state, or local law of an owner, designated representative, pharmacist-in-charge, or officer of the licensed facility [OR OF AN EMPLOYEE OF THE FACILITY] not later than 30 days after the date of the disciplinary decision, felony charge, or criminal conviction. (Eff. 9/17/2011, Register 199; am 4/16/2016, Register 218; am 6/29/2018, Register 226; am 1/19/2024, Register 244)

Authority: AS 08.01.075 AS 08.80.030 AS 08.80.315

AS 08.80.005 AS 08.80.261 AS 08.80.460

12 AAC 52.992 is repealed and readopted to read:

12 AAC 52.992. Administration of vaccines, epinephrine, and related emergency medications. (a) Before a pharmacist or pharmacy technician who holds a national certification or a pharmacist intern acting under the supervision of a pharmacist may administer a human vaccine or related emergency medication to a patient who does not have immunization

contraindications as listed by the CDC, FDA, or manufacturer's package insert, or to a patient under a prescription drug order from a prescriber, the pharmacist or pharmacy technician who holds a national certification or pharmacist intern acting under the supervision of a pharmacist

- (1) must successfully complete a course accredited by the ACPE or a comparable course for pediatric, adolescent, and adult immunization practices;
- (2) must maintain certification and keep documentation in adult and pediatric cardiopulmonary resuscitation (CPR) and automated external defibrillator (AED) training;
- (3) who has not administered a vaccine during the past 10 years, must successfully complete a course set out under (1) of this subsection; and
- (4) must adhere to the applicable provisions of 12 AAC 52.320 and 12 AAC 52.325, including continuing education requirements under 12 AAC 52.320(e).
- (b) A pharmacy that administers a human vaccine or related emergency medication under this section
- (1) must stock the following emergency medications in an emergency medication kit that is separate from the regular dispensing inventory and that is carried by the pharmacist if providing off-site immunizations:
 - (A) oral and injectable diphenhydramine; and
 - (B) adult and pediatric auto-inject epinephrine devices or injectable epinephrine;
- (2) must maintain a policies and procedures manual detailing the immunization practices that must be followed; the policies and procedures manual must
 - (A) designate either the pharmacist-in-charge or an assigned vaccine coordinator who will be responsible for maintaining the policies and procedures manual;

- (B) document that the policies and procedures manual has been reviewed and updated annually;
- (C) address how vaccine-related adverse reactions are to be reported to the CDC's and FDA's Vaccine Adverse Event Reporting System (VAERS);
- (D) address proper vaccine storage, handling, and maintenance, including maintaining manufacturer-recommended temperatures during transportation of vaccines;
 - (E) address proper disposal of used or contaminated supplies;
- (F) contain a written emergency protocol for handling accidental needlesticks and adverse reactions, including the administration of related emergency medications; and
 - (G) detail how records must be kept;
- (3) must have access to the CDC's *Epidemiology and Prevention of Vaccine-Preventable Diseases*, 14th edition, 2021, adopted by reference, for reference to routinely used vaccines and the diseases they prevent; and
- (4) must display the licensee's certification of completing an immunization course described in (a)(1) of this section.
- (c) A pharmacist or pharmacy technician who holds a national certification or a pharmacist intern acting under the supervision of a pharmacist administering a human vaccine must
- (1) offer the patient or the patient's agent the current vaccine information statement (VIS) issued by the CDC for each vaccine administered; and
 - (2) comply with 7 AAC 27.650.
 - (d) A pharmacist may independently administer epinephrine auto-injectors.

- (e) A pharmacist may independently prescribe epinephrine auto-injectors to a person who has completed an epinephrine auto-injector training program approved by the board under AS 17.22.020(b).
- (f) Failure to comply with this section constitutes unprofessional conduct and is a basis for the imposition of disciplinary sanctions under AS 08.01.075.
 - (g) In this section,
- (1) "CDC" means the United States Department of Health and Human Services, Centers for Disease Control and Prevention;
- (2) "FDA" means the United States Food and Drug Administration. (Eff. 7/9/2017, Register 223; am 4/3/2020, Register 234; am 5/19/2023, Register 246; am

1 / 19 / 2024, Register 249)

Authority: AS 08.01.075 AS 08.80.116 AS 08.80.261

AS 08.80.030 AS 08.80.168 AS 08.80.480

12 AAC 52.993(6) is amended to read:

(6) review and approve applications for licensure [OR REGISTRATION] as long as the applicant meets the requirements established for the license type for which **the applicant is** [THEY ARE] applying. (Eff. 10/31/2019, Register 232; am 7/7/2022, Register 243; am

1 / 19 / 2024, Register 249)

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.270

- 12 AAC 52.995(a) is amended by adding new paragraphs to read:
 - (42) "facility" means a pharmacy, wholesale drug distributor, drug room, remote

pharmacy, third-party logistics provider, outsourcing facility, or manufacturer who is licensed under AS 08.80 and this chapter;

- (43) "Internet-based pharmacy" means a person, entity, or Internet website that knowingly or intentionally delivers, distributes, or dispenses, or offers or attempts to deliver, distribute, or dispense prescription drugs or devices by means of the Internet;
- (44) "standard of care" means care provided by a licensee that is within the accepted standard of care that would be provided in a similar setting by a reasonable and prudent licensee with similar education, training, and experience.

(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)

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 change the period at the end of 12 AAC 52.995(a)(41) to a semicolon.)))