Chapter 52. Board of Pharmacy.

(Words in **boldface and underlined** indicate language being added; words [CAPITALIZED AND BRACKETED] indicate language being deleted. Complete new sections are not in boldface or underlined.)

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 ____/____/_____, Register _____)

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12 AAC 52.240(d) is repealed:

(d) Repealed ____/____/_____ [UNLESS THE BOARD IS SATISFIED THAT THE PHARMACIST HAS BEEN ADEQUATELY TRAINED IN THE PROCEDURES OUTLINED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 ____/____/_____, Register _____)

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 ____/____/_____, Register _____)

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 ____/____/_____, Register _____)

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]

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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 ____/____/_____, Register _____)

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:

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(Eff. 1/16/98, Register 145; am _____/_____/_____, Register _____)

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:

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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 ____/____/_____, Register _____)

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 ____/____/_____, Register _____)

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.)))